Effective Health Care Program

Comparative Effectiveness Review
Number 99

Outpatient Case Management for Adults With Medical Illness and Complex Care Needs

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Prepared by:
Oregon Evidence-based Practice Center
Portland, OR

Investigators:
David H. Hickam, M.D., M.P.H.
Jessica W. Weiss, M.D., M.C.R.
Jeanne-Marie Guise, M.D., M.P.H.
David Buckley, M.D., M.P.H.
Makalapua Motu'apuaka, B.S.
Elaine Graham, M.L.S.
Ngoc Wasson, M.P.H.
Somnath Saha, M.D., M.P.H.

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others— make well informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input from are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director
Evidence-based Practice Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Christine Chang, M.D., M.P.H.
Task Order Officer
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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Key Informants

Charles Boult, M.D, M.P.H., M.B.A.
Professor, Johns Hopkins School of Public Health
Director, Lipitz Center for Integrated Health Care; the Eugene and Mildred Lipitz Professor in Health Care Policy
Baltimore, MD
Kenneth S. Fink, M.D., M.G.A., M.P.H.
Division Administrator
Med-Quest Division, Hawaii State Medicaid
Kapolei, HI

David Labby, M.D.
Medical Director
Care Oregon
Portland, OR

Margaret Leonard, M.S., R.N.-B.C., F.N.P.
President of the Board of Directors Case Management Society of America
Niskayuna, NY

Michael O'Dell, M.D., M.S.H.A., F.A.A.F.P.
Chair, Department of Family and Community Medicine
University of Missouri–Kansas City
Kansas City, MO

Lois Wessel, R.N., C.F.N.P.
Associate Director for Programs
Association of Clinicians for the Underserved
Tysons Corner, VA

Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts.

Dena M. Bravata, M.D., M.S.
Affiliate and Investigator
Center for Health Policy, Stanford University
Stanford, CA

Charles Boult, M.D, M.P.H., M.B.A.
Professor, Johns Hopkins School of Public Health
Director, Lipitz Center for Integrated Health Care; the Eugene and Mildred Lipitz Professor in Health Care Policy
Baltimore, MD

Kenneth S. Fink, M.D., M.G.A., M.P.H.
Division Administrator
Med-Quest Division, Hawaii State Medicaid
Kapolei, HI

Margaret Leonard, M.S., R.N.-B.C., FNP
President of the Board of Directors
Case Management Society of America
Niskayuna, NY

Kathryn M. McDonald, M.M.
Executive Director, Senior Scholar
Center for Health Policy, Stanford University
Stanford, CA

Hussein A. Tahan, D.N.Sc., R.N.
Consultant
International Health Care Management & Consulting
Secaucus, NJ

Edward H. Wagner, M.D., M.P.H., FACP
Director
Group Health Cooperative of Puget Sound
Senior Investigator of the MacColl Institute
Seattle, WA

Peer Reviewers

Thomas Bodenheimer, M.D., M.P.H.
Adjunct Professor
University of California, San Francisco
RWJ Foundation
San Francisco, CA

Matthew Burke, M.D.
Senior Clinical Advisor
Health Resources and Services
Administration
Rockville, MD

Neil Kirschner, Ph.D.
Senior Associate
Regulatory and Insurer Affairs
American College of Physicians
Washington, DC

Margaret Leonard, M.S., R.N.-B.C., FNP
President of the Board of Directors
Case Management Society of America
Niskayuna, NY

Pamela Mitchell, Ph.D., R.N.
Professor Emeritus
University of Washington School of Nursing
Seattle, WA

Cheryl Schraeder, Ph.D., R.N.
Clinical Associate Professor
University of Illinois at Chicago
Mahomet, IL

Hussein A Tahan, D.N.Sc., R.N.
Consultant
International Health Care Management &
Consulting
Secaucus, NJ

Outpatient Case Management for Adults With Medical Illness and Complex Care Needs

Structured Abstract

Objectives. In this evidence review we evaluated outpatient case management (CM) as an intervention strategy for chronic illness management. We summarized the existing evidence related to the effectiveness of CM in improving patient-centered outcomes, quality of care, and resource utilization in adults with chronic medical illness and complex care needs. We also assessed the effectiveness of CM according to patient and intervention characteristics.

Data sources. Articles were identified from searches of the MEDLINE®, CINAHL®, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects. The databases were searched through August 2011.

Review methods. Two reviewers evaluated abstracts and articles against prespecified inclusion criteria. Eligible studies were quality rated and data were extracted, entered into tables, and summarized. Due to the heterogeneity of outcomes, meta-analyses were not conducted. Systematic reviews were retrieved for reference, but data from pooled results of published reviews were not included in our analysis.

Results. Of the 5,645 citations identified, we screened and reviewed 1,201 full-length articles and included 153 articles representing 109 studies. Many of the published trials of CM examined programs that targeted specific patient conditions, and the approaches to CM were diverse. Overall, the interventions tested in the studies were associated with only small changes in patient-centered outcomes, quality of care, and resource utilization. While CM can improve some types of health care utilization, there are minimal effects on overall costs of care. For selected populations, the characteristics of successful interventions included intense CM with greater contact time, longer duration, face-to-face visits, and integration with patients' usual care providers.

Conclusions. Recognizing the heterogeneity of study populations, interventions, and outcomes, we sought to elucidate the conditions under which CM was effective. We found that CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness.

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Executive Summary

Background

Chronic diseases are the leading cause of illness, disability, and death in the United States.[1] Providing medical care for chronic illness is often complex, as patients require multiple resources, treatments, and providers. One strategy for improving care for chronic conditions is to develop programs that improve care coordination and implement care plans.[2,3,4] Case management (CM) is one such supplemental service, in which a person, usually a nurse or social worker, takes responsibility for coordinating and implementing a patient's care plan, either alone or in conjunction with a team of health professionals.

CM tends to be more intensive in time and resources than other chronic illness management interventions, and it is important to evaluate its specific value. CM is often utilized when the coordination and integration of care is difficult for patients to accomplish on their own. CM usually involves high-intensity engagement with patients, and case managers often adopt a supervisory role in comprehensively attending to patients' complex needs.[5] Conceptually, a case manager can be seen as an agent of the patient, taking a "whole-person" (rather than solely clinical or disease-focused) approach to care, and serving as a bridge between the patient, the practice team, the health system, and community resources.

The coordinating functions performed by a case manager include helping patients navigate health care systems, connecting them with community resources, orchestrating multiple facets of health care delivery, and assisting with administrative and logistical tasks. Case managers also can perform clinical functions, including disease-oriented assessment and monitoring, medication adjustment, health education, and self-care instructions. Such clinical functions are often the defining aspects of other chronic illness management interventions. In the context of chronic illness care, they are central to the role of a case manager, but a case manager also performs coordinating functions.

The evolution of CM models in health care and their expanding use in chronic illness management has led to the term "case management" being used to describe a wide variety of interventions. As a result, there is no consensus about the core components of CM. Moreover, the term "case management" is often used interchangeably with other forms of chronic illness management interventions such as "disease management" and "self-management support."

Individual CM programs usually are customized for the clinical problems of the population being served. Thus, a CM program for homeless people with AIDS has a much different mix of activities than a program serving patients with dementia and their caregivers or one designed to improve the quality of diabetes care. Some CM interventions include primarily coordinating functions while others focus mainly on clinical activities. Other programs target patients with characteristics—limited social support or physical or mental disability—that make them particularly vulnerable to lack of care coordination, while others serve unselected populations with a given chronic illness. Case management interventions can be intensive, with multiple face-to-face interactions and home visits, while others may entail only infrequent telephone calls. In some programs, case managers operate independently, while in others, they work closely with a patient's usual care provider or with a multidisciplinary team of health professionals. The variability of CM interventions is a comparative effectiveness issue that is addressed in this report. We examine a wide variety of CM approaches and define when and where CM leads to consistent effects on outcomes that are meaningful to patients and health care systems.

Objectives

As noted, the situations in which CM has been used are numerous and diverse. In recognition of the substantial heterogeneity of purposes, approaches, and populations included within the broad category of CM, we limited the scope of this review in a number of ways. We aimed to define and identify a subset of CM models representing a sizable category of CM that is common and meaningful for patients and their caregivers. We also aimed to circumscribe the scope of included CM models to ensure that the review would be adequately focused and practical. Such an approach allows for a more complete understanding of the evidence regarding the included category of CM. We necessarily excluded certain types of CM. We limited the scope of this review to CM interventions for medical, as opposed to psychiatric, illness. CM is often used to improve the management of psychiatric illnesses such as depression, schizophrenia, or substance use disorders. CM in those contexts, however, is substantively different in its nature and objectives from CM for chronic medical illness. Although we did not include studies in which the goal of CM was primarily to improve psychiatric care, we did include studies in which CM was used to improve chronic medical illness care among patients who also had psychiatric illness. Similarly, we included models of case management that integrate care for psychiatric disorders that are associated with significant medical comorbidities, such as dementia. Additionally, we restricted the review to CM programs having an ongoing and sustained relationship between the case manager and patient. Hence, despite promising evidence for certain models of short-term, intensive CM or models that focus on transitional care, we did not include such models in this review.[6,7] We also limited the scope of this review to outpatient settings.

This report summarizes the existing evidence addressing the following Key Questions:

Key Question 1:

In adults with chronic medical illness and complex care needs, is case management effective in improving:

a. *Patient-centered outcomes*, including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?
b. *Quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?
c. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

Key Question 2:

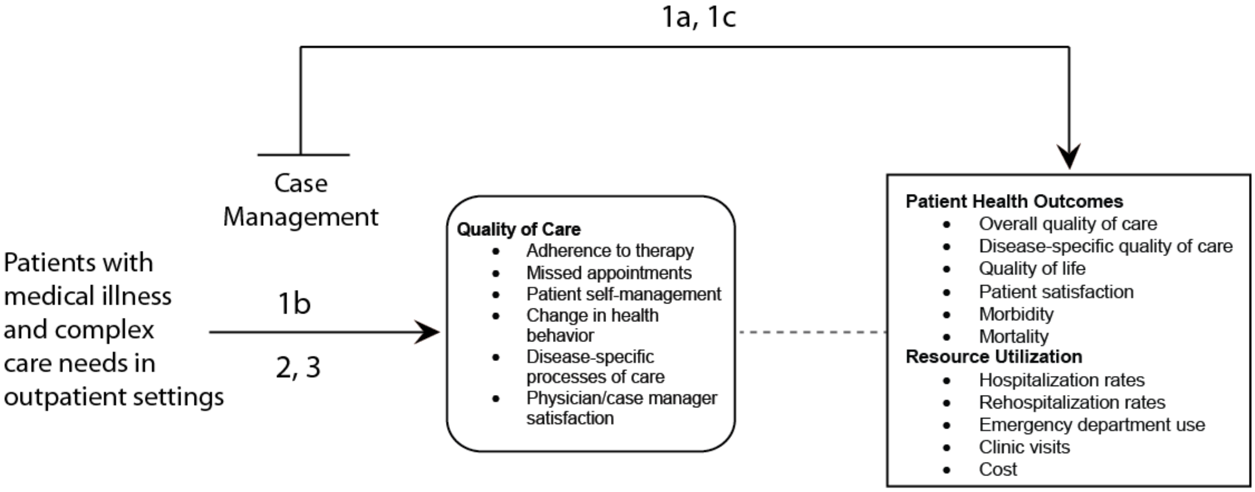
Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3:

Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

The analytic framework (Figure A) depicts the Key Questions in the framework of the populations, intervention, and outcomes considered in the review.

Figure A. Analytic framework



Note: Numbers refer to Key Questions.

Methods

Input From Stakeholders and Topic Refinement

Input from stakeholders was received during several phases of the project. In a topic refinement phase, the scope of the project was refined with input from a panel of Key Informants including representatives of public organizations and societies with an interest in CM, individuals who perform CM research, experts on the chronic care model, and practicing case managers. The Key Questions for the report were then revised and posted for public comment on the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care (EHC) Web site for 4 weeks. Public comments were received by the study team and were considered for additional refinements of the Key Questions. A Technical Expert Panel (TEP) helped refine Key Questions, identify important issues, and define parameters for the review of evidence. The TEP also reviewed the research protocol, which is posted on the AHRQ EHC Web site (effectivehealthcare.ahrq.gov). Statements of potential conflicts of interest for all participants, researchers, and authors were reviewed by AHRQ. The draft report was reviewed by an AHRQ Task Order Officer and an associate editor prior to peer review. Simultaneous with the peer review period, the draft report was posted on the AHRQ EHC Web site where it was available for 4 weeks for public comment. A disposition table detailing peer reviewer and public comments and the authors' responses will be posted on the AHRQ EHC Web site 3 months after posting of the final report.

Data Sources and Selection

We worked with medical librarians who have extensive experience with conducting literature searches for comparative effectiveness reviews. We searched MEDLINE® (Ovid), CINAHL® (EBSCO), the Cochrane Central Register of Controlled Trials (Ovid EBM Reviews), the Cochrane Database of Systematic Reviews (Ovid EBM Reviews), and the Database of Abstracts of Reviews of Effects (Ovid EBM Reviews). We searched by broad level subject terms and keywords. The search was limited to English language materials and adult populations. The search covered the time period through August 2011. Gray literature searches included clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, and WHO Trial Registries). Additional studies were identified by reviewing the reference lists of published clinical trials and review articles that addressed CM.

We developed criteria for inclusion and exclusion of studies based on the Key Questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) as described below. The titles and abstracts for all citations were reviewed independently by two team members. Full-text articles were retrieved if one or both of the reviewers judged the citation to be possibly relevant. The full-text articles then were reviewed independently by two team members for inclusion/exclusion. Disagreements were adjudicated by a third team member.

Populations of Interest

This review focuses on adults with medical illness and complex care needs in outpatient settings. A main criterion in choosing studies for inclusion was the existence of complex care needs. Complex care needs were defined broadly, and we included studies with case definitions based on health care resource utilization, patient health status, and/or multifactor assessments that included measures such as socioeconomic status or patient self-efficacy. The included studies sometimes addressed populations in which psychiatric problems, such as depression or dementia, were important comorbid conditions. Studies in which the primary clinical problem was a psychiatric disorder (other than dementia) and in which CM was used primarily to manage mental illness or a substance abuse disorder were excluded.

Interventions

We define CM as a process in which a person (alone or in conjunction with a team) manages multiple aspects of a patient's care. Key components of CM include planning and assessment, coordination of services, patient education, and clinical monitoring. We excluded studies in which the case manager was a licensed independent practitioner, such as a primary care physician, a geriatrician, or a nurse practitioner. This is because such CM is part of the primary medical care provided to the patient rather than a separate clinical service.

Comparators

In most studies, CM is compared with usual care (i.e., care without a CM component). Usual care can be quite variable across studies, but in most cases the comparator was the same milieu of clinical services without a distinct CM component. When a study compared two or more different types of CM, then the comparator was the alternative type of CM. For clinical trials and other studies having a comparison group, we specifically examined the study's reports for information about contamination (provision of CM or other care coordination services to the control group).

Outcomes of Interest

The outcomes of interests are specified in the Key Questions listed above. The three categories of outcomes are patient-centered outcomes, quality of care outcomes, and resource utilization outcomes. These categories were derived from the set of outcomes specified in descriptions of CM programs in the literature. These programs addressed the needs of defined patient populations and have discrete clinical goals. These three categories reflect the categories of goals that usually are addressed in CM.

Comparative effectiveness reviews (CERs) commonly classify outcomes as either benefits or harms. The CM literature has generally not classified harms of CM. Thus, the outcomes listed above are not classified as either benefits or harms.

Timing

A level of longitudinal engagement with patients was a criterion for study inclusion. We excluded studies that provided CM for only short durations (30 days or less). This criterion excluded many studies that evaluated short-term posthospitalization programs (often termed “transitional care” programs). Such programs fall into a large category of inpatient discharge planning activities that are beyond the scope of this review.

Settings

We included only studies in the outpatient setting, including primary care, specialty care, and home care settings. No geographic limitations were applied.

Types of Studies

We included randomized trials and observational studies pertinent to the Key Questions. The observational studies included studies using nonexperimental designs such as cohort, case-control and pre-post designs. Previously published systematic reviews were not included as part of the evidence base but were compared with the results of the current review.

Evidence Synthesis

Data were abstracted and used to assess applicability and quality of the study: study design; inclusion and exclusion criteria; population and clinical characteristics (including sex, age, ethnicity, primary disease, comorbidities, complex care needs, and insurance carrier); CM intervention characteristics (including case manager professional identification and prior training); pre-intervention training for case managers; caseload and the nature of care provided by the intervention (e.g., patient education, coordination of services, medication monitoring, and adjustment); results for each outcome, focusing on the outcomes of interest (patient-centered, resource utilization, and process of care outcomes). All data abstracted from included studies were verified for accuracy and completeness by a second team member. Disagreements were adjudicated by the lead investigator.

We used predefined criteria to assess the potential for bias in individual controlled trials and observational studies adapted from methods proposed by Downs and Black[8] (observational studies) and methods developed by the U.S. Preventive Services Task Force.[9,10] Individual studies were rated as “good,” “fair,” or “poor.” Because of the broad range of models of CM, we grouped the studies by the types of program and the clinical problems that were chiefly addressed. For the majority of studies, these groupings were based on particular diagnoses, such as congestive heart failure (CHF), diabetes, or dementia, and studies of programs that addressed the needs of older adults with severe illness. We reviewed the findings of the studies for each of these categories and then assessed overall findings (across population groups), as related to the project’s Key Questions.

We performed a qualitative data synthesis because the heterogeneity in populations and interventions generally did not allow for quantitative synthesis.

The strength of evidence for each Key Question was initially assessed for the outcomes applicable to each patient category. Our approach is consistent with the methods described by Owens et al.[11] to evaluate the body of evidence for each outcome in each patient category. This approach uses the following categories:

- Quality (good, fair, poor)
- Consistency (consistent, inconsistent, unknown)
- Directness (direct or indirect)
- Precision (precise, imprecise)

Without formal pooled analyses, we were not able to assess the possibility of publication bias. The strength of evidence was assigned an overall grade of High, Moderate, Low, or Insufficient according to a four-level scale.[11]

A defining characteristic of comparative effectiveness reviews is their intent to evaluate "the extent to which the effects observed in published studies are likely to reflect the expected results when a specific intervention is applied to the population of interest under "real-world" conditions.[12] There is not currently an agreed-upon system or tool to evaluate applicability, so we describe applicability according to the PICOTS format. Specifically, since outcomes and interventions are often specific to patient populations and medical conditions, we detail results of case management according to patient populations. Additionally, factors about the intervention of CM itself may influence applicability. For example the intensity of the intervention may not be feasible across settings. Therefore, these factors are described within each section when possible.

Results

Overall, the multiple search sources yielded 5,645 citations, of which 1,201 full-text articles were retrieved and 153 articles were judged to be relevant (109 total studies). The majority were randomized trials. The studies were sorted by patient population and were assigned to the following categories:

- Older adults with one or more chronic diseases (20 studies/30 articles)
- Frail elderly (14 studies/17 articles)
- Dementia (15 studies/26 articles)
- Congestive heart failure (12 studies/12 articles)
- Diabetes mellitus (12 studies/24 articles)
- Cancer (6 studies/8 articles)
- Chronic infections (HIV or tuberculosis) (15 studies/17 articles)
- Other medical problems (15 studies/19 articles)

The specific outcomes reported in studies varied across the population groups, particularly for the patient-centered outcomes (Key Question 1a). Thus, the applicability of conclusions drawn from the evidence syntheses often is specific to the individual patient populations. These population-specific conclusions are summarized in Table A below.

The sample sizes of the studies of CM were variable, but many of the studies included fairly small samples of patients. Thus, for most studies subgroup analyses were not possible. For Key Question 2, the population comparisons were usually based on indirect comparisons from separate studies.

Nearly all of the clinical trials of CM programs compared a single type of program with a usual care condition. There were very few trials that directly compared more than one model of

CM. This limited the evidence available for Key Question 3. Another limitation was that many studies included incomplete information about the content of the CM that was delivered to patients.

Due to heterogeneity in the characteristics of CM interventions and the limitation of small sample sizes in many studies, the strength of evidence for the conclusions often is only low or moderate. This applies to statements about both positive effects and the lack of effect on outcomes. However, in some cases there were consistent findings in large clinical trials of uniform populations. In such cases, the evidence statements were assigned high strength of evidence ratings.

Key Question 1a. In adults with chronic medical illness and complex care needs, is case management effective in improving *patient-centered outcomes*?

Mortality

Patients provided CM did not experience lower mortality in general populations of patients with chronic illness, in the frail elderly, those with HIV infection, or in patients with specific diseases such as cancer, congestive heart failure, or dementia.

Quality of Life and Functional Status

CM interventions produced mixed results in terms of improving patients’ quality of life (QOL) and functional status. In general, CM was frequently successful in improving aspects of functioning and QOL that were directly targeted by the interventions. For instance, CM was successful in improving caregiver stress among persons caring for patients with dementia and CHF-related QOL among patients with CHF. The measures used to evaluate QOL and functional status varied across studies, and overall, the improvements in QOL and functional status achieved by CM were either small or of unclear clinical significance. CM was less successful in improving overall QOL and functioning, as indicated by global measures not specific to a particular condition.

Ability To Remain at Home

One measure of the clinical significance of improvements in functioning for elderly patients is the ability to remain at home and avoid nursing home placement. This outcome was often the primary objective of CM programs for patients with dementia. In most studies of the frail elderly and of patients with dementia, CM was not effective in maintaining patients’ ability to live at home. Evidence from one study suggests that a high-intensity CM intervention sustained over a period of several years can produce a substantial delay in nursing home placement for patients with dementia.

Disease-Specific Health Outcomes

The effect of CM on disease-specific outcomes was inconsistent. In some studies, CM had a positive impact on specific symptoms, including pain and fatigue in patients with cancer and depressive symptoms among caregivers of patients with dementia. Notably, however, CM had an inconsistent impact on clinical outcomes among patients with diabetes, including glycohemoglobin levels, body weight, and lipids.

Patient Satisfaction With Care

CM interventions were generally associated with improved patient (and caregiver) satisfaction, although satisfaction with CM varied across interventions. Studies measuring patient satisfaction typically reported overall satisfaction with care, rather than satisfaction in specific domains. Satisfaction was most substantially improved in the domain of coordination among health care providers.

Key Question 1b. In adults with chronic medical illness and complex care needs, is case management effective in improving *quality of care*?

Disease-Specific Process Measures and Receipt of Recommended Services

CM was effective in increasing the receipt of recommended health care services when it was an explicit objective of the CM intervention. For instance, CM interventions designed to improve cancer therapy adherence for patients with breast and lung cancer were successful in increasing the receipt of radiation treatment, as recommended in clinical guidelines. The effect of CM on guideline-recommended care in general, however, was less consistent. Studies showed only sporadic effects on elements of quality of care, such as receipt of appropriate medications for patients with CHF or diabetes, or receipt of appropriate preventive services for elderly patients.

Patient Self-Management

CM was effective in improving patient self-management behaviors, including dietary and medication adherence, for specific conditions such as CHF or tuberculosis, when patient education and self-management support were included within CM interventions.

Adherence

Few studies measured the frequency of missed appointments or other adherence measures as an outcome of CM interventions.

Key Question 1c. In adults with chronic medical illness and complex care needs, is case management effective in improving *resource utilization*?

Hospitalization Rates

Although hospitalization rates were often included as an outcome, trials of CM generally did not demonstrate reductions in these rates.

Emergency Department Use

CM had a variable effect on emergency department (ED) use. Several studies found reduced ED use in patients receiving CM, but other studies found no effect.

Clinic Visits

Few studies measured the frequency of clinic visits as an outcome of CM interventions. Those that did generally found varying results, and no conclusions can be drawn about this outcome.

Overall Expenditures

Most studies examining the impact of CM on the overall cost of care showed no significant difference between groups of patients receiving CM and control groups. Although the cost of CM programs often was modest relative to overall costs among patients with high utilization, the effect of CM on reducing utilization was minimal.

Key Question 2: Does the effectiveness of case management differ according to *patient characteristics*?

Medical Conditions

Individual studies had inconsistent findings on whether CM interventions are more successful for patients with high disease burden. While it is possible that there is a mid-range of disease burden in which CM is most effective, the evidence base does not permit defining how to identify such patients.

Age

Most studies of CM included mainly elderly patients, making it difficult to determine impact of age on CM effectiveness.

Socioeconomic Status

Studies did not routinely report the effect of CM according to socioeconomic indicators among enrolled patients. Some studies explicitly targeted low-income or homeless populations. There was no apparent pattern to suggest an influence of patients' socioeconomic status on the effectiveness of CM.

Social Support

Few studies explicitly evaluated patients' level of social support. However, studies that targeted patients with limited social support did not tend to find better results.

Formally Assessed Health Risk

Some studies explicitly targeted patients considered to be at high risk of poor outcomes. The methods used to evaluate risk, however, varied substantially across studies. The studies have not defined a specific level of risk for which CM is most effective for improving outcomes.

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*?

Setting

Characteristics of the setting in which CM was implemented (e.g., integrated health system, home health agency, outpatient clinic) did not clearly influence the effectiveness of CM.

Case Manager Experience, Training, Skills

Studies did not consistently provide details about the experience, training, or skills of case managers. In most studies the case managers were registered nurses, and some had specialized training in caring for patients with the conditions targeted by the CM intervention (e.g., diabetes, cancer). There was low strength of evidence indicating that pre-intervention training of nurses in providing CM for the targeted conditions, the use of protocols or scripts to guide clinical management, and collaboration between a case manager and a physician (or multidisciplinary team) specializing in the targeted clinical condition, resulted in more successful interventions.

Case Management Intensity, Duration, Integration With Other Care Providers

There was low strength of evidence that more intense CM interventions, as indicated by greater contact time, longer duration, and face-to-face (as opposed to only telephone) visits, produced better outcomes, including functional outcomes and lower hospitalization rates.

Case Manager Functions

Case managers typically performed multiple functions. These included but were not limited to assessment and planning, patient education, care coordination, and clinical monitoring. In general, emphasis on specific functions varied according to patients' conditions and the primary objectives of specific CM interventions. For example, interventions among patients with cancer typically focused on coordination and navigation, while interventions for patients with diabetes and CHF focused more on patient education (for self-management) and clinical monitoring. Most studies did not carefully measure the amount of effort case managers devoted to different functions, making it difficult to discern the degree to which emphasis on different case manager functions impacted CM effectiveness.

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a: In adults with chronic medical illness and complex care needs, is case management effective in improving ***patient-centered outcomes*****,** including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?	**Older adults with one or more chronic diseases**	***Mortality.*** CM programs that serve patients with one or more chronic diseases **do not** reduce overall mortality (9 studies).	High
Key Question 1a	**Older adults with one or more chronic diseases**	***Functional status.*** CM programs that serve patients with one or more chronic diseases **do not** result in clinically important improvements in functional status (3 studies).	High
Key Question 1a	**Frail elderly**	***Mortality.*** CM **does not** affect mortality in frail elders (5 studies).	Low
Key Question 1a	**Frail elderly**	***Nursing home admissions.*** CM programs that serve frail elderly patients **do not** decrease nursing home admissions (2 studies).	Low

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a	**Dementia**	***Mortality.*** Patients with dementia who receive services from CM programs **do not** have lower mortality rates (12 studies).	High
Key Question 1a	**Dementia**	***Problematic behavioral symptoms.*** CM programs that serve patients with dementia **do not** reduce problematic behavioral symptoms.	Moderate
Key Question 1a	**Dementia**	***Caregiver depression and strain (burden).*** CM programs that serve patients with dementia **do** reduce depression and strain among caregivers (13 studies).	Moderate
Key Question 1a	**Dementia**	***Time to nursing home placement.*** CM programs that serve patients with dementia and have duration of no longer than 2 years **do not** confer clinically important delays in time to nursing home placement (9 studies).	Moderate
Key Question 1a	**Congestive heart failure**	***Mortality.*** CM programs that serve adults with CHF **do not** reduce mortality (6 studies).	Low
Key Question 1a	**Congestive heart failure**	***Patient satisfaction.*** CM programs that serve patients with CHF **do** increase patient satisfaction (3 studies).	Moderate
Key Question 1a	**Congestive heart failure**	***Quality of life.*** CM programs that serve patients with CHF **do** improve CHF-related quality of life (6 studies).	Low
Key Question 1a	**Diabetes mellitus**	***Glucose management*.** CM programs that serve adults with diabetes **do** improve glucose management (12 studies).	Moderate
Key Question 1a	**Diabetes mellitus**	***Lipids, BMI/weight*.** CM programs that serve adults with diabetes **do not** improve measures of lipid management or BMI/weight. (8 studies).	Moderate
Key Question 1a	**Diabetes mellitus**	***Mortality*.** CM programs that serve adults with diabetes **do not** reduce mortality (1 study).	Low
Key Question 1a	**Diabetes mellitus**	***Glucose control.***CM improves glucose control among adults with diabetes.	Low
Key Question 1a	**Cancer**	***Satisfaction with care*.** CM programs that serve patients with cancer **do** improve satisfaction with care (4 studies).	Moderate
Key Question 1a	**Cancer**	***Cancer-related symptoms, functioning, quality of life, survival*.** CM **does** improve selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall quality of life or survival (8 studies).	Low

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a	**HIV**	***Mortality*. ** CM programs that serve adults with HIV infection **do not** improve survival (2 studies).	Low
Key Question 1b: In adults with chronic medical illness and complex care needs, is case management effective in improving ***quality of care***, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?	**Older adults with one or more chronic diseases**	***Patient perception of care coordination*.** CM programs that serve patients with one or more chronic diseases **do** increase patients' perceptions of the coordination of their care (2 studies).	High
Key Question 1b	**Dementia**	***Clinical guideline adherence*.** CM programs that focus on clinical guideline measures for care of dementia **do** increase adherence to those measures (1 study).	Low
Key Question 1b	**Congestive heart failure**	***Self-management behaviors*.** CM **does** increase patients' adherence to self-management behaviors recommended for patients with CHF (3 studies).	Moderate
Key Question 1b	**Cancer**	***Appropriate treatment*.** CM programs that serve patients with cancer **do** increase the receipt of appropriate (i.e., guideline-recommended) cancer treatment (2 studies).	Moderate
Key Question 1b	**Tuberculosis**	***Treatment success*.** Short-term CM programs that emphasize medication adherence **do** improve rates of successful treatment for tuberculosis in vulnerable populations (4 studies).	Moderate
Key Question 1c: In adults with chronic medical illness and complex care needs, is case management effective in improving ***resource utilization*,** including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?	**Older adults with one or more chronic diseases**	***Medicare expenditures*.** CM programs that serve patients with one or more chronic diseases **do not** reduce Medicare expenditures (3 studies).	High
Key Question 1c	**Older adults with one or more chronic diseases**	***Hospitalization rates*.** CM programs that serve patients with one or more chronic diseases **do not** reduce overall rates of hospitalization (17 studies).	Moderate

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1c	**Frail elderly**	***Hospitalization rates.*** CM **does not** decrease acute hospitalizations in the frail elderly (11 studies).	Low
Key Question 1c	**Dementia**	***Health care expenditures*****.** CM **does not** change total health care expenditures for patients with dementia (6 studies).	Moderate
Key Question 1c	**Diabetes**	***Hospital readmission rates*****.** CM **does not** reduce hospitalization rates among adults with diabetes.	Low
Key Question 1c	**Cancer**	***Health care expenditures*****.** CM programs that serve patients with cancer **do not** affect overall health care utilization and cost of care (5 studies).	Low
Key Question 1c	**Other medical problems**	***Emergency department visits.*** CM programs that serve populations that have chronic obstructive pulmonary disease (COPD) or are homeless **do** reduce emergency department visits (3 studies).	Low
Key Question 2: Does the effectiveness of case management differ according to ***patient characteristics*****,** including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?	**Older adults with one or more chronic diseases**	***Disease burden*****.** CM programs that serve patients with one or more chronic diseases are more effective for reducing hospitalization rates among patients with greater disease burden (2 studies).	Low
Key Question 3: Does the effectiveness of case management differ according to ***intervention characteristics*****,** including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?	**Older adults with one or more chronic diseases**	***Personal contact*****.** CM programs that serve patients with one or more chronic diseases are more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians (4 studies).	Low
Key Question 3	**Dementia**	***Duration*****.** CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than 2 years are more effective for delaying nursing home placement than programs providing services for 2 years or less (1 study).	Low

Table A. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 3	**Congestive heart failure**	***Integration with multidisciplinary team.*** CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers.	Low
Key Question 3	**Cancer**	***Intensity, integration, training, protocols.*** CM programs that serve patients with cancer are more effective when the CM is more intensive, better integrated with patients' usual care providers, and employs preintervention training and care protocols (3 studies).	Low

BMI = body mass index; CHF = congestive heart failure; CM = case management; COPD = chronic obstructive pulmonary disease

Note: This table does not include statements for which the evidence was insufficient to draw a conclusion.

Discussion

CM is a strategy for improving the delivery of clinical services to patients with complex needs. Based on the entire range of interventions described in the included studies, the types of patients who potentially could benefit from CM generally fell into four categories:

- Patients with progressive, life-threatening chronic diseases that can be improved with proper treatment, such as CHF or HIV infection.
- Patients with progressive, debilitating, and often irreversible diseases for which supportive care can enhance independence and QOL, such as dementia or multiple chronic diseases in the aged.
- Patients with progressive chronic diseases for which self-management can improve health and functioning, such as diabetes mellitus.
- Patients for whom serious social problems impair their ability to manage disease, such as the homeless.

For all of these clinical categories health care resources generally are available but may be inaccessible or poorly coordinated. Case managers can help surmount these problems, but the role of the case manager is complex. Depending on the organization and strategy of CM programs, the case manager can play distinctly different roles:

- A care provider who helps patients to improve their self-management skills and/or helps caregivers to be more effective in helping and supporting patients.
- A collaborative member of the care delivery team who promotes better communication with providers and advocates for implementation of care plans.
- A patient advocate who evaluates patient needs and works to surmount problems with access to clinical services.

There are multiple strategies for fulfilling these roles, and CM programs are consequently complex and often difficult to replicate. Organizationally, programs can be freestanding or imbedded in clinical settings (usually primary care or specialty practices). Case managers can interact with patients in their homes, in clinics, or by telephone. They can have outpatient caseloads of hundreds or only a few dozen, and they can follow prespecified protocols or develop personalized care plans based on patient assessments. Case managers can work independently or can function as a member of a CM team. The studies of CM use a variety of approaches to describe their programs, and full specification of the programs' content often is not possible. Acknowledging this heterogeneity of study populations, interventions, and outcomes, we sought to discern the conditions under which CM was effective or ineffective.

There is a substantial evidence base about CM for complex chronic diseases. More than 50 randomized trials and a smaller number of good-quality nonexperimental studies have been conducted in a variety of patient populations. The total number of participants in these studies approaches 100,000. The majority of these studies have given good descriptions of the patient populations, making it possible to organize the evidence by population groups. The clinical trials have included both highly innovative and targeted programs and community-based programs that service broad population groups. In some cases, there has been enough similarity in patient populations that indirect comparisons of different types of programs can be made with moderate confidence.

The cumulative evidence about CM is sufficient to draw several conclusions, some of which pertain to the inability of CM programs (as they have been commonly deployed) to achieve some desired outcomes. Generally, the conclusions reached in this report pertain only to specific patient populations. Because CM programs generally are customized to the patient groups served, it usually is not possible to apply the results to other patient populations. In this review, we found that, on balance, CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. The most positive findings are that CM improves the quality of care, particularly for patients with serious illnesses that require complex treatments (cancer and HIV). For a variety of medical conditions, CM improves self-management skills. CM also improves QOL in some populations (CHF and cancer) and tends to improve satisfaction with care. For the caregivers of patients with dementia, targeted CM programs improve levels of stress, burden, and depression.

We found a low strength of evidence that CM is effective in improving resource utilization for patients with CHF, COPD, or those with chronic homelessness. In most other cases, CM programs have not demonstrated cost savings. For patients who receive CM for multiple chronic diseases, there is a high strength of evidence that the programs do not reduce Medicare expenditures. While the effectiveness of CM may depend on selection of the appropriate target population, the published studies suggest that this type of careful case selection is difficult to implement. In the published studies, criteria for enrolling patients in CM programs were generally broad measures, such as levels of overall health care utilization or hospitalization within a prior time period.

Because of the relatively low number of trials that compare different types of CM models, conclusions about the features of programs that are most effective can be made only with a low strength of evidence. The results of trials across different clinical conditions suggest that CM effectiveness was greater when the intervention was lengthy, high in patient contact, and included face-to-face (rather than telephone-only) interactions. This finding validates the premise that the relationship between case manager and patient is likely to be a key ingredient for successful CM interventions. CM also appears to be most effective when the case manager works closely with patients' usual care providers (usually primary care physicians) and/or collaborates with a physician (or multidisciplinary team of health care providers) with expertise in managing the targeted medical condition. This finding suggests that CM may be most effective when case managers are embedded within a collaborative, team-based intervention model. Finally, there also is some evidence that CM is successful in achieving outcomes when the intervention includes specific training modules and protocols that are tailored towards those outcomes. This suggests that the breadth and flexibility of CM may need to be complemented by focused efforts—including specific training, guidelines, and protocols—to achieve explicitly targeted outcomes.

Implications for Future Research

The existing evidence base includes a large number of randomized trials comparing CM with "usual care." While the components of usual care were quite variable across studies, in some cases (particularly the Medicare Coordinated Care Demonstration [MCCD] trial)[13] the studies had large sample sizes and overall good quality. Thus there is a relatively low yield in continuing to repeat such studies. Instead, future clinical research needs to address the gaps in the current evidence base. These gaps include:

- Lack of effective risk assessment tools for choosing candidates for CM. Some published trials[14] have used existing tools, but no studies have compared tools or rigorously examined patient subgroups to learn which patients achieve the greatest benefits from CM. The factors included in better risk profiles could include:
    - Demographics including age, gender, and ethnicity
    - Living situation and ability to meet basic living needs
    - Access to primary care and other health care services
    - Social support
    - Health care utilization profiles
    - Clinical risk factors for adverse outcomes.
- Lack of understanding of the length of time to continue CM. Nearly all trials have set seemingly arbitrary durations of the intervention (often 1 to 2 years). It is not known when the benefits of the intervention have been achieved. Some of the negative results may be due to the CM being too short. This is particularly important if developing an effective long-term relationship between the patient and case manager affects the program's success.
- Imprecision about the intensity of CM. Existing trials have infrequently examined whether patient outcomes are influenced by the frequency of case manager contact, the length and content of the contacts, and the approach to followup of problems.

Other examples of CM elements that should be explicitly described in future research include:

- Training received by case managers
- Case manager experience
- Specific functions of case managers and the distribution of effort devoted to different activities
- Modes of contact (clinic visits, home visits, telephone calls)
- Average caseload
- Relationship to other health care providers
- Use of protocols, guidelines, and information technology

CM typically involves case managers providing both direct clinical support and coordination for patients, as well as education and empowerment to enable patients to better manage their own conditions and coordinate their own care. Better specification of intervention components and population characteristics would contribute to greater understanding of when interventions should emphasize direct support compared with patient education.

Many CM interventions employed more than one case manager, but few studies examined the effectiveness of CM delivered by different case managers. CM is a human intervention, and the effectiveness of CM may vary substantially according to the skills, experience, and personality of the person delivering the intervention. Understanding how much variability there is from one case manager to another would provide valuable information about the degree to which CM can be standardized and the importance of choosing individuals to implement CM.

Because studies comparing CM with usual care have generally found only small differences in important outcomes, it is uncertain whether future research that compared CM with other interventions would be fruitful. Interventions that are less intensive or more narrowly focused may be effective for changing certain outcomes but are unlikely to show important differences from the results with CM as it was deployed in the previous studies.

Glossary

Case management (CM): A health care service in which a single person, working alone or in conjunction with a team, coordinates services and augments clinical care for patients with chronic illness.

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Introduction

Background

Chronic diseases are the leading cause of illness, disability, and death in the United States.[1] Nearly half of all adults in the United States have at least one chronic disease, and 43 percent of adults covered by both Parts A and B of Medicare have three or more chronic diseases.[2] Providing medical care for chronic illness is often complex. Patients require multiple resources, treatments, and providers that, in many health care settings, are not integrated into a coherent system of care. This fragmentation puts patients with serious or multiple chronic illnesses at risk of experiencing inadequate quality of care and makes their health care expenditures substantially higher than for those who have minor or no chronic conditions.[3]

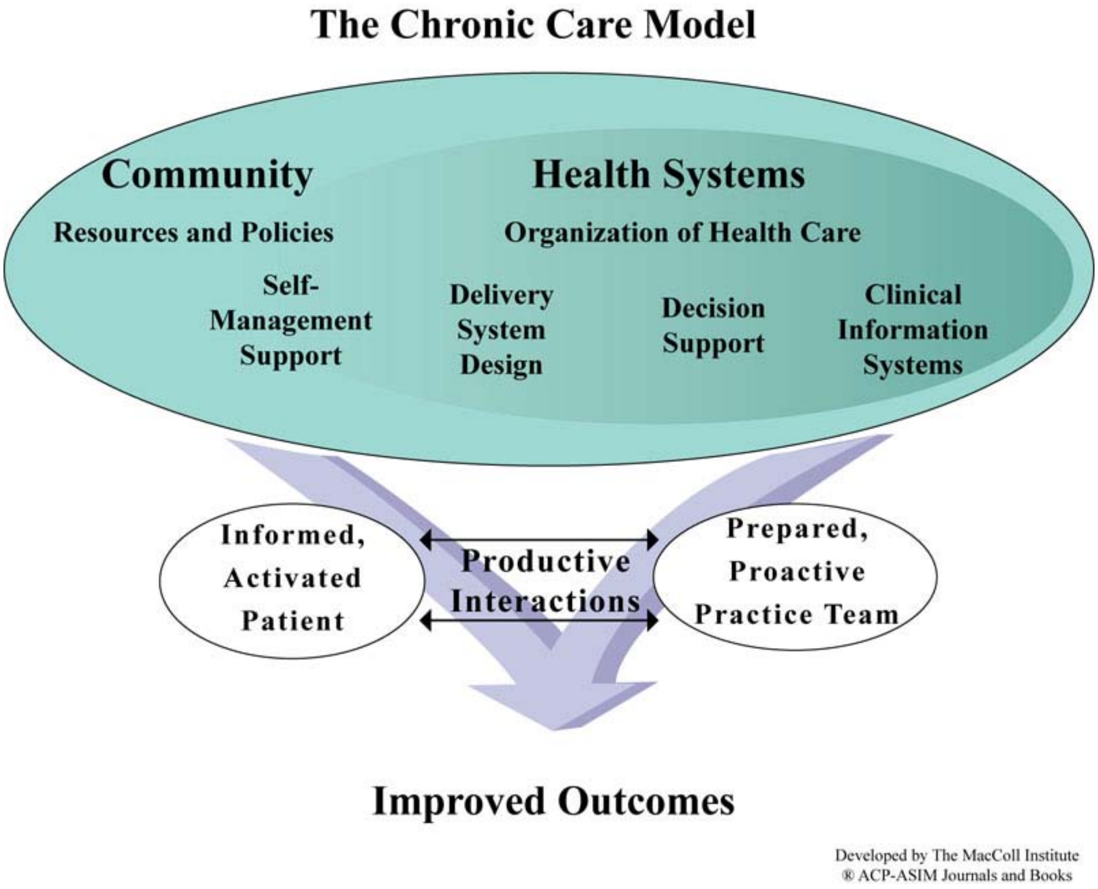
A strategy to improve the coordination and efficiency of care for chronic conditions is to add supplemental services and personnel to improve care coordination and implement care plans.[4-6] Case management (CM) is one such supplemental service, in which a single person, usually a nurse or social worker, takes responsibility for coordinating and implementing a patient's care plan, either alone or in conjunction with a team of health professionals. Early models of CM were developed as part of the community health nursing movement of the early twentieth century. They were designed largely to promote patient self-help and coordinate community resources.[7] A central feature of these models was that the nurse case manager had roles in both coordinating services and providing clinical care directly.[8] In the 1970s CM was widely used to meet the needs of patients with chronic psychiatric diseases.[9-11] In the AIDS epidemic of the 1980s, CM was adopted to coordinate treatment programs for HIV-infected individuals. At about the same time, a model of CM for the frail elderly began to be disseminated.[12] In the 1990's training programs for case managers were greatly expanded, and case management certification programs were established.

The evolution of CM models in health care, and their expanding use in chronic illness management, has led to the term "case management" being used to describe a wide variety of interventions. As a result, there is no consensus as to what constitutes CM. Moreover, the term "case management" is often used interchangeably with other forms of chronic illness management interventions, such as "disease management," and "self-management support." The health professionals administering those programs, usually nurses, are often referred to as case managers. The conflation of these different terms—and their unsystematic use in describing nurse-led, chronic illness management interventions—makes it challenging to examine the contribution of CM as a distinct entity. For example, McDonald et al. reviewed 75 systematic reviews of studies evaluating the effectiveness of care coordination strategies for patients with chronic illness.[6] Many of these strategies were nurse-led interventions for patients with diabetes, congestive heart failure (CHF), and other chronic conditions, and 21 of the systematic reviews reported evaluating CM as an explicit objective. Most of these systematic reviews included studies of interventions that carried the label "case management" but did not typically define CM or distinguish it from other nurse-led interventions. Most of these reviews also did not isolate the effects of CM from other clinical interventions.[6]

Distinguishing Case Management From Other Interventions

We sought to add to the existing body of evidence on chronic illness management interventions by evaluating the distinct contribution of CM as a specific strategy. CM tends to be more intensive in time and resources than other chronic illness management interventions. To distinguish CM from other interventions, we drew upon definitions of CM in the literature and those used by professional organizations of case managers (see Appendix A). We also consulted with members of our Technical Expert Panel (TEP) who are experts in the field of CM. Those definitions and expert opinions indicated that a defining feature of CM is the central role of the case manager as comprehensive coordinator of a patient's care. The coordinating functions performed by a case manager include helping patients navigate health care systems, connecting them with community resources, orchestrating multiple facets of health care delivery, and assisting with administrative and logistical tasks. These *coordinating* functions are distinct from *clinical* functions, including disease-oriented assessment and monitoring, medication adjustment, health education, and self-care instructions. Such clinical functions are often the defining aspects of other chronic illness management interventions that are staffed by nurses.[13] In the context of chronic illness care, they are central to the role of a case manager as well, but a case manager also performs coordinating functions. The role of case managers in chronic illness care, and their distinction from other professionals involved in chronic illness management support, can be illustrated using the Chronic Care Model (see Figure 1).

Figure 1. Chronic care model



Note: Reprinted with permission.

Many chronic illness management interventions include professionals (usually nurses) who are members of a clinical practice team or perform discrete clinical functions (e.g., clinical monitoring and education) on behalf of the practice team. A case manager also performs these functions, but a central role of the case manager is to coordinate and integrate different types of services, including community resources, health systems, and the practice team, on behalf of the patient. CM is often utilized when such coordination and integration are inherently challenging and difficult for patients to accomplish on their own. CM usually involves high-intensity engagement with such patients, and case managers often adopt a supervisory role in comprehensively attending to patients' complex needs.[14] Conceptually, a case manager can be seen as an agent of the patient, taking a "whole person" (rather than solely clinical or disease-focused) approach to care, and serving as a bridge between the patient, the practice team, the health system, and community resources. Features of CM programs, based on the interventions described in the studies included in this review, are summarized in Table 1.

Table 1. Features of case management programs

Features Shared With Other Chronic Illness Management Programs
• Clinical assessment
• Care planning
• Health education
• Self-care instructions
• Monitoring clinical parameters
• Adjusting medications
• Communicating with practice team
Distinctive Features of Case Management
• Prominent supervisory role in coordinating multiple aspects of care
• High-intensity, longitudinal engagement with patient (and families or other caregivers)
• Functioning as patient advocate/agent
• Comprehensively assessing, monitoring, and addressing patients' needs (e.g., physical, psychological, social, emotional)
• Facilitating access to community resources, including social services
• Mainly for patients with complex care needs

In defining the functions of CM, two general models have been described. The gatekeeper (or interrogative) model focuses on controlling access to and ensuring efficient use of clinical services, while the patient advocacy (or brokering) model focuses on coordinating services and improving the quality of care. In current practice, a combined model that utilizes both approaches is most commonly used.[15-17] However, not all chronic illness management interventions that include clinical and coordinating activities are CM. A defining aspect of CM is that it involves a single person or small group of people (i.e., case managers) who are responsible for those activities. Other chronic illness management interventions—including "multidisciplinary teams" and "organized specialty clinics"[6]—may include clinical and coordinating activities as part of their overall approach to care, but such team-based interventions are distinct from CM. Another feature of CM is the level and duration of engagement with patients. Some chronic illness management interventions, particularly those designed to smooth transitions of care, include clinical and coordinating functions but are limited to one or two encounters with the patient. CM involves longitudinal engagement with patients, allowing for the development of a case manager-patient relationship.

Finally, CM is a supplemental intervention that occurs in addition to (and often in conjunction with) "usual" clinical care. A primary care or specialist practitioner caring for a patient may perform both clinical and coordinating activities, may be the principal person responsible for those functions, and may have a longitudinal relationship with the patient. But these "usual care" practitioners (e.g., primary care practitioners) are not considered case managers.

Variability of Case Management Implementation

Even when CM is defined explicitly—as a longitudinal intervention in which a single person, working alone or in conjunction with a team, coordinates services and augments clinical care for patients with chronic illness—there is wide variation in its implementation. Individual CM programs usually are customized for the clinical problems of the population being served. Thus, a CM program for homeless people with AIDS has a much different mix of activities than a program serving patients with dementia and their caregivers, or one designed to improve the quality of diabetes care. Some CM interventions include primarily coordinating functions, while others focus mainly on clinical activities. Some target patients with characteristics—limited social support or physical or mental disability—that make them particularly vulnerable to lack of care coordination, while others serve unselected populations with a given chronic illness. Some interventions are intensive, with multiple face-to-face interactions and home visits, while others entail only infrequent telephone calls. In some, case managers operate independently, while in others, they work closely with a patient's usual care provider or with a multidisciplinary team of health professionals. This variability of CM interventions makes it challenging to evaluate the effectiveness of CM as a discrete entity. It is therefore of potentially greater interest to evaluate the impact of specific components within CM intervention "packages." However, in many studies, the way in which CM is implemented is poorly described, making it difficult to study the individual components of CM interventions.

Scope and Key Questions

The Agency for Healthcare Research and Quality (AHRQ) commissioned this Comparative Effectiveness Review (CER) to examine the evidence for the effectiveness of CM programs for chronic illness patients with complex care needs. To define the scope of the review, we used the framework described above to define CM interventions. Specifically, we considered interventions in which case managers had a substantive role in performing both clinical and coordinating functions. Although some interventions may include coordinating functions without explicitly describing them, we only included interventions in this review for which those functions were central enough to the manager's role to be described as part of the intervention. Because the balance of clinical and coordinating activities varies widely across CM interventions, our review included a diverse array of interventions in which case manager roles spanned a continuum, from predominantly clinical to predominantly coordinating in nature.[18] We used the description of the intervention and its components, rather than its label, to make decisions about which interventions had the defining characteristics of CM as described above. Thus, we did not include all interventions that were labeled in the literature as CM, and we sometimes included interventions carrying other labels (including care management and disease management).

As noted, the situations in which CM has been used are numerous and diverse. In recognition of the substantial heterogeneity of purposes, approaches, and populations included within the broad category of CM, we limited the scope of this review in a number of ways. We aimed to define and identify a subset of CM models representing a sizable category of CM that is common and meaningful for patients and their caregivers. We also aimed to circumscribe the scope of included CM models to ensure that a review of this type would be adequately focused and practical. Such an approach allows for a more complete understanding of the evidence regarding the included category of CM. We limited the scope of this review to CM interventions for medical, as opposed to psychiatric, illness. CM is often used to improve the management of psychiatric illnesses such as depression or schizophrenia, as well as substance use disorders. CM in those contexts, however, is substantively different in its nature and objectives from CM for chronic medical illness. Although we did not include studies in which the goal of CM was primarily to improve psychiatric care, we did include studies in which CM was used to improve chronic medical illness care among patients who also had psychiatric illness. Similarly, we included models of care management that integrated care for both medical and psychiatric illness. Additionally, we restricted the review to CM that was characterized by an ongoing and sustained relationship between the case manager and patient. Hence, despite promising evidence for certain models of short-term, intensive CM or models that focus on transitional care,[19-21] we did not include such models in this review. We also limited the scope of this review to outpatient settings. This report summarizes the existing evidence addressing the following Key Questions in the outpatient setting:

Key Question 1:

In adults with chronic medical illness and complex care needs, is case management effective in improving:

a. *Patient-centered outcomes,* including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?
b. *Quality of care,* as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?
c. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

Key Question 2:

Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3:

Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

Organization of the Report

Following this introduction are chapters on methods; results; summary and discussion, including limitations of the review; conclusions; and future research. The reference list appears at the end of the report, along with a table of abbreviations used throughout the report. The results chapter is divided into several major sections: search results, with a study flow diagram; overall effectiveness of case management and results for each of the Key Questions; and effectiveness of case management in defined patient populations. The defined patient populations are—

- Older adults with one or more chronic diseases
- Frail elderly

- Patients with dementia
- Patients with congestive heart failure
- Patients with diabetes mellitus
- Patients with cancer
- Patients with serious chronic infections
- Patients with other medical problems

Each section on a defined patient populations presents—

- An overall description of studies
- Key points related to the evidence about patient-centered outcomes (quality of care, health care utilization, patient characteristics, and intervention characteristics)
- Analysis of effectiveness of case management by outcome (patient-centered outcomes, quality of care outcomes, and resource utilization)
- Analysis of effectiveness of case management by patient characteristics
- Analysis of effectiveness of case management by intervention characteristics

Methods

Topic Development and Refinement

The original topic nomination was submitted to the Agency for Healthcare Research and Quality (AHRQ) by a member of the general public. It proposed a comparative effectiveness review of case management (CM) (performed by certified nurse case managers) for improving utilization and costs of health services. The original nomination specified a broad population of interest ("all patients") and did not further specify the outcomes of interest. Because a literature scan identified diverse populations, interventions, and outcomes, the nomination was further scoped during topic refinement to produce more specific Key Questions.

During a topic refinement phase, the scope of the project was refined with input from a panel of Key Informants. Key Informants included representatives of public organizations and societies with an interest in CM, individuals who have performed CM research, experts on the chronic care model, and practicing case managers. This input led to revision of the Key Questions, which were posted for public comments. A Technical Expert Panel (TEP) was then formed to review Key Questions, identify important issues, and define parameters for the review of evidence. The TEP also reviewed the research protocol, which is posted on the AHRQ Web site (effectivehealthcare.ahrq.gov). Discussions among the project investigators, TOO, Key Informants, and the TEP occurred during a series of teleconferences and via email. In addition, input from the TEP was sought during compilation of the report when questions arose about the scope of the review.

The AHRQ Task Order Officer (TOO) was involved throughout this project. The TOO facilitated a common understanding among all parties involved in the project, resolved ambiguities, and advised on the scope and processes of the project. The TOO and other staff at AHRQ reviewed the report for consistency, clarity, and to ensure that it conformed to AHRQ standards. AHRQ staff did not participate in the literature search, data analysis, or interpretation of the results.

Three Key Questions are addressed in the present report. One pertains to outcomes in patients and caregivers who receive services from case managers (Key Question 1), one addresses associations between patient factors and the results of CM (Key Question 2), and one addresses comparison among different types and models of CM (Key Question 3).

Search Strategy

To identify articles relevant to each Key Question, we worked with medical librarians who have extensive experience with conducting literature searches for comparative effectiveness reviews. We searched MEDLINE® (Ovid), CINAHL® (EBSCO), the Cochrane Central Register of Controlled Trials (Ovid EBM Reviews), the Cochrane Database of Systematic Reviews (Ovid EBM Reviews), and the Database of Abstracts of Reviews of Effects (Ovid EBM Reviews). We searched by broad level subject terms and keywords. The search was limited to English language materials and adult populations (see Appendix B for search strings and time spans searched). The choice of specific terms used in the search strings was guided by the attempt to distinguish among CM as defined for this report and the multiple other types of nursing-based and focused disease management interventions. The database searches included the time period through August, 2011. Retrieved citations were imported into an electronic database, EndNote® X3, for deduplication and tracking.

Other approaches were also used to identify evidence about CM for complex chronic illness care. Additional studies were identified by reviewing the reference lists of published clinical trials and review articles that addressed CM. Gray literature searches included clinical trial registries: ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, and WHO Trial Registries.

Study Selection

We developed criteria for inclusion and exclusion of studies based on the Key Questions and the populations, interventions, comparators, outcomes, timing, and setting (PICOTS) approach (see Appendix C). To reduce bias and enhance consistency in our study selection process, we initially had three reviewers review 100 citations for inclusion and calculated kappa values to estimate inter-reviewer reliability. After discussing and reconciling disagreements between reviewers, the same three team members reviewed an additional 100 citations. We continued this process until the kappa values reached >0.50 for each pair of reviewers. Two reviewers then reviewed each title and abstract for inclusion and exclusion, using our pre-established inclusion/exclusion criteria to determine potential eligibility for inclusion in the evidence synthesis. All citations judged to be possibly included by one or both of the reviewers were retrieved as full-text articles.

Each full-text article was reviewed independently by two team members using pre-established criteria for inclusion. If there was consensus between the two, then the article was either included or excluded. In cases of disagreement, a senior investigator reviewed the article and made the decision on inclusion and exclusion. A data file of excluded studies with reasons for exclusion was maintained (Appendix D).

After the draft report was posted for public comment, the search was updated to capture any new publications. Literature identified during the updated search went through the same process of dual review as all other studies considered for inclusion in the report. All new studies identified by this process as meeting the established criteria for inclusion are incorporated in the final report.

PICOTS Framework

Populations of Interest

This review focuses on adults with medical illness and complex care needs in the outpatient setting. A main criterion in choosing studies for inclusion was the existence of complex care needs. Complex care needs was defined broadly and we included studies with case definitions based on health care resource utilization, patient health outcomes, and/or multifactor assessments that include measures such as socioeconomic status or patient self-efficacy. Appendix E provides examples of similar definitions of complex care needs from a variety of organizations. The included studies sometimes addressed populations in which psychiatric problems, such as depression or dementia, were important comorbid conditions.

The population of interest included all adults with medical illness and complex care needs. To identify the broadest sample of literature relevant to CM for such patients, we did not want to limit the results of the literature search to any particular disease condition or conditions. Our search was designed to include all subpopulations with ***any*** medical illness and complex care needs for whom CM had been studied. However, we excluded studies in which the primary clinical problem was a psychiatric disorder (other than dementia) and in which CM was used primarily to manage mental illness or a substance abuse disorder.

Interventions

The definition of CM used to make decisions about inclusion/exclusion is described in detail in the Introduction section of this report. We define CM as a process in which a person (alone or in conjunction with a team) manages multiple aspects of a patient's care. Key components of CM include planning and assessment, coordination of services, patient education, and clinical monitoring.

Comparators

In most studies, CM is compared with usual care (i.e., care without a CM component). Usual care can be quite variable across studies and generally consisted of the array of services generally available to the population studied. When a study compared two or more different types of CM, then the comparator was the alternative type of CM. However, in most cases the comparator was the same milieu of clinical services without a distinct CM component. For clinical trials and other studies having a comparison group, we specifically examined the study's reports for information about contamination (provision of CM or other care coordination services to the control group).

Outcomes of Interest

The outcomes of interests are specified in the Key Questions, as follows:

a. *Patient-centered outcomes*, including mortality, quality of life (QOL), disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care.
b. *Quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior.
c. *Resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits).

These categories were derived from the set of outcomes specified in the published evaluations of CM programs. Clinical programs that utilize CM address the needs of defined patient populations and have discrete clinical goals. These three categories of outcomes reflect the clinical goals of CM programs. In some cases certain reported outcomes were not used for this report if the methods used for the measurement were judged inadequate or were not consistent across studies.

Comparative effectiveness reviews commonly classify outcomes as either benefits or harms. The CM literature has not classified harms of CM. Thus, the outcomes listed above are not classified as either benefits or harms.

Timing

Longitudinal engagement with patients was a criterion for study inclusion. We excluded studies that provided CM for only short durations (30 days or less). This criterion excluded many studies that evaluated short-term posthospitalization programs (often termed "transitional care" programs). Such programs fall into a large category of inpatient discharge planning activities that are beyond the scope of this review.

Settings

We included only studies in the outpatient setting, including primary care, specialty care, and home care settings. No geographic limitations were applied.

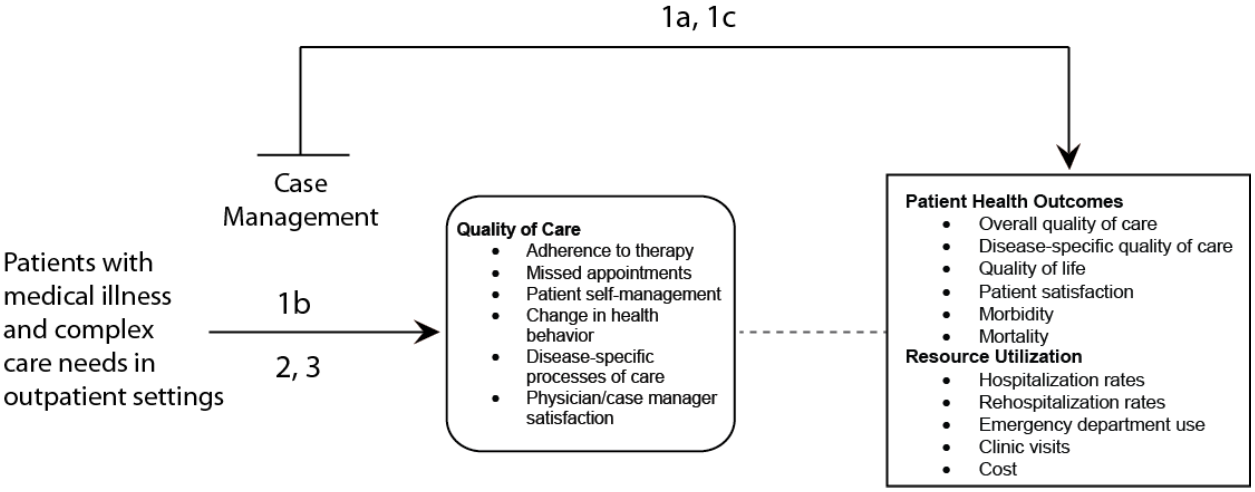
Types of Studies

We included trials and observational studies pertinent to the Key Questions. We retrieved and evaluated for inclusion and exclusion any randomized trial. We also included studies using nonexperimental designs, including cohort, case-control and pre/post designs. Previously published systematic reviews were not included as primary evidence. However, systematic reviews that used definitions of CM that were consistent with that used in this project were used to identify any additional primary studies that had not previously been identified. Inclusion and exclusion criteria are detailed in Appendix C.

Analytic Framework

We developed an analytic framework (Figure 2) that specifies the relationships between the interventions and outcomes. This analytic framework depicts the chain of logic for using evidence to answer the Key Questions.

Figure 2. Analytic framework



Note: Numbers refer to Key Questions.

Data Extraction and Data Management

After studies were selected for inclusion based on the Key Questions and PICOTS, the following data were abstracted and used to assess applicability and quality of the study: study design; inclusion and exclusion criteria; population and clinical characteristics (including sex, age, ethnicity, primary disease, comorbidities, complex care needs, and insurance carrier); CM intervention characteristics (including case manager professional identification and prior training); preintervention training for case managers; caseload and the nature of care provided by the intervention (e.g., patient education, coordination of services, medication monitoring, and adjustment); and results for each outcome, focusing on the outcomes of interest (patient-centered, resource utilization, and process of care outcomes). We also recorded the number of patients randomized relative to the number of patients enrolled, how similar those patients were to the target population, and the funding source. We recorded intent-to-treat results when available. These data are presented in the evidence tables (see Appendix I). All data abstracted from included studies were verified for accuracy and completeness by a second team member.

Quality Assessment of Individual Studies

We assessed the quality of randomized trials and cohort and case control studies based on the predefined criteria listed in Appendix F. We also adapted criteria from methods proposed by Downs and Black[22, 23] (observational studies) and methods developed by the U.S. Preventive Services Task force.[24] The criteria used are consistent with the approach recommended by AHRQ in the Methods Guide for Comparative Effectiveness Reviews.[25] We used the term "quality" rather than the alternate term "risk of bias"; both refer to internal validity.

We rated the quality of each controlled trial based on the methods described in the published reports about randomization, allocation concealment, and blinding; the similarity of compared groups at baseline; maintenance of comparable groups; adequate reporting of dropouts, attrition, crossover, adherence, and contamination; loss to followup; the use of intention-to-treat analysis; and ascertainment of outcomes.[23]

Individual studies were rated as "good," "fair," or "poor" (see Appendix G). Studies rated "good" have the least risk of bias, and results are considered valid. Good-quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment; low dropout rates and clear reporting of dropouts; appropriate means for preventing bias; and appropriate measurement of outcomes.

Studies rated "fair" are susceptible to some bias, but it is not sufficient to invalidate the results. These studies do not meet all the criteria for a rating of good quality, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The "fair" quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair quality studies are *likely* to be valid, while others are only *probably* valid.

Studies rated "poor" have significant flaws that imply biases of various types that may invalidate the results. They have a serious or "fatal" flaw in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting; or serious problems in the delivery of the intervention. The results of these studies are at least as likely to reflect flaws in the study design as they are to reflect the true differences between the interventions that were compared. We did not exclude studies rated poor quality a priori, but poor quality studies were considered to be less valid than higher-quality studies when synthesizing the evidence, particularly when discrepancies between studies were present.

Applicability

Applicability is an indicator of the extent to which research included in a review might be useful for informing clinical and/or policy decisions. Applicability depends on the particular question and the needs of the user of the review. Because it depends on context, there is no generally accepted universal rating system for applicability. We based our approach on the guidance described by Atkins et al.[23, 26] to assess applicability of the evidence for the Key Questions addressed in this review. We describe features of the included studies that are relevant to applicability in terms of the elements of PICOTS. We considered the specific clinical and policy questions for CM interventions. For example, CM interventions are often tailored specifically to the needs of particular patient populations making results only pertinent to those populations (e.g., HIV positive, dementia, diabetes, etc); for this reason we provide detailed results by specific patient populations. This choice to describe results according to condition offers greater clarity on applicability of the results and avoids over-generalization of the results of case management interventions for specific conditions to all cases of CM. Additionally, factors about the intervention of CM itself may influence applicability. For example the intensity of the intervention may not be feasible across settings. Therefore, these factors are described within each section when possible.

Data Synthesis

CM has been studied in a large range of clinical settings and for diverse patient groups. Many CM programs target individuals with particular diseases or clinical needs, and the programs are tailored for those patient needs. Because of the broad range of models of CM, we grouped the studies by the population groups and the clinical problems that were chiefly addressed. For the majority of studies, these groupings were based on particular diagnoses (such as congestive heart failure, diabetes, or dementia). There also were studies on programs that addressed the needs of older adults that generally fell into one of two groups—older adults with multiple chronic conditions or the frail elderly. We reviewed the findings of the studies for each of these categories and then assessed overall findings (across population groups), as related to the project's Key Questions. For all outcomes the amount of heterogeneity among the individual studies precluded formal meta-analyses.

Grading the Body of Evidence for Each Key Question

The strength of evidence for each Key Question was initially assessed for the outcomes applicable to each patient category. We used the approach described by Owens et al.[27] to evaluate the body of evidence for each outcome in each patient category. This approach uses the following categories:

- Quality (good, fair, poor)
- Consistency (consistent, inconsistent, unknown)
- Directness (direct or indirect)
- Precision (precise, imprecise)

Without formal pooled analyses, we were not able to assess publication bias. The strength of evidence was assigned an overall grade of High, Moderate, Low, or Insufficient according to a four-level scale:

- High—High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect. When the conclusion is that the intervention (in this case, CM) does not have a significant effect on an outcome, the sample size and statistical power of the existing studies are high enough to warrant confidence in the stated conclusion.
- Moderate—Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate. In the case of negative results, the statistical power of existing studies may be

only modest, and the conclusion could be changed by a new study examining a substantially larger patient population.

- Low—Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- Insufficient—Evidence either is unavailable or does not permit estimation of effect. This includes situations in which the results of multiple studies are highly heterogeneous.

Because the published studies often examined specific patient populations, the content of the CM interventions generally were tailored to the clinical problems of those patient groups. Thus, there is a considerable diversity of programs. Comparisons across programs and populations need to account both for differences in the populations and differences in the content of the CM programs.

A wide variety of outcomes were included in these studies. After reviewing all of the studies, we categorized the outcomes according to the three parts of Key Question 1. In some cases the patient-centered outcomes were unique to the type of CM programs used for particular patient populations. The following outcomes were evaluated for strength of evidence:

Key Question 1a: Patient-Centered Outcomes

- Multiple populations
    - Mortality
    - Quality of life (QOL)
    - Functional status
    - Patient satisfaction
- Frail elderly
    - Nursing home admissions
- Dementia
    - Ability to remain at home (time to nursing home placement)
    - Caregiver depression and strain (burden)
- Cancer
    - Symptoms caused by cancer
    - Depression
- Diabetes
    - Glucose management
    - Cholesterol control
    - Body weight

Key Question 1b: Quality of Care

- Multiple populations
    - Receipt of guideline-recommended clinical services
    - Patient self-management behaviors
    - Medication adherence
    - Missed appointments
    - Patient perception of care coordination

Key Question 1c: Resource Utilization

- Multiple populations
    - Hospitalization rates
    - Emergency department (ED) visits
    - Appointments with primary care and specialty providers
    - Overall expenditures

Key Question 2: Variation due to Patient Characteristics

- Multiple populations
    - Variation among racial/ethnic groups
    - Variation among socioeconomic groups
    - Variation attributable to social support

Key Question 3: Variation due to Intervention Characteristics

- Multiple populations
    - Variation due to intensity of CM
    - Variation due to duration of CM
    - Variation due to training and supervision of case managers
    - Variation due to integration with other clinical programs

In describing the available evidence about the effects of CM programs on these outcomes, we first summarize the evidence for the three Key Questions. We then provide detailed descriptions of the evidence for the patient populations that fell within this report's scope. In the detailed descriptions provided later in this report, specific citations to individual studies are included. Table 17 (see the Conclusions section) provides the specific evidence statements (with strength of evidence for each) upon which the general summary statements are based. The strength of evidence tables appear in Appendix H.

Peer Review and Public Commentary

Peer review was provided by experts in chronic illness care and CM; representatives of AHRQ and an associate editor also provided comments. The draft report also was posted on AHRQ's Effective Health Care (EHC) Web site for 4 weeks to elicit public comments. We addressed all reviewer comments, revising the text as appropriate, and summarized changes to the report in a disposition of comments document that will be made available 3 months after the final CER is posted on the EHC Web site.

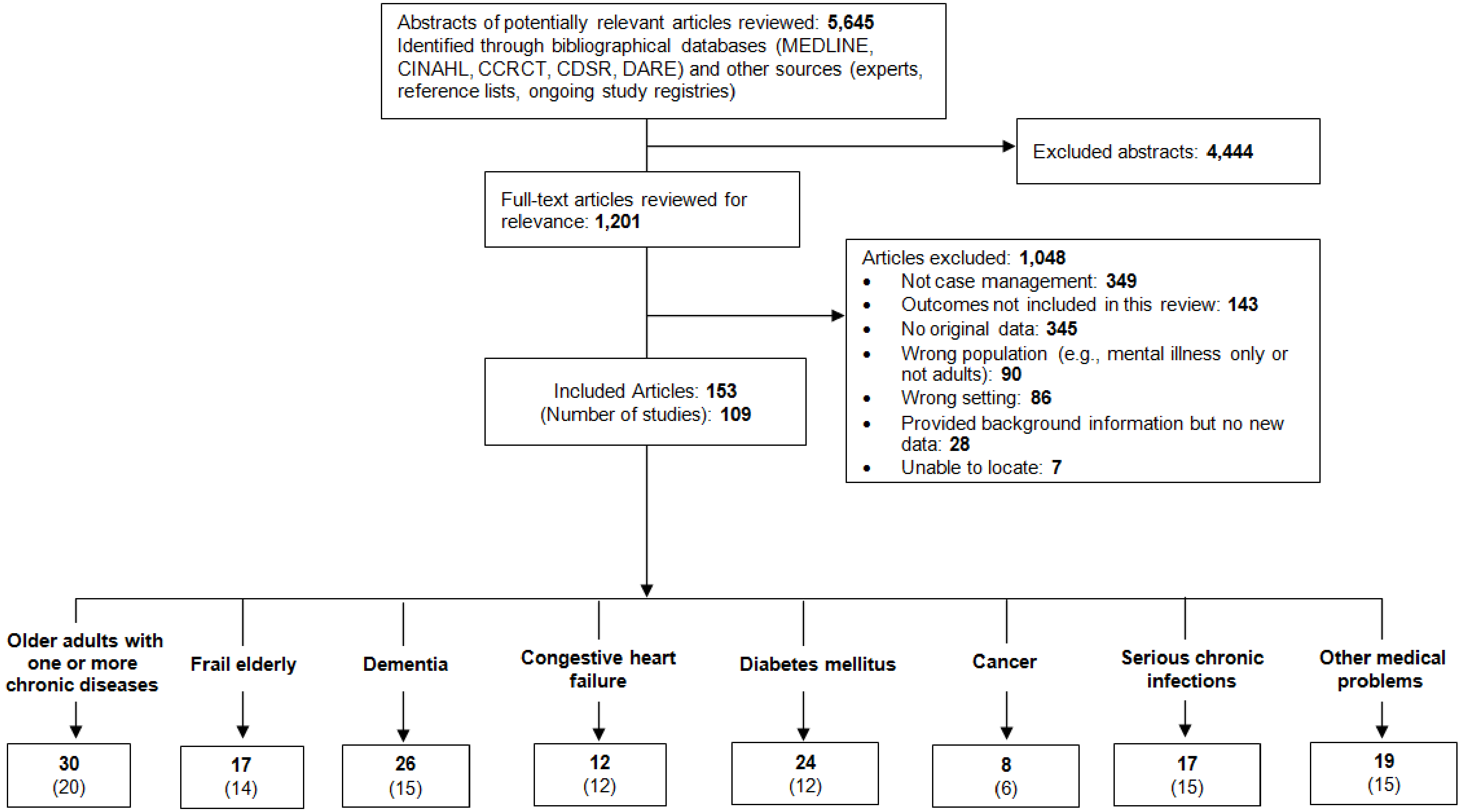
Results

Search Results

A summary of the search results is presented in Figure 3. We obtained 5,645 citations from the initial and updated database searches, by reviewing reference lists of published studies and systematic reviews, and by reviewing registries of ongoing studies.

After a review of the citation titles and abstracts, 1,201 were selected as possibly relevant by at least one of the two reviewers. Full articles were retrieved for all of these. After review of the full articles, a total of 152 articles were selected as relevant by two reviewers and included in the review. One additional study was identified through a registry of VA Cooperative Studies but was published after the date of the update search.[28] This study was added, bringing the total to 153 articles. Due to multiple publications for some studies, this represented 109 total studies of case management (CM). After examination of the gray literature search results, no additional studies were included. Appendix D contains a list of included and excluded articles.

Figure 3. Study flow diagram



Overall Effectiveness of Case Management

Our review examined studies of CM that provide longitudinal services to patients, generally for a duration of at least 6 months and often extending for longer than 1 year. The individual studies were diverse but generally fell into two categories. The first category is evaluations of innovative programs targeted at specific patient groups. These studies often featured a close relationship between program developers and the evaluation teams. While some such studies included small sample sizes and short durations of follow-up, others included hundreds of participants and sometimes lengthy follow-up. [29-31] The second major category was a group of formal demonstration projects, most commonly funded by the U.S. Centers for Medicare & Medicaid Services. These studies tended to be large, including geographically diverse clinical sites, and they commonly had evaluations performed by research teams that had no history of working with the clinical programs.[32-37] While the first category of studies examined novel programs that may be uniquely suited to their patient populations, the second category examined clinical programs that were likely to be typical of how such programs are implemented and disseminated in community settings. In general, these two types of studies are complementary, and we attempted to account for program diversity in estimating the strength of evidence for the Key Questions.

The overarching finding of our review is that, when CM was deployed in a variety of community settings, its impacts tended to be limited to narrowly specified outcomes such as patterns of the care received and certain measures of the status of the underlying disease. However, it had minimal impact on more general patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. On balance, CM interventions tested in randomized trials were more often unsuccessful than successful in improving prespecified outcomes. The most notable example of the limited impact of CM was the Medicare Coordinated Care Demonstration project (MCCD), in which over 18,000 patients, predominantly elderly persons with multiple chronic illnesses, were enrolled in a prospective randomized trial conducted in 15 separate CM programs across the United States.[32] Twelve of these 15 programs met our criteria for inclusion in this report. In assessing multiple outcomes—including health outcomes, quality of care, hospitalizations, and overall expenditures—there were only sporadic and isolated successes. Only three of the programs, one of which was small and could not be sustained, showed potential return on investment.

Although this summative conclusion of minimal impact reflects the balance of findings from our review, it was not a consistent finding across all studies. Some studies enrolled general populations with chronic illness, while others targeted patients with clinical or sociodemographic characteristics that put them at risk for inadequate care, poor outcomes, or high resource utilization (e.g., patients with high utilization of services or with limited social support). Other studies tested CM for the management of specific clinical conditions (e.g., diabetes, dementia). The goals of CM varied across different clinical conditions, patient populations, and settings. For instance, CM intended to delay nursing home placement for community-dwelling patients with dementia was very different—in content, implementation, and intensity—from CM intended to improve physiologic and metabolic measures (such as glycemic control) among outpatients with diabetes. We therefore synthesized data for specific patient groups (typically defined by clinical condition), in which the goals of CM interventions were relatively similar. We then sought common themes that cut across groups. In this section we present the findings of our crosscutting synthesis.

Key Question 1a. In adults with chronic medical illness and complex care needs, is case management effective in improving *patient-centered outcomes*?

Mortality

While reducing mortality was rarely the principal outcome examined in the studies, it was often measured and reported. Patients who were provided CM did not experience lower mortality in general populations of patients with chronic illness, in the frail elderly, those with AIDS, or in patients with congestive heart failure.

Quality of Life and Functional Status

CM interventions produced mixed results in terms of improving patient QOL and functional status. In general, CM was sometimes successful in improving aspects of functioning and QOL that were directly targeted by the interventions. For instance, CM was successful in improving caregiver stress among persons caring for patients with dementia and congestive heart failure (CHF)-related QOL among patients with CHF. The measures used to evaluate QOL and functional status varied across studies, and overall, the improvements in QOL and functional status achieved by CM were either small or of unclear clinical significance. CM was less successful in improving overall QOL and functioning, as indicated by global measures not specific to a particular condition.

Patient Satisfaction With Care

CM interventions were generally associated with improved patient (and caregiver) satisfaction, although satisfaction with CM varied across interventions. Studies measuring patient satisfaction typically reported overall satisfaction with care, rather than satisfaction in specific domains. Some studies found that CM improves patient perceptions of coordination among health care providers.

Ability to Remain at Home

One measure of the clinical significance of improvements in functioning for elderly patients with chronic conditions is the ability to remain at home and avoid nursing home placement. This outcome was often the primary objective of CM programs for patients with dementia. In most studies of the frail elderly and of patients with dementia, CM was not effective in maintaining patients' ability to live at home. Evidence from one study suggests that a high-intensity CM intervention sustained over a period of several years can produce a substantial delay in nursing home placement for patients with dementia.

Disease-Specific Health Outcomes

The effect of CM on disease-specific outcomes was inconsistent. In some studies, CM had a positive impact on specific symptoms, including pain and fatigue in patients with cancer and depressive symptoms among caregivers of patients with dementia. Some studies also found that CM had a positive impact on glycohemoglobin levels for adults with diabetes. However, CM has not been found to have a significant benefit for improving lipid levels or body weight in this population.

Patient Satisfaction With Care

CM interventions were generally associated with improved patient (and caregiver) satisfaction, although satisfaction with CM varied across interventions. Studies measuring patient satisfaction typically reported overall satisfaction with care, rather than satisfaction in specific domains. Satisfaction was most substantially improved in the domain of coordination among health care providers.

Key Question 1b. In adults with chronic medical illness and complex care needs, is case management effective in improving *quality of care*?

Disease-Specific Process Measures and Receipt of Recommended Services

CM was effective in increasing the receipt of recommended health care services when it was an explicit objective of the CM intervention. For instance, CM interventions designed to improve cancer therapy for patients with breast and lung cancer were successful in increasing the receipt of radiation treatment, as recommended in clinical guidelines. In a study of low-income adults who already were enrolled in primary care, CM was found to improve measures of cardiac risk. The effect of CM on guideline-recommended care in general, however, was less consistent. Studies showed only sporadic effects on elements of quality of care, such as receipt of appropriate medications for patients with CHF or diabetes, or receipt of appropriate preventive services for elderly patients.

Patient Self-Management

CM was effective in improving patients’ self-management behaviors, including dietary and medication adherence, for specific conditions such as CHF or tuberculosis, when patient education and self-management support were included within CM interventions.

Missed Appointments

Few studies measured the frequency of missed appointments as an outcome of CM interventions.

Key Question 1c. In adults with chronic medical illness and complex care needs, is case management effective in improving *resource utilization*?

Hospitalization Rates

Although hospitalization rates were often included as an outcome, trials of CM generally did not demonstrate reductions in these rates.

Emergency Department Use

CM had a variable effect on ED use. Several studies found reduced ED use in patients receiving CM, but other studies found no effect.

Clinic Visits

Few studies measured the frequency of clinic visits as an outcome of CM interventions. Those that did found varying results. CM sometimes was associated with increased rates of physician visits and sometimes with decreased rates.

Overall Expenditures

Most studies examining the impact of CM on the overall cost of care showed no significant difference between groups of patients receiving CM and control groups. Although the cost of CM programs often was modest relative to overall costs among patients with high utilization, the effect of CM on reducing utilization is minimal.

Key Question 2. Does the effectiveness of case management differ according to *patient characteristics*?

Medical Conditions

Individual studies had inconsistent findings on whether CM interventions are more successful for patients with high disease burden. While it is possible that there is a mid-range of disease burden for which CM is most effective, the evidence base does not permit defining how to identify such patients.

Age

Most studies of CM included mainly elderly patients, making it difficult to determine impact of age on CM effectiveness.

Socioeconomic Status

Studies did not routinely report the effect of CM according to socioeconomic indicators among enrolled patients. Some studies explicitly targeted low-income populations. There was no apparent pattern to suggest an influence of patient socioeconomic status on the effectiveness of CM.

Social Support

Few studies explicitly evaluated patients’ level of social support. However, studies that targeted patients with limited social support did not tend to find better results.

Formally Assessed Health Risk

Some studies explicitly targeted patients considered to be at high risk of poor outcomes. The methods used to evaluate risk, however, varied substantially across studies. The studies have not defined a specific level of risk for which CM is most effective for improving outcomes.

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*?

Setting

Characteristics of the setting in which CM was implemented (e.g., integrated health system, home health agency, outpatient clinic) did not clearly influence the effectiveness of CM.

Case Manager Experience, Training, Skills

Studies did not consistently provide details about the experience, training, or skills of case managers. In most studies the case managers were registered nurses, and some had specialized training in caring for patients with the conditions targeted by the CM intervention (e.g., diabetes, cancer). There was some evidence that pre-intervention training of nurses in providing CM for the targeted conditions, the use of protocols or scripts to guide clinical management, and collaboration between a case manager and a physician (or multidisciplinary team) specializing in the targeted clinical condition, resulted in more successful interventions.

Case Management Intensity, Duration, Integration With Other Care Providers

Studies across multiple patient groups suggested that more intense CM interventions, as indicated by greater contact time, longer duration, and face-to-face (as opposed to only telephone) visits, produced better outcomes, including functional outcomes and lower hospitalization rates. The most successful interventions generally had more contacts between case managers and patients and were more integrated with the hospitals and physicians where patients received care.

Case manager Functions

Case managers typically performed multiple functions. These included but were not limited to assessment and planning, patient education, care coordination, and clinical monitoring. In general, emphasis on specific functions varied according to patients' conditions and the primary objectives of specific CM interventions. For example, interventions among patients with cancer typically focused on coordination and navigation, while interventions for patients with diabetes and CHF focused more on patient education (for self-management) and clinical monitoring. Most studies did not carefully measure the amount of effort case managers devoted to different functions, making it difficult to discern the degree to which emphasis on different case manager functions impacted CM effectiveness.

Effectiveness of Case Management in Defined Patient Populations

Population: Older Adults With One or More Chronic Diseases

Contemporary models of CM use clinical approaches that are applicable to a variety of diseases and conditions. Clinical programs that meet the needs of a broad patient population potentially are more sustainable, and the largest clinical trials of CM have been studies of programs that take a generalist approach. The primary goal of many of these studies has been to determine whether CM can reduce health care expenditures by preventing acute hospitalizations and reducing use of other expensive services. At the same time, CM programs for the elderly frequently have been dominated by approaches that attempt to define *subpopulations* at particular risk. The basic premise is that a healthy, highly functional older adult is less likely to need CM than one of the same age who has a greater burden of illness. Selection of older adults for inclusion in CM, therefore, has taken a wide variety of approaches. These include purely administrative assessments such as previous utilization, especially hospitalization, certain chronic illnesses, or prior costs of care. Evaluations of such CM programs are included in this section. Subsequent sections of this report will review the evidence about programs that select participants on the basis of either targeted assessments of patient-reported functional and health status (the frail elderly) or on the basis of specific clinical diagnoses such as dementia or congestive heart failure. However, it is important to note that the studies of general populations of older adults with various chronic illnesses (analyzed in this section) include populations of patients that have characteristics and medical problems that are very similar to the populations included in the studies of particular diseases (such as congestive heart failure, diabetes, or cancer) that are described in the subsequent sections of this report.

Description of Studies

We identified seven randomized trials of CM programs that delivered services to broad populations of older adults (see Appendix I, Evidence Table 1). Four were rated good quality,[29, 32-34, 38] and three were rated fair[35, 39-41] (see Appendix G). Six trials were conducted in the United States[29, 32, 34, 35, 38, 39] and one in the Netherlands.[40, 41] Two trials were published between 1994 and 1997.[34, 39] Five trials were published between 2003 and 2011.[29, 32, 35, 38, 40, 41] In addition to the seven randomized trials, we identified four studies of CM for community-dwelling Medicare populations that used nonexperimental designs, one good quality,[42] and three fair quality studies.[43-45] These four studies examined groups of patients who received CM services in existing programs and used matching techniques to construct comparison groups. We also identified nine other observational studies that used either historical controls, a nonequivalent comparison group, or did not have a comparison group;[46-55] all but two[46, 49] of these studies were poor quality (see Appendix I, Evidence Table 2, and Appendix G).

Other closely related clinical approaches have been developed for older adults with chronic diseases. These were not included in this review, based on our definition of CM. First, team-based geriatric practices, including the Program for All-Inclusive Care of the Elderly (PACE) and the Home-based Primary Care (HBPC) program of the Department of Veterans Affairs, were excluded because they tended to have provider-led interventions, and the role of the case manager was less clear in most of them.[56, 57] Rather, these approaches tended to involve team-based discussion and coordination that was either the source of primary care or essentially replaced primary care. Similarly, the Geriatric Resources for Assessment and Care of Elders project (GRACE)[58] also was excluded. This model used home-based care by a team consisting of a nurse practitioner and social worker to provide guidance and assistance to older adults.

The largest randomized trial of CM was conducted between 2002 and 2005 in multiple sites in the United States.[32, 33, 59, 60] Known as the Medicare Coordinated Care Demonstration (MCCD), the study was funded by the Centers for Medicare & Medicaid Services (CMS). The 15 clinical sites had submitted proposals to CMS to participate in the project. The evaluation was managed by a separate organization that collected all outcome data. Participants were enrolled and randomized through 2005. Because each clinical program was managed separately, this study was in fact a set of single-site clinical trials, each using identical methodology. The study reports listed outcome data separately for each site. Of the 15 sites, one was a hospice program, one was conducted in a long-term care facility, and one did not provide care coordination. Because these did not meet our definitions for study setting or intervention characteristics, we dropped these three sites from our analyses, leaving 12 sites used for this report. The total sample size for these 12 sites was 16,301. There was a significant variation in size across these 12 sites, ranging from 211 to 2,657 participants per site. For all seven of the clinical trials in this category, the total number of participants is 31,935.

The *populations* in five of the six U.S. trials were Medicare beneficiaries living independently who were judged to be at high risk of medical complications and the attendant utilization of health care services.[29, 32, 34, 35, 38] Eligibility criteria for all but one of the programs included in the MCCD trial[32] included one or more targeted chronic conditions; seven of the 12 programs also required a recent hospitalization—either within a year prior to enrollment (six programs) or within the prior 60 days (one program). The average monthly Medicare expenditures at baseline for the study sample overall was nearly three times that of beneficiaries nationwide; baseline expenditures for study participants in six programs averaged more than $2000 per month, but less than $600 per month in three programs. In the study reported by Boult et al.[29] participants were identified as being at high risk of heavy health services use during the upcoming year by using a claims-based predictive model. Study participants (n=904) had four chronic diseases on average, over 40 percent rated their health as fair/poor, and 25-30 percent had diminished functional status by activities of daily living (ADL) or instrumental activities of daily living (IADL) measures. The study reported by Newcomer et al.[35] had enrollment criteria of *either* being age 80 years or older *or* being 65 or older with at least one qualifying chronic condition; over 70 percent of the sample population (n=3079) was 80 years or older, which is a notable difference compared with the percentage of this age group in the other study samples. The study reported by Martin et al.[38] also had a notable difference in the study sample; enrollment was open to all members of a health maintenance organization (HMO) who resided within the study catchment area and were at least 65 years of age (n= 8504). During the study period, a total of 1,640 participants in the intervention group (38.5 percent) were evaluated for CM based on an electronic algorithm or a low score on a general health measurement. The study reported by Schore et al.[34] enrolled patients with one of a set of qualifying diagnoses who had been hospitalized over the prior year. The most frequent diagnoses were congestive heart failure and chronic obstructive pulmonary disease (COPD). The study reported by Fitzgerald et al.[39] enrolled patients being discharged from an acute hospitalization at a VA medical center. The mean age of participants was 64 years, and comorbidities included COPD, heart disease, diabetes, and heart disease. The study conducted in the Netherlands (n=208)[40] enrolled participants being discharged from an acute hospitalization with a case complexity score indicating the need for case management. The mean age of participants was 64 years and comorbidities included circulatory, respiratory, and gastrointestinal disorders.

CM *interventions* in these studies focused on patient self-management education, health status monitoring, and coordination of health care (see Table 2). Case managers in all of the studies were nurses. Across studies, the vast majority of contacts with patients were via the telephone. In-person contacts generally were reserved for initial assessments, although in four programs included in the MCCD trial,[32] participants were contacted in person nearly once a month. The length of CM intervention was 6 months in one trial,[40] 12 months in one,[35] and 20 months in one.[29] In the MCCD trial,[32] programs varied widely in participant's average length of exposure to a CM intervention, with a range of 18 to 38 months. One study[38] did not report exposure time for the participants who received CM during the study period. In one study, CM was managed via teams having caseloads of 800-1000 study participants on each of four teams. A small fraction of the cases (50-70 participants per team) received more intense CM.[38]

Table 2. Characteristics of case management interventions for older adults with one or more chronic diseases (randomized trials)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Boult 2011[29] Wolff 2010[61] Boyd 2010[62] Boult, 2008[63] Good	20	In person and telephone	• Assessment • Planning • Clinical monitoring • Transitional care • Coordination • Education • PS Support	NR	50-60	Integrated	Yes	RN	Yes	Yes
Fitzgerald 1994[39] Fair	12	In clinic and telephone	• Assessment • Planning • Education • Coordination	1.6 contacts per patient per month	NR	Integrated	Yes	Nurse	Yes	Yes
Latour, 2006[40] Latour, 2007[41] Fair	6	Home visits, in clinic, and telephone	• Assessment • Planning • PS Support • Coordination	Home visits every 2 months minimum, rate of other contacts NR	NR	Integrated	Yes	Nurse	NR	NR
Martin 2004[38] Good	18	In clinic and telephone	• Assessment • Planning • Education • Coordination	NR	50-70	Integrated	Yes	Nurse	NR	Yes
Newcomer 2004[35] Fair	12	Telephone	• Assessment • Planning • Coordination	7.7 hours of contact per year for each patient	1:60 actively managed at any one time (caseload 250)	Integrated	Yes	Nurse	NR	NR

Table 2. Characteristics of case management interventions for older adults with one or more chronic diseases (randomized trials) (continued)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Peikes 2009[32] Good	36	Telephone; In person contacts (generally reserved for initial assessments, although nearly once a month for four programs)	• Education • Clinical monitoring	Overall number of contacts (range per month): (1.2-8.2) In person contacts (range per month): (0.09-0.97)	Generally between 50 and100 (range 1:30 to 1:200)	Generally integrated—varying degrees	NR	RN (11 programs) LPN (1 program)	Yes	Yes
Schore 1999, 1997[33, 34] Good	12-24	Telephone, with varying levels of in-person contact	• Assessment • Service coordination • Self-care education • Emotional support to clients and caregivers	Average hours of contact per client per month: 0.6-1.5 hours	74-100	Integrated in one of the three programs studied	No	RN or MSW	Yes	Yes

CM = case manager; LPN = licensed practical nurse; MSW = master of social work; NR = not reported; PS = psychosocial; RN = registered nurse

The *comparator* in these trials was "usual care," meaning the standard services provided in each study setting but without the CM intervention.

All of these trials examined both utilization and health status *outcomes* (see Table 3). Patient-centered outcomes included mortality, measures of mental and physical health, QOL, and patient satisfaction. Quality of care outcomes also were examined in two trials[32, 62] and included measures of self-management support, service arrangement, and general and disease-specific preventative care. Resource utilization measures included hospitalizations, skilled nursing facility admissions, ED utilization, outpatient visits, home care, and overall costs.

The *timing* of the CM interventions in two of the studies[29, 32] was similar in that participants were identified as already being high utilizers of health care services. CM was initiated to improve patient health and reduce the need for ED, hospitalization, and acute care services. In two studies, CM was initiated upon hospital discharge after an acute event;[39, 40] in one study,[35] CM was initiated proactively among a population with increased risk of high service utilization due to advanced age or chronic conditions; and in one study,[38] the CM intervention was offered to a subset of disease management program participants at a point when their health care needs were deemed to have become complex.

The *settings* of the CM programs varied. The MCCD trial[32] included three hospital-based programs, five commercial disease management or care coordination programs, two programs operated in academic medical center, a program in an integrated health care system, and a program in a retirement community. The majority of these programs serviced large metropolitan areas but four serviced rural areas. The study reported by Schore examined three CM programs.[34] One program was integrated with the family medicine and geriatrics departments of a teaching hospital, and the other two were based in free-standing community organizations. In the other four studies conducted in the United States,[29, 35, 38, 39] the CM programs were health plan based or health system based, while the study conducted in the Netherlands was hospital based.[40]

Key Points Related to Older Adults With One or More Chronic Diseases

- CM programs that serve patients with multiple chronic diseases do not reduce overall mortality (strength of evidence: high). (See Appendix H. Strength of Evidence.)
- CM programs that serve patients with one or more chronic diseases do not result in clinically important improvements in functional status (strength of evidence: high).
- CM programs that serve patients with one or more chronic diseases increase patients' perceptions that their care is better coordinated and of higher quality (strength of evidence: high).
- CM programs that serve patients with one or more chronic diseases do not reduce Medicare expenditures (strength of evidence: high).
- CM programs that serve patients with one or more chronic diseases do not reduce overall rates of hospitalization (strength of evidence: moderate).
- CM is more effective for reducing hospitalization rates among patients with greater disease burden (strength of evidence: low).
- CM is more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

Five clinical trials and four observational studies examined mortality among patients who received CM. In the MCCD trial,[32] 3-year mortality rates ranged from 10 to 40 percent for the 11 programs for which mortality was reported. Mortality rates in the groups receiving CM were slightly lower in six of these programs and higher in the other five.

Overall mortality rates in three other trials were low. In Martin's trial,[38] 19-month mortality was 4 percent in the CM group and 5 percent in the control group. Newcomer et al.[35] reported 12-month mortality of 3 percent in both the CM and control groups. Fitzgerald et al.[39] reported 12-month mortality of 10.5 percent for each group. In the trial conducted in the Netherlands, 6-month mortality rates were similar (7-8 percent) in both the CM and control groups.[40]

One observational study reported a mortality benefit with CM.[42] In this study of U.S. Medicare beneficiaries the CM group included patients who were referred to and completed intake into a CM program linked to primary care clinics. The comparison group included patients followed in similar clinics that did not have CM programs. Patients in the comparison group were selected by matching for age and diagnosis. Two-year mortality rates were 13 percent in the CM group and 17 percent in the control group. This difference was marginally significant (p=0.07).

Another U.S. observational study examined mortality over 5 years of followup and found no effect of CM on this outcome.[43] Two family medicine clinics were compared, with only one offering a CM program. Study participants in both clinics were individuals who had three or more clinic visits in the prior year. Average age of the participants was 76 years, and the CM was provided by a nurse practitioner based in the experimental clinic. Five-year mortality was 27 percent in both groups. Two European observational studies found similar mortality rates between CM groups and comparison groups of similar age.[44, 52]

Because of the minimal changes in mortality rates across multiple clinical settings, we concluded that CM programs that serve broad populations of patients with chronic diseases do not affect mortality rates. This has a high strength of evidence due to the large cumulative sample size of these studies (including the MCCD trial).

Functional Status

Evidence about functional outcomes was reported in three clinical trials. The MCCD trial[32] conducted surveys of random samples of participants 10 months after entry into the study. One site did not participate in the survey due to dropping out of the study and another site did not participate because of program focus (it enrolled only patients receiving active cancer treatment). For the remaining 10 sites, response rates were reported to be about 95 percent. Sample sizes were at least 350 participants in each of the CM and control groups for each site. The MCCD collected self-reports for ADLs and IADLs. In none of the programs was there consistent improvement in ADLs or IADLs with CM. Martin[38] also used a survey measure to assess patient functioning at 18 months. The only significant change was a slightly lower rate of deterioration of social functioning in the CM group. Newcomer[35] also found no difference between CM and control groups in measures of physical and mental functioning at 12 months.

Psychological Measures

The MCCD trial[32] also examined psychological measures in the 10-month participant survey. Three of the 10 programs found significantly better scores on a measure of stress in the CM groups. However, CM was not associated with better scores on a depression screen in any of the programs. Another trial examined measures of caregiver depression and burden but found no difference in these measures between the CM and control groups. This finding did not change when evaluating subgroups of caregivers who had higher and lower levels of time commitments to caregiving.[61]

Patient Satisfaction

Two trials assessed participant satisfaction. The MCCD survey included four items on satisfaction with explanations received from providers. There were no consistent trends in these measures for any of the ten programs when comparing the CM and control groups.[32] The study reported by Schore also found minimal effects on patient satisfaction in three CM programs that served a Medicare population.[34]

Quality of Care Outcomes

The MCCD survey included two types of quality measures: perception of care coordination and self-care behaviors. In eight of the ten programs in the MCCD trial, participants in the CM group gave higher ratings of the impression that clinicians kept in touch with each other, and this difference was statistically significant in six.[32] The MCCD survey also included several measures of health behavior associated with chronic illness care. No more than one program showed an effect of CM on each of four measures of diet and exercise. None of the programs showed differences between the CM and control groups for self-reported medication adherence. In addition, none of the programs showed an effect of CM on a question about planning for physician visits. Similar findings were found in an earlier trial, with no effect of CM on medication adherence or on self-monitoring of blood pressure.[33] In another trial, both patients and caregivers were asked to rate care coordination. Both patients and caregivers in the CM group gave significantly higher ratings.[61, 62] None of the other trials included measures of care coordination or self-care.

Using Medicare claims data the MCCD trial also measured receipt of preventive services. No consistent effects of CM on vaccination rates or rates of colon cancer screening were found.[32] Two of 11 programs had higher mammography rates in the CM group.[32] for patients with diabetes, effects of CM on quality measures were mixed. One of 11 programs had higher rates of eye examinations and microalbumin measurements with CM. Two other programs had higher rates of glycosylated hemoglobin testing with CM. In three out of 11 programs, CM was associated with higher rates of lipid testing among patients with diabetes and/or coronary disease.[32] Another trial conducted in a Medicare population found no effect of CM on rates of influenza vaccination or smoking cessation.[33]

An observational study having a pre-post design examined changes in physiological measures with 3 months of CM.[49] Blood pressure, glucose, and cholesterol levels decreased moderately, compared with the pre-CM values. However, there was no non-CM comparison group in this study.

Resource Utilization Outcomes

All seven of the randomized trials and eight observational studies included utilization outcomes. The most common utilization measure was hospitalization rates. In the MCCD study, one of the 12 programs found a significantly lower hospitalization rate in the CM group.[32] This program had a per capita yearly hospitalization rate of 0.98 in the control group and 0.82 in the CM group. A second program that had a high hospitalization rate in the control group (per capita rate of 2.1) had a marginally significant (p=0.07) reduction in the rate to 1.6 with CM.

There were similar findings in the other clinical trials. Newcomer[35] found no difference between the CM and control groups in the following measures: overall hospital admissions, readmissions, or nursing home admissions. Boult[29] also found no significant difference between CM and control groups in the rates of hospital admissions, 30-day readmissions, and nursing home admissions. Boult did find an interaction between insurance coverage and CM effects on nursing home admissions. There was a greater reduction of nursing home admissions with CM for members of a staff-model health maintenance organization than for patients covered by fee for service plans.[29] Hospital admissions and total inpatient days also were not different between CM and control groups in the trials reported by Martin,[38] Fitzgerald,[39] and Schore.[33] Martin's study found that nursing home admission rates were low in both groups (less than 4 percent per year), but total nursing home days was modestly lower in the CM group.[38] In the Netherlands trial, hospital admission rates were similar over 6 months in the CM and control groups.[40]

The observational studies had differing findings on hospitalizations. In a good quality study, 2-year hospitalization rates were not significantly reduced (32 percent in CM group; 35 percent in control group).[42] Three other studies[43-45] also found no difference between CM and control groups in hospitalization rates or total inpatient days. A poor quality Australian observational study compared acute hospitalization rates for patients currently receiving CM with rates during the 12 preceding months. The rates were 28 percent lower, while the rates did not change in a comparison group.[46] Two poor quality observational studies reported a significant reduction in hospital admissions with CM over a 6-month period[48, 50]

Three clinical trials[29, 35, 38] and two observational studies [45, 52] examined nursing home utilization in this population. Overall, the findings were inconsistent. A good-quality clinical trial [38]and the two observational studies found that CM was associated with lower rates of nursing home utilization. However, the utilization was very low in the clinical trial (fewer than one nursing home day per person per year). The fair quality observational study found average one-year nursing home use to be 8.4 days in a CM group and 12.6 days in a comparison group.[45] A poor quality European observational study found 1-year rates of nursing home placement to be 7 percent in the CM group and 13 percent in the comparison group.[52] Another good-quality clinical trial [29] found no significant effect of CM on nursing home admission rates, although a patient subgroup enrolled in a health maintenance organization had lower nursing home use with CM. Finally, a fair quality trial[35] found the nursing home placement rate to be significantly higher among patients who received CM. Because of the inconsistency of these findings, we concluded that there is insufficient evidence to draw a conclusion about the impact of CM on nursing home use among elderly patients with one or more chronic diseases.

Two trials and three observational studies examined ED visits. Both the Boult and Newcomer trials found no difference in ED visits between the CM and control groups.[29, 35] However, an observational study found significantly lower rates of visits to both EDs and urgent care clinics in the CM group,[43] and another observational study found a 54 percent reduction in ED visits in a CM group.[53] An Australian observational study also found lower ED visit rates in a CM group, compared with the 12-month period prior to enrolling in CM.[46]

In this population, there are not consistent findings on the effect of CM on the utilization of a variety of outpatient services. One trial[39] and one observational study[45] reported modest increases in primary care visits for the CM group. Another trial[29] and an observational study[43] both found no effects of CM on rates of primary care or specialty clinic visits in the United States. The U.S. trial also found that the CM group had significantly lower use of home health services.[29] An observational study of European programs found no difference in utilization of home nursing, caregiver services, physical therapy, and occupational therapy between a CM group and a comparison group.[52]

In this population, CM had minimal effects on the overall costs of care. In the MCCD trial, none of the 12 programs had significantly lower overall Medicare expenditures in the CM group.[32] Total costs also were not significantly different between CM and control groups in another U.S. trial.[38] An additional U.S. trial measured only the costs of inpatient hospitalizations. It found no difference between the CM and control groups.[35] A fair quality observational study in the United States found higher overall costs in a group receiving CM compared with a similar group that did not receive CM.[45] A regression analysis that controlled for costs in the previous year estimated a cost savings. However, the comparability of the control group was not well described in this study.

Table 3. Characteristics and outcomes of studies of case management for older adults with one or more chronic diseases (randomized trials)

Author Year Quality	Patient Population	Disease Severity	Setting	Sample Size	Health Outcomes	Patient and Caregiver Experience	Quality of Care	Resource Utilization, Cost
Boult 2011[29] Wolff 2010[61] Boyd 2010[62] Boult, 2008[63] Good	Older adults (age 65 years or older) with multiple morbidities	High risk of heavy health services use; Four chronic diseases on average	Community-based primary care practices within three health care systems	850	NR	↑Quality of care ratings = Caregiver depression, stress, productivity	NR	= Hospitalizations, SNF admissions, ED visits, OP visits *(overall and in highest risk subgroup)* Fewer SNF admissions and days *(analysis of insurance subgroups, ↑ for Kaiser-insured)* ↑ Fewer home health care episodes
Fitzgerald 1994[39] Fair	Age ≥ 45 years discharged from an acute hospitalization in a VA medical center	Recent hospitalization	Primary care clinic in the VA health system	668	= Mortality	NR	↑ More primary care contact	= Hospital admissions and days, ED visits, SNF admissions ↓ More SNF days
Latour, 2006[40] Latour, 2007[41] Fair	Mean age range 62-65 years, discharged from an acute hospitalization	Previous hospitalization within 5 years	Hospital-based program, Amsterdam, Netherlands	147	NR	= Quality of life and psychological functioning	NR	= Hospital admissions and days, general care utilization = Cost
Martin 2004[38] Good	Medicare beneficiaries (Medicare Choice Plus) >65 years old	NR	HMO	6,158	= Mortality = General health, mental health, physical function ↑ Social function	↑ Satisfaction with health care plan	NR	= Hospital admissions and days, SNF admissions ↑SNF days = Cost
Newcomer 2004[35] Fair	High-risk elderly (age ≥ 80 years or age ≥ 65 with at least one chronic disease condition)	70% of participants ≥ 80 years old	Health-plan based	3,079	= Mental and physical health = Mortality	NR	NR	= Hospital days, ED visits, Nursing home admissions

Table 3. Characteristics and outcomes of studies of case management for older adults with one or more chronic diseases (randomized trials) (continued)

Author Year Quality	Patient Population	Disease Severity	Setting	Sample Size	Health Outcomes	Patient and Caregiver Experience	Quality of Care	Resource Utilization, Cost
Peikes 2009[32] Good	Medicare beneficiaries covered by FFS/traditional Medicare with one or more chronic conditions	High utilizers of health care services; Recent hospitalization (7 of 12 programs)	Hospital-based programs (3), commercial disease management or care coordination programs (5), academic medical center programs (2), integrated health care system program (1), retirement community (1). Four programs serviced rural areas	18,402 (program ranges 211—2657)	**↑=↓** *(mixed results)*: Functional status = Mortality	**↑=↓** *(mixed results)*: Patient satisfaction ratings	**↑** Receipt of health education **↑**= *(mixed results)*: General and disease-specific preventive services = Self-management understanding and adherence	Annual hospitalizations: = (10 programs) **↑** (1 program) **↓** (1 program) = Overall Medicare expenditures (*Subgroup Analysis - 1 program;* hospitalizations and expenditures: **↑** for highest risk subgroup)
Schore 1999, 1997[33, 34] Good	Medicare beneficiaries who had a hospitalization for a specified chronic disease in the previous year	Recent hospitalization	One program hospital-base. Two other programs based in free-standing community organizations.	2,382	= Symptoms, weight gain Overall one-year mortality rate 14-27% in the three programs (not broken down for comparison between CM and control groups)	**↑** Patient satisfaction	**↓** Self-care and preventive care measures	= Hospitalization rates and total expenditures

ED = emergency department; FFS = fee-for-service; HMO = health maintenance organization; NR = not reported; OP = outpatient; SNF = skilled nursing facility
Note: **↑** Better with case management; = No difference; **↓** Worse with case management.

Effectiveness of Case Management by Patient Characteristics

Although the studies of CM in this population group included large numbers of participants, there were few analyses of patient subgroups. One of the programs included in the MCCD study conducted a risk stratification of its participants at the time of enrollment. For the 30 percent of participants having the highest severity, hospitalization rates were 29 percent lower with CM, and total expenditures were 20 percent lower. This higher risk group was defined as patients having average Medicare monthly expenditures of between $900 and $1200 per month.[32]

One observational study compared mortality and hospitalization rates among people with diabetes with the entire population of participants.[42] In the subgroup of patients with diabetes, 2-year mortality rates were similar to those in the entire patient sample. However, those who received CM had significantly lower mortality (18 vs. 13 percent at 2 years).

The hospitalization rate also was significantly lower with CM (30 percent in CM group; 39 percent in control group).[42] No other studies have examined subgroups of people with diabetes for these outcomes.

Effectiveness of Case Management by Intervention Characteristics

In the MCCD study, the two CM programs that had the greatest reductions in reducing hospitalization rates were compared with the remaining programs by a variety of programmatic characteristics. Several differences were found. First, the two successful programs averaged one in-person contact between the patient and case manager per month, compared with a median of 0.3 such contacts in the other programs. Second, participants in these two successful programs were more likely to report that they had received instructions on how to take their medications. he successful programs also tended to be closely linked to providers. The case managers frequently traveled to primary care sites for direct communication with physicians and also had close contacts with hospitals to provide followup of patients after acute hospitalizations. Another feature of the successful CM programs was the continuity of the relationship between the case manager and medical providers, defined as a single case manager assigned to each physician's patients.[32]

Indirect comparisons can be made between the MCCD study and other trials by intervention characteristics. The large trial reported by Martin[38] featured high caseloads by the case managers and consequently little face-to-face patient contact. This trial showed few benefits of CM. The Newcomer trial[35] also had relatively high caseloads (about 250 per case manager), and this study found minimal benefits of CM. These findings suggest that CM effectiveness may be related to face-to-face time with patients. However, Schore et al.[34] found that a case management program that had more face to face contact with clients resulted in no difference in outcomes when compared with two other programs that used primarily telephone contact with clients (with similar case manager caseloads across the three programs).

Population: The Frail Elderly

As people with multiple chronic illnesses age, the cumulative result is a declining ability to live independently. CM programs potentially can help the frail elderly to avoid or reduce functional loss, improve QOL, and maintain independence. For people who are frail, these programs also have the potential to forestall hospitalizations, ED visits, and skilled nursing facility use. The reduction of utilization of these services potentially can be accomplished through coordinating care for complex illnesses, preventing adverse events (such as urinary tract infections, pressure ulcers, falls, and the like), and preventing disease exacerbations. The approach to CM is often broad and holistic so as to meet the needs of individual patients, rather than an emphasis on single disease indicators.

The CM programs included in the frail elderly category share many characteristics with programs that targeted the population of patients with multiple chronic diseases. Case managers in the frail elderly programs also needed to coordinate care for multiple chronic diseases. We used two criteria to differentiate between the two types of programs. These included:

- Patients in the frail elderly programs tended to have a higher prevalence of functional deficits.
- The frail elderly programs placed more emphasis on maintaining functioning and delaying nursing home placement, while the chronic disease programs tended to emphasize care of specific diseases.

The two types of programs nearly always had mean patient ages greater than 70 years, but more of the frail elderly programs had mean ages greater than 80 years.

Description of Studies

We found eight randomized trials of CM programs for the frail elderly (see Appendix I, Evidence Table 3). Four were rated good quality,[30, 64-66] three were rated fair,[67-69] and one was rated poor[70] (see Appendix G). The trials were conducted in the United States,[30, 66, 68] Canada,[67] Italy,[64] Sweden,[65] and Hong Kong.[69, 70] The studies were published between 1998 and 2010. Sample sizes ranged from 92 to 792 participants (total N=2,417). We also identified six observational studies of CM for the frail elderly (see Appendix I, Evidence Table 4). Three were rated as having fair methodological quality,[71-73] and three were rated poor.[74-76] Four of the studies were conducted outside the United States.[71, 72, 74, 76] All the studies defined cases on the basis of older age and presence of functional deficits.

The *populations* in the clinical trials were all elderly with some marker of frailty. All used an assessment of functional status in screening patients for eligibility, primarily through assessment of ADLs or IADLs. Mean patient age ranged from 74 to 85 years, with the mean in four studies being 80 or older.[64-67] Three trials included a recent hospital admission or ED visit among the eligibility criteria.[67, 69, 70]

CM *interventions* in these studies focused on health care and community resource coordination (see Table 4). The clinical functions most often assessed were propensity to fall or functional status. Case managers were most commonly nurses, although some studies utilized other type of health care worker with geriatric expertise (e.g., physician assistant, social worker, allied health worker). Average caseloads varied widely among studies, ranging from 10 to 100. Interventions almost uniformly involved home visits in addition to telephone followup; the frequency of contacts varied among the studies. The case manager in one study initiated contact during a clinic visit and subsequent contact was via telephone only.[30] The duration of study interventions ranged from 3 to 24 months (see Table 4). In general, reporting of case manager activity and location was poor; few studies identified how much the case manager interacted with the patient.

Comparators for CM were dependent on setting. In each study the comparator was usual care but without the CM component. The hospital-based studies[69, 70] used usual hospital discharge services as comparators, the health care plan-based study[66] used usual plan care, one study[30] used usual primary clinic care, and four[64, 65, 67, 68] used the package of home care and community services available to all study participants.

Table 4. Characteristics of case management interventions for the frail elderly (randomized trials)

Author Year Quality	Duration	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Applebaum 2002[68] Fair	6, 12, or 18 months	Home visits	• Assessment • Coordination	NR	75-100	Integrated	Yes	Nurse	NR	NR
Bernabei 1998[64] Good	12 months	Home visits	• Assessment • Monitoring • Coordination	Every 2 months	20	Integrated	Yes	Trained in geriatric assessment and CM	Yes	NR
Gagnon 1999[67] Schein 2005[77] Fair	10 months	Home visits, phone	• Assessment • Monitoring • Coordination	3.6 home visits/ month 2.8 calls/ month	45	Integrated	Yes	Nurses with geriatric experience	Yes	NR
Kristensson 2010[65] Good	3 months	Home visits, phone	• Assessment • Monitoring • Coordination	NR	23	Integrated	Yes	Nurses specialized in geriatric nursing	Yes	NR
Leung 2004a[69] Fair	6 months	Phone, home visits if needed	• Assessment • Monitoring • Coordination	NR	10	Integrated	Unclear	Trained in nursing elderly patients	NR	NR
Leung 2004b[70] Poor	6 months	Home visits, phone	• Assessment • Monitoring • Coordination • Education	NR	65	Unclear	Unclear	Social worker and nurse	NR	NR
Marshall 1999[66] Long 2000[78] Long 2002[17] Good	24 months	Home visits, phone	• Assessment • Monitoring • Coordination	NR	70	Integrated	Yes	Nurse and social worker with prior geriatric CM experience	NR	Yes
Rubenstein 2007[30] Good	12 months; followup at 2 and 3 years	Phone	• Assessment • Monitoring • Coordination	Every 3 months	NR	Integrated	Yes	Physician assistant with geriatric expertise	NR	NR

CM = case management; NR = not reported

Targeted *outcomes* in the trials included patient-centered outcomes and resource utilization (Table 5). Patient-centered outcomes included mortality, measures of mental and physical health and functional status, satisfaction with health care, QOL, and measures of caregiver burden. Resource utilization measures included ED utilization, hospitalizations, nursing home admissions, outpatient visits, community service use, and overall costs. One study[30] measured a quality outcome: the recognition and evaluation of common geriatric clinical problems.

The *timing* of the CM interventions varied and depended on how the study populations were identified. In essence, the interventions were initiated either in the course of the slow process of becoming frail or following a high risk clinical event. In three studies, CM interventions were initiated for participants with a recent history of hospitalization or ED use;[67, 69, 70] three were initiated for participants enrolled or enrolling in a home-care assistance program;[64, 65, 68] and two were initiated in populations already followed in primary care practices.[30, 66]

Settings for the trials varied; one was health plan-based,[66] two were hospital-based,[69, 70] one was conducted within the Veterans Affairs Medical Center (VAMC) health care system[30] and four were community-based, one in the United States[68] and three within national health care systems.[64, 65, 67]

Key Points Related to the Frail Elderly

- CM does not affect mortality in frail elders (strength of evidence: low). (See Appendix H. Strength of Evidence.)
- CM does not decrease acute hospitalizations in the frail elderly (strength of evidence: low).
- CM does not decrease nursing home admissions in the frail elderly (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

Two of the good-quality trials measured mortality, and both found no reduction in the intervention group at 1 year[64] or 3 years of followup.[30] A fair quality trial[69] reported 12-month mortality of 4 percent in the intervention group and 9 percent in the control group, but this study had a total sample size of only 92, so there was low confidence in this difference. Another fair quality trial[68] reported no difference in mortality. The other four trials did not report mortality. A fair quality observational study[72] also reported no difference in one-year mortality between the CM and comparison groups.

Functional Outcomes

There was marked heterogeneity in the studies of the frail elderly for the effects of CM on functional status. The study reported by Rubenstein and colleagues[30] was rated as having good methodological quality, had the largest sample size, and had the longest followup (3 years). This study found that measures of functional status did not change significantly over time in either the CM or the control group. However, another good-quality trial[64] found significantly better improvement in ADLs in the CM group. A fair quality trial[66] found no change in ADL or IADL scores in the CM group over 2 years but worsening of these scores in the control group. Four other trials[67-70] also found no difference between CM and control groups in ADL or IADL scores over 6-12 months. A poor quality observational study[76] found improvement in functional status with CM, but a fair quality observational study[72] did not find improvement with CM in their frail elderly group. A good quality trial that had a small sample size (23 participants per study arm) found no effect of CM on self-rated health,[65] and a fair quality observational study had a similar finding.[71]

Quality of Care Outcomes

One good-quality trial[30] had measures of the process of care as a primary outcome. This evaluation focused on five geriatric conditions that were assessed by medical record review. Documentation of all five problems was substantially higher for the CM patients. Clinical evaluation of the problems also was higher in the CM group. None of the other studies evaluated such outcomes.

Resource Utilization Outcomes

A primary rationale for CM for the frail elderly is to avoid unnecessary hospitalizations or ED visits. All seven of the eight clinical trials examined one or more utilization measures. In the good-quality trial by Rubenstein,[30] about one-third of participants in both groups were hospitalized in each of 3 years of followup, with no difference in rates between the CM and control groups. In the other good-quality trial conducted in the United States[66] hospitalization rates averaged 37 percent per year, without a significant difference between the CM and control groups. A fair quality trial and a fair quality observational study also found no difference in rates of hospitalization between the CM and control groups at 6[68, 73] and 18 months.[68] Significant differences were not found in hospitalization rates between CM and control groups in either the trial conducted in Canada,[67] or in a Canadian observational study,[76] or in a trial in Hong Kong.[70] However, trials conducted in Italy[64] and a second Hong Kong trial[69] found reductions in hospitalization rates with CM. Two poor quality observational studies found opposite effects of CM on hospitalization rates, with a small study in the United States reporting reduced hospitalizations [75] and a larger study in the United Kingdom finding no significant effect.[74]

Three trials looked at changes in ED visits. Marshall[66] found no effect of CM on ED visits in the United States, while Gagnon[67] found that CM was associated with higher rates of ED visits in Canada. In the Italian trial,[64] the CM group had significantly fewer ED visits. A fair quality observational study in the United States found that ED visit rates were similar in CM and comparison groups.[73] One trial[64] also examined nursing home admissions and found no difference between the CM and control groups over 12 months.

CM has variable effects on use of outpatient services. The good-quality U.S. trial[30] found that outpatient referrals to a variety of specialty services were significantly higher in the CM group than in the control group. However, the other U.S. trial[66] found no significant difference in the numbers of outpatient visits between the CM and control groups. A trial conducted in Hong Kong[70] found only small changes in outpatient visits with CM.

Three of the trials evaluated costs of care. A fair quality trial in the United States used total Medicare payments as the measure of cost and found no significant difference between the CM and control groups over 18 months.[68] A good-quality trial in the United States estimated the total costs of care using approximations.[66] The estimated costs were higher in the CM group than in the control group in both years of the study. A good-quality Italian trial[64] also used an approximation method to estimate costs and found total costs to be significantly lower in the CM group, primarily due to the lower hospitalization rate. One poor quality observational study found a decrease in health care expenditures in the CM group,[71] and two poor quality observational studies found a reduction in costs due to decreased hospital admissions.[74, 75] Because of the inconsistency of these findings, we concluded that the evidence is insufficient to draw a conclusion about the effect of CM on overall costs for the frail elderly population.

Table 5. Characteristics and outcomes of studies of case management for the frail elderly (randomized trials)

Author Year Quality	Patient Population	Sample Size	Health Outcomes	Quality of Care	Resource Utilization, Cost
Applebaum 2002[68] Fair	Elderly, chronically disabled, receiving in-home services, high utilization of hospital and ED	297	= Mortality = Functional status	NR	= Hospitalizations /length of stay = Nursing home admissions = Outpatient health services =Costs
Bernabei 1998[64] Good	Mean Age = 80 Recipients of home health services or home assistance programs	199	= Mortality ↑ Functional status	↑ Evaluation of geriatric conditions	↑ Fewer hospitalizations and ED visits = Nursing home admissions ↑Lower costs
Gagnon 1999[67] Schein 2005[77] Fair	Frail elderly post-discharge from the ED at risk for hospitalization	427	= Functional status	NR	= Hospitalizations ↓ More ED visits
Kristensson 2010[65] Good	Mean age > 80 years with daily activity limitations, high utilization of hospital, outpatient, or primary care	92	= depression, perceived health	NR	NR
Leung 2004a[69] Fair	Frail elderly with two or more chronic illnesses and recent repeat hospitalizations	46	↑ Fewer mortalities = Functional status	NR	↑ Fewer hospitalizations
Leung 2004b[70] Poor	Mean age 75 years, recently discharged from hospital, with one or more chronic diseases	260	= Functional status	NR	= Hospitalizations and ED visits ↑ Length of hospital stay
Marshall 1999[66] Long 2000[78] Long 2002[17] Good	Age ≥ 75 years with poor functional status, high utilizations of ED and/or hospital	532	↑ Functional status	NR	= Hospitalizations and ED visits ↓Costs
Rubenstein 2007[30] Good	Age ≥ 65 years Elderly population with problems such as falls, urinary incontinence, depression, memory loss, and functional impairment	532	= Mortality = Functional status	NR	= Hospitalizations

ED = emergency department; NR = not reported

Note: ↑Better with case management; = No difference; ↓Worse with case management

Effectiveness of Case Management by Patient Characteristics

The modest sample size of the trials of CM for the frail elderly generally precludes subgroup analysis within this patient category. No studies examined age as a variable, and there generally were not good measures of comorbidity burden. There is no particular patient subgroup that appears to achieve greater success with CM.

Effectiveness of Case Management by Intervention Characteristics

The studies of frail elders generally included little information about the intensity of CM delivered, although all used relatively low caseloads (fewer than 100 patients) for the case managers. The greatest variation in outcomes was in measures of functional status, but none of the studies identified unique program characteristics that were linked to better functional outcomes.

Population: Patients With Dementia

Dementia is a disabling chronic disease for which the prevalence steadily increases with advancing age. It is estimated that about 14 percent of people in the United States who are older than 70 currently have dementia[79] People with dementia have decreasing functional abilities over time, requiring the assistance of caregivers for their daily needs. Providing such assistance in institutional settings (such as nursing homes) is expensive and often is associated with isolation and medical complications. Avoiding or delaying placement in nursing homes has been widely regarded as a desirable clinical goal. There have been many major initiatives to examine possibly beneficial interventions. CM is one approach that has been studied.

Description of Studies

We identified 13 randomized trials of CM programs for patients with dementia (see Appendix I, Evidence Table 5); seven were rated good quality,[31, 80-85] two were rated fair quality,[86, 87] and four were rated poor quality[36, 88-91] (see Appendix G). The trials were conducted in the United States,[31, 36, 80, 84, 85, 89, 91] the United Kingdom,[85] Hong Kong,[86, 87] Canada,[88] Finland,[81, 82] the Netherlands,[83] and Australia.[85] They were published between 1990 and 2011. Sample sizes ranged from 78 to 8,138 participants (total N = 10,160). However, the majority of these studies were relatively small with 10 of the 12 trials having fewer than 100 participants in their CM intervention arms.[80-83, 85-89, 91]

The *populations* in all 13 studies were patients with dementia still living at home. The majority of patients lived with a caregiver. Each study enrolled a primary caregiver along with the patient (a study dyad) or involved the caregiver in the CM intervention. Mean patient age ranged from 68 to 83, with eight studies having a patient population averaging 78 years or older. In three studies that required the primary caregiver be a spouse, the mean age range of the spouse caregiver was 71 to 74 years.[31, 82, 85] In studies that included caregivers other than spouses (most commonly a patient's child), the mean age of caregivers ranged from 44 to 66. Patient eligibility for five of the studies included a diagnosis of Alzheimer's Disease,[31, 80, 85, 86, 88] the other eight a diagnosis of dementia (unspecified type).[36, 81-84, 87, 89, 91] One study also included patients with a diagnosis code for memory loss.[91]

CM *interventions* in these studies focused on both patient and caregiver, with the majority emphasizing caregiver support (see Table 6). Intervention components aimed at caregivers included education on problem solving, communication, and coping skills provided through workshops, support groups, and individual counseling sessions. Those CM programs with control over budgeted services had the ability to provide caregivers additional services, such as respite and homemaking. Intervention components aimed at the patient included social and recreational activities, behavioral interventions, pharmacotherapy, and monitoring. Case managers in these studies were generally registered nurses or social workers. Caseloads (reported in only six studies) ranged from 25 to 100, most commonly 50 to 75. Case managers generally had face-to-face contact with patients and/or caregivers, in addition to telephone followup. The time horizon of most studies was 12-24 months, although one study[31] followed the participants for more than 5 years.

The *comparator* group in 12 of the trials received "usual care", which was defined as customary care through a primary care clinic, or more often through a community agency, without an assigned case manager. One study[89, 90] was a head-to-head comparison: CM by an individual nurse case manager compared with CM by a team that included a nurse and a social worker. The team-based model in this study entailed more direct in-person interactions with clients, while the individual model was based on telephone interactions.

Targeted *outcomes* in these studies included patient and/or caregiver health, patient/caregiver satisfaction, quality of care, and resource utilization (see Table 7). Patient health outcomes included measures of dementia-related behavioral problems, cognition and function, QOL, and most often (8 of 13 studies) the ability to remain in the home. Caregiver health outcomes included measures of burden, depression, and QOL. Quality of care was measured by receipt of care consistent with clinical guidelines and measures of medication management (cholinesterase inhibitors, antidepressants, and other protocol driven treatments). Resource utilization measures included ED utilization, hospitalizations, nurse and physician visits, use of community services, and overall costs. Note that nursing home placement was classified as a patient health outcome due to its strong relationship to QOL.

The *timing* of a CM intervention can be considered in terms of where the patients are in the course of their disease process. Dementia is nearly always a progressive disorder, with decline in mental function and functional status over time. There is no clinical consensus on when in the course of the illness an intervention like CM would be most effective. As mentioned previously, all the patients in these 13 studies were still living at home. The majority had dementia of mild or moderate severity (for example, mean scores on the Folstein Mini Mental Status Scale of 15-20). Two studies specifically targeted patients with early dementia.[83, 88]

The *setting* for CM programs varied. Two were aligned with primary care clinics,[80, 84] but more commonly they were situated within community agencies[31, 85, 86, 89, 91] or national health care entities.[81, 82, 88]

In addition to the 13 randomized trials described above, we identified two observational studies, one rated fair quality[92]and one rated poor quality.[93] (See Appendix I, Evidence Table 6.) One study was conducted in the United Kingdom.[92] Mean age of the participants was 80 and 70 percent were women, the majority of whom lived alone. The other trial was conducted in the United States.[93] Participants ranged in age from 43 to 95 years and almost 75 percent lived with a caregiver. The comparison group in each of these studies included individuals followed in a similar community program that did not offer CM.

Table 6. Characteristics of case management interventions for patients with dementia (randomized trials)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Callahan 2006[80] Good	12	Home visits, clinic, phone	• Clinical monitoring • Counseling and support	8 face-to-face; 7 calls	75/year	Integrated	Yes	APNs (geriatric NPs)	NR	Yes
Chien 2008[86] Fair	6	Home visits, support groups	• Clinical monitoring • Planning • Counseling and support • Caregiver support • Education	12 home visits; 12 support sessions	Unclear	NR	Yes	Nurse	Yes	Yes
Chu 2000[88] Poor	18	Home visits, phone	• Planning • Counseling and support • Caregiver support • Education	Monthly (increased as needed	NR	Integrated	Yes	SW	NR	NR
Clark 2004[91] Poor	12	Phone	• Clinical monitoring • Counseling and support • Education • Coordination	10/year (based on need)	NR	Integrated	NR	SW	NR	Yes
Eggert 1991[89] Zimmer 1990[90] Poor	Unclear	Home visits, phone	• Assessment • Monitoring • Coordination • Care plan development	NR	40-45	No Integrated	No	2 CMs per team: community health nurse and social worker	NR	No
Eloniemi-Sulkava 2001[81] Good	24	Home visits, phone	• Counseling and support • Caregiver support • Education	Varied: 1/month to 5/day	50 (maximum)	Access to the program physician	Yes	RN (public health)	Yes	NR

Table 6. Characteristics of case management interventions for patients with dementia (randomized trials) (continued)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Eloniemi-Sulkava 2009[82] Good	20 to 24	Home visits, clinic, phone	• Counseling and support • CG support • Education	Varied: Calls to and from families (range 1-91); Home visits (range 1–43); Office visits (range1–4)	50-60 couples	Integrated	Yes	APN (3.5 years advanced education and 1 year education in dementia	Yes	NR
Jansen 2011[83] Jansen 2005[94] Good	12	Home visits, Phone	• Clinical monitoring • Planning • Education • Coordination	≥2 Home visits; Calls, every 3 months; Time: 11 hours/year (range: 1 – 28 hours)	~ 33 dyads	Integrated	No med management by CMs, presumably PCP	Nurse (specialized in geriatric care)	Yes	Yes
Lam 2010[87] Fair	4	Home visits, phone	• Assessment • Education • Monitoring • Coordination	(Median): Home visits (3); Phone (8); clinic (2)	59	Integrated	NR	Occupational therapist	NR	NR
Mittelman 2006[31] Mittelman, 2004a[95] Mittelman, 2004b[96] Roth 2005[97] Good	Unlimited	Clinic, phone, support groups	• Counseling and support • CG support • Education • Coordination	NR	NR	NR	NR	SW (“family counselor”)	NR	NR

Table 6. Characteristics of case management interventions for patients with dementia (randomized trials) (continued)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Mittelman et al. 2008[85]; Brodaty 2009[98] Good	24	Clinic, phone	• Counseling and support • CG support • Education • Coordination	NR	NR	NR	NR	Counselor	NR	NR
Newcomer, 1999a, 1999b, 1999c[36, 99, 100] Miller 1999[37] Shelton 2001[101] Poor	Up to 36	NR	• Clinical monitoring • CG support • Education • Coordination	Minimum of 6 in 4 months	Model A: 1:100; Model B: 1:30	No integration with primary care services	No integration	SW and nurses	NR	NR
Vickrey 2006[84] Good	12	Home visits, Phone	• Planning • Education • Coordination	2 home visits; 15 phone calls/year	50 dyads	Integrated (summary assessments sent to PCP)	NR	Primarily SWs	Yes	Yes

APN = advanced practice nurse; CG = caregiver; CM = case management; NP = nurse practitioner; NR = not reported; PCP = primary care provider; RN = registered nurse; SW = social worker

Key Points Related to Patients With Dementia

- Patients with dementia who receive services from CM programs do not have lower mortality rates (strength of evidence: high). (See Appendix H. Strength of Evidence.)
- CM programs that serve patients with dementia and have a duration of no longer than 2 years do not confer clinically important delays in time to nursing home placement (strength of evidence: moderate).
- CM programs that serve patients with dementia reduce depression and strain among caregivers (strength of evidence: moderate).
- CM programs that serve patients with dementia do not reduce problematic behavioral symptoms (strength of evidence: moderate).
- CM programs that focus on clinical guideline measures for dementia increase adherence to those measures (strength of evidence: low).
- CM does not change total health care expenditures for patients with dementia (strength of evidence: moderate).
- CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than 2 years are more effective for delaying nursing home placement than programs providing services for 2 years or less (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

Ten clinical trials[31, 37, 80-84, 86, 88, 89] and two observational studies[92, 93] reported mortality rates. The time frames ranged from 1 to 3 years in all but one study, which followed patients for more than 10 years.[31] Deaths often were not recorded after nursing home placement, which could bias the reported rates. The death rates varied considerably in the control groups, ranging from 3 percent at 18 months[88] to 35 percent at 2 years.[92] Across this group of studies, there was no trend toward significantly different mortality rates in the groups that received CM.

Patient's Ability to Remain at Home

A total of eight randomized trials and one observational study examined the patient's ability to remain at home. Two clinical trials had sample sizes of more than 100 participants per group.[31, 36] Mittelman and colleagues[31] conducted a long-term trial of CM for caregivers of patients with dementia at a single clinical site (New York City). The study had good methodological quality. It began in 1987, and participant accrual extended over 10 years.

Caregivers were required to be the spouse, the primary caregiver, and living with the person with Alzheimer's disease. The case managers were family counselors, who interacted primarily with the caregiver, and followed a protocol focused on strategies for coping with stressful situations in the caregiving role. The CM activities extended over the entire duration of followup (as long as 10 years). There are no other studies of CM in this clinical domain that continued the intervention longer than 2 years.

Over the initial 6 years of followup in the New York trial, nursing home placement was about 12 percent a year in the control group and about 9 percent a year in the intervention group. By 11 years, about 80 percent of the control group patients and 70 percent of the intervention group patients had either died or moved to a nursing home. The authors estimated that the intervention delayed nursing home placement by an average of about 18 months.

The Medicare Alzheimer's Disease Demonstration and Evaluation (MADDE) was a uniquely large clinical trial.[36, 37, 99, 100] The MADDE study enrolled more than 8000 volunteers into a prospective randomized trial of CM between 1989 and 1991. The project was conducted in eight states, and the models of CM varied considerably across sites. While the programs included components designed to reduce caregiver stress, the fidelity of the intervention across the multiple sites is unknown. The overall rating of methodological quality is poor. The overall rate of nursing home placement in the MADDE study was 43.5 percent at 3 years of followup. There was no significant difference in this rate between the intervention and control groups. Subgroup analyses examined the case manager's caseload and relationship of the caregiver to the patient (spouse vs. nonspouse). There were no significant effects of receipt of CM on nursing home placement rates in these subgroups.[37]

Six smaller clinical trials examined nursing home placement rates as an outcome measure. Four of these were judged to have good methodological quality. All continued the CM for 2 years or less. Eloniemi-Sulkava and colleagues reported a randomized trial of CM in Finland, with a total of 100 participants enrolled between 1993 and 1995.[81] Thirty-one percent of patients had moved to nursing homes at the end of 2 years. While the overall rate did not differ between the experimental and control groups, a Cox regression analysis found that patients in the intervention group moved to nursing homes significantly later (p=0.04) than patients in the control group. These results suggest a mild benefit of CM in maintaining patients at home that is not sustained over time. Eloniemi-Sulkava then reported on a second clinical trial, also in Finland, with the participants being recruited in 2004.[82] This trial included a total of 125 participants and had very similar results to the earlier Finnish trial. The overall rate of nursing home placement was 26 percent at 2 years, with no significant difference in the overall rate between intervention and control groups.

Two other good-quality studies failed to find an effect of CM on rates of nursing home placement. Mittelman[85] repeated the model of CM that previously had been found to delay nursing home placement when continued long-term.[31] This replication trial was conducted in the United Kingdom, Australia, and the United States. However, the number of participants was small (between 52 and 54 participants in each country), and the duration of CM was only up to 2 years. The mean time to nursing home placement was 4.1 years in the intervention group and 4.3 years in the control group. Overall nursing home placement rates were lower in the United States than in the other two countries. Callahan[80] also conducted a trial of CM for patients with dementia. The intervention lasted 12 months and emphasized caregiver skills for coping with bothersome patient symptoms. The nursing home placement rate was 5 percent at 18 months, with no difference between the intervention and control groups. A fair quality trial in Hong Kong found decreased rates and duration of institutionalization for the intervention group at 12 months.[86]

One fair quality observational study[92] and two poor quality trials[88-90] did not provide evidence that would change the conclusions reached from the studies described above. Chu[88] reported a small (total of 74 participants) clinical trial that had poor methodological quality. At 18 months of followup, the nursing home placement rate was 28 percent in the control arm. There was no significant difference in placement rate between the intervention and control groups. The authors estimated that CM delayed nursing home placement by an average of 53 days among patients with more severe dementia. In an observational study[92] conducted in the

United Kingdom 43 patients in a CM program were compared with 43 matched controls who did not receive CM. At 2 years, 31 percent of all patients had died. Twenty-one percent of the CM patients had been placed in a nursing home compared with 33 percent of the patients in the comparison program. Finally, a poor quality clinical trial of two types of CM in the State of New York included a subgroup analysis of the participants who had dementia.[90] Nursing home utilization was nearly identical among patients receiving CM by individual case managers when compared with patients who received a more intensive model of CM by a team that included a nurse and a social worker.

Patient and Caregiver Health Outcomes

One of the major challenges in caring for patients with dementia is management of problematic behavioral symptoms. Studies of CM have used a variety of methods to measure such symptoms, using two different but related approaches. The first approach is to use a questionnaire such as the neuropsychiatric inventory (NPI) that measures the caregiver's report of the severity of symptoms. The second approach is to assess measures of strain or burden experienced by the caregiver due to performing the caregiving role. Thus, these are measures of the frequency/severity of patient behaviors and the caregiver's stress in dealing with these behaviors. Since the same caregiver usually completes both types of measure, the measurements are not independent. Also, because a variety of different instruments have been used, we will report the trends in such measurements for each study rather than separating out each type of assessment.

Of the 13 randomized trials of CM for dementia, 11 included measures of the caregivers' perceptions of the patients' behaviors. Five of these trials had good methodological quality. The trial reported by Mittelman had both the longest duration of CM and the longest followup period.[95] This study found no difference over time between the CM and control groups in the frequency of problematic behaviors. However, caregiver stress associated with the behaviors was significantly lower in the CM group and this effect persisted over a 4-year period. The caregivers in the CM group also reported lower scores on a depression scale, but this difference did not persist beyond 3 years.

Mittelman and colleagues also performed a second randomized trial to replicate the original study.[85] This trial continued CM for only 2 years. While caregiver burden scores were lower in the CM group, this was not statistically significant. Caregiver depression scores were significantly lower in the CM group during the followup period. While depression scores increased over time in the control group, they decreased over time in the CM group.

Other clinical trials rated as either good or fair quality have had shorter followup periods, but their results generally are consistent with those found by Mittelman.[85] Callahan[80] included caregiver assessments of the NPI, a rating of patient depression, and a measure of caregiver stress at 6, 12, and 18 months, although the CM program ended at 12 months. The NPI scores were better in the CM arm at both 12 and 18 months. Measures of caregiver stress also were better in the CM arm at 12 and 18 months. Vickrey[84] assessed caregiver confidence and QOL after 18 months of CM. Confidence increased modestly in the CM group, but measures of QOL and caregiver strain did not change. Jansen[83] conducted a trial of 12 months of CM. This trial found no differences between the CM and control groups in measures of caregiver depression, QOL, or caregiver burden. Chien[86] conducted a fair quality trial in which patient NPI scores and a caregiver burden measure did not change over 12 months in the control group. In the CM group, both measures significantly improved at 12 months. Lam[87] assessed caregiver outcomes after a 4-month CM intervention. There was no change in measures of caregiver stress and QOL for the CM and control groups at 4 and 12 months. Psychological health scores were unchanged at 4 months but increased for CM caregivers at 12 months.

Of three other clinical trials rated as poor quality, one[91] found mild effect of CM on improvement of patient symptoms at 12 months and one[88] found no effect on symptoms. Two of these trials[88, 99] found no effect of CM on caregiver burden or depression. An observational study[92] found decreased caregiver burden in the group receiving CM. Another observational study[93] found a positive effect of CM on caregiver stress, well-being, and endurance.

Quality of Care Outcomes

The clinical trials of CM for patients with dementia generally have provided only limited data about the effects of the programs on processes of care. However, Vickrey and colleagues[84] reported a good-quality randomized trial that had adherence to dementia care guidelines as its primary outcome. The study had 23 prespecified dementia guidelines that were included in the clinical protocol for CM. These fell into four clinical domains: assessment, treatment, education/support, and safety. At 18 months, the care was judged to be adherent to a mean of 33 percent of the guidelines in the control group and 64 percent of the guidelines in the CM group. No other studies of CM have examined its effect on guideline adherence.

Resource Utilization Outcomes

Multiple studies have examined the effect of CM on the use of outpatient and inpatient care. While various individual utilization measures have been studied, there is a sufficient body of evidence to draw a conclusion about the effects of CM only for measures of overall costs. Three randomized trials and one observational study evaluated the effect of CM on costs of care for patients with dementia. These studies evaluated costs over 1-2 years of followup. Duru[102] examined costs in a good-quality trial evaluating health care, caregiving, and out-of-pocket costs over 18 months. The monthly cost for CM was modest (mean $118). Total costs (from either a societal or payer perspective) were slightly higher in the control group, but this was not statistically significant. Another good-quality trial also found slightly higher total costs in the control group, but the difference was not statistically significant.[82] The MADDE trial was a large trial that included an incentive to use home-care services by the CM group. It found that CM had little effect on Medicare expenditures.[36] In an observational study[92] total costs were higher in the CM group, primarily due to higher utilization of clinic visits and acute care hospitalizations. Overall there is a moderate strength of evidence indicating that CM has little effect on the overall cost of care in this population.

There is insufficient evidence to draw conclusions about CM effects on specific types of utilization in this population. In the good-quality trial reported by Callahan,[80] the frequency of primary care clinic visits was higher in the CM group but acute care hospitalization rates did not differ between groups. A lower quality trial[91] found that the CM group had a higher rate of physician visits but lower rates of ED visits and hospitalizations. In an observational study, both psychiatric and medical hospitalizations were higher in the CM group.[92]

For in-home services, one good-quality trial[84] and a fair quality trial[87] found that patients in the CM groups had higher utilization of respite and outside caregiver services. Jansen's good-quality study[83] found no differences in utilization of in-home services between the CM and control groups. A lower-quality trial[88] also found that the CM and control groups did not differ in the use of in-home services. Another low-quality trial[100] found increased use of community services among patients receiving CM, but this trial included a financial benefit for these services (in the CM but not the control group), so it is a biased evaluation of this effect. Overall, there is only a small body of evidence about the effect of CM on use of in-home services among patients with dementia.

Effectiveness of Case Management by Patient Characteristics

As previously described, most of these studies had sample sizes of less than 100 participants in each study arm, which provided little power for subgroup analyses. In two clinical trials, the participants were stratified by severity of dementia. Using time to nursing home placement as the outcome, the differences between intervention and control groups was greatest among those with the greatest severity of dementia, suggesting that these individuals were more likely to benefit from CM.[82, 88] Another trial[91] performed regression analyses to see if patient characteristics were associated with utilization outcomes, but these results found no clear trends.

Effectiveness of Case Management by Intervention Characteristics

The only head-to-head trial comparing two different approaches with CM was an older randomized trial of individual compared with team-based CM.[90] This trial tested the hypothesis that a team-based approach that provided more frequent patient contact and more home visits would lead to superior outcomes. It had poor methodological quality and had negative findings. For indirect comparisons, the major evidence comes from Mittelman's good quality trial conducted in New York City.[31] As described above, this program provided long-term CM (up to 10 years) and specialized in providing services to live-in spouse caregivers. All other CM programs that have been studied served a variety of spouse and nonspouse caregivers and continued services no longer than 2 years. The positive findings in the Mittelman study suggest that long-term specialized CM programs for this clinical problem may have superior success in reducing caregiver depression and stress and in delaying nursing home placement.

Table 7. Characteristics and outcomes of studies of case management for patients with dementia (randomized trials)

Author Year Quality	Patient Population	Disease Severity (Usual Care: Intervention)	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Callahan 2006[80] Good	AD patients from a community health center and VAMC; 70% CG living with patient	MMSE (mean): 18.6 vs. 17.5 (Moderate)	Primary care practices	84	↑ Behavioral symptoms = Cognition, function = Time to nursing home placement	↑ CG depression	NR	= Hospitalization rates = Hospital days Physician or nurse visits *(more with CM)*
Chien 2008[86] Fair	Elderly Chinese patients with dementia; 100% CG living with patient	MMSE (mean): 17.3 vs. 17.5 (Moderate)	Dementia center	88 dyads	↑ Behavioral symptoms ↑ Placement rates, number of days institutionalized	↑ CG QOL ↑ CG burden	NR	↑ Service utilization
Chu 2000[88] Poor	Individuals with early stage AD; CG living with patient: a) CM= 65%; b) Control= 81%	MMSE (%): ≤23 = 40 vs. 50 ≥24 = 60 vs. 50	Home care program (Canada)	75 dyads	= Cognitive impairment, behavior problems, depression, delayed institutionalization	= CG burden	NR	NR
Clark 2004[91] Poor	HMO (Kaiser) clients with dementia	NR	AD center	89	↑ Depression	↑ Satisfaction	NR	↑ Hospital admissions, ED visits
Eggert 1991[89] Zimmer 1990[90] Poor	Elderly, with dementia, eligible for skilled nursing care (subgroup analysis of larger study). Living alone: a) team CM= 24%; b) Control= 33%	NR	Community	520	= Function	= Satisfaction with health care	NR	= Nursing home utilization ↑ Fewer hospital days

Table 7. Characteristics and outcomes of studies of case management for patients with dementia (randomized trials) (continued)

Author Year Quality	Patient Population	Disease Severity (Usual Care: Intervention)	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Eloniemi-Sulkava 2001[81] Good	Patients in the Soc. Insurance Program with dementia 92% CG living with patient	MMSE (mean): 15.3 vs. 14.4 MMSE (%): Mild = 38 vs. 40 Moderate = 38 vs. 24 Severe = 24 vs. 36	Department of Public and General Practice in the University of Kuopio	100 dyads	↑ Delayed institutionalization = Residential placement at 2 years	NR	NR	NR
Eloniemi-Sulkava 2009[82] Good	AD dementia patients and spouses 100% CG living with patient	MMSE (mean): 14.2 vs. 13.4 CDR (%): Mild = 24.2 vs. 27 Moderate = 54.8 vs. 55.5 Severe = 21 vs. 17.5	Central Union for the Welfare of the Aged in Helsinki	125 dyads	= Residential placement at 2 years	NR	NR	= Cost
Jansen 2011[83] Jansen 2005[94] Good	Community dwelling adults 44% CG living with patient	MMSE (mean): 22.7 vs. 22.0 (Mild)	NR	99	= Patient's QOL	= CG burden, CG QOL, CG depression	NR	NR
Lam 2010[87] Fair	Community dwelling Chinese with mild dementia	MMSE (mean): 18.0 vs. 17.6 (Mild)	Community-based	102	= Cognitive impairment, behavior problems, depression	= CG burden	NR	NR
Mittelman 2006[31] Mittelman, 2004a[95] Mittelman, 2004b[96] Roth 2005[97] Good	CG living with patient and at least one relative living in the area	GDS (%): 4 (Mild) = 31.53 vs. 35.47 5(Moderate) = 37.93 vs. 44.83 6/7(Severe) = 30.54 vs. 19.7	Community-based (NYU Alzheimer's Disease Centers and support groups)	406	↑ Delayed institutionalization = Behavior problems	↑ CG burden, ↑ CG depression	NR	NR

Table 7. Characteristics and outcomes of studies of case management for patients with dementia (randomized trials) (continued)

Author Year Quality	Patient Population	Disease Severity (Usual Care: Intervention)	Setting	Sample Size	Health Outcomes	Patient and CG Experience	Quality of Care	Resource Utilization, Cost
Mittelman et al. 2008[85]; Brodaty 2009[98] Good	CG living with patient and at least one relative living in the area	MMSE (mean): 19.8 vs. 20.9 (Mild)	NR (3-country study: USA, UK, and Australia)	158 dyads	= Residential placement at 5 years,	↑ CG depression	NR	NR
Newcomer 1999[36] Poor	Medicare patients in the MADDE project; 74% CG living with patient	MMSE (%): 0 = 10.0 vs. 10.6 1-5 = 8.1 vs. 8.5 6-10 = 10.5 vs. 10.2 11-15 = 16.9 vs. 15.6 16-20 = 20.6 vs. 21.5 21-25 = 18.0 vs. 18.9 25-30 = 9.4 vs. 8.9 Missing = 6.3 vs. 5.9 (Moderate)	Community-based (8 demonstration sites)	5,307	= Permanent nursing home entry	= CG burden, CG depression	↑ Service use likelihood	= Medicare expenditures
Vickrey 2006[84] Duru 2009[102] Good	Well-educated, predominantly white Medicare recipients; 70% CG living with patient	Blessed-Roth scale: 6.3 vs. 5.7	Community based within the health care organization	354 dyads	↑ Prescription for Cholinesterase inhibitors or antidepressants	= CG QOL ↑ CG social support	↑ Care quality ↑Community assistance	= Cost

AD = Alzheimer's disease; CG = caregiver; CM = case management; ED = emergency department; GDS = Global Deterioration Scale; HMO = health maintenance organization; MMSE = Mini-mental State Examination; NR = not reported; NYU = New York University; U.K. = United Kingdom; U.S. = United States; QOL = quality of life; VAMC = Veterans Affairs Medical Center

Note: ↑Better with case management; = No difference; ↓Worse with case management.

Population: Patients With Congestive Heart Failure

Congestive heart failure (CHF) is an illness associated with substantial morbidity and mortality in the elderly and is characterized by frequent exacerbations that make it the leading cause of hospitalizations among Medicare beneficiaries.[103, 104] Nurse-led interventions, including CM, are commonly used to improve CHF management, with the goals of improving patients' QOL, maintaining clinical stability, and preventing CHF exacerbations and hospitalizations. CM functions used to achieve these goals typically include educating patients to enhance their self-management knowledge and skills; coordinating and facilitating access to multiple clinical providers and services; monitoring clinical parameters; and sometimes adjusting medication regimens and doses.

Description of Studies

We found 11 clinical trials of CM for patients with CHF (see Appendix I, Evidence Table 7); five were rated as good quality,[105-109] four fair,[110-113] and two poor[114, 115] (see Appendix G). Sample sizes of the included trials ranged from 58 to 1049 patients (total N for all studies = 3,804). The studies were published between 1993 and 2010. We also identified one, small, poor quality observational study from our search.[116] (See Appendix I, Evidence Table 8.)

The *populations* in the 11 trials varied, ranging from members of a large health maintenance organization who were at low risk for hospitalization[105] to patients with predominantly severe CHF, living in a low-income, urban neighborhood.[109] Other studies fell within this spectrum, with patients who had moderate (New York Heart Association class II and III) heart failure[106, 107, 110-113, 115] and were at increased risk for hospitalization.[107, 110, 111, 115] Three studies included only patients with systolic heart failure, typically indicated by a left ventricular ejection fraction of less than 35 to 45 percent,[108-110] while others included patients with both systolic and diastolic dysfunction.[105-107, 111-113] The mean age in most studies ranged from 60 to 80. A feature of most of these studies that differs from the studies of CM in all other clinical categories in this report is that in all of the studies except two,[108, 109] the patients were enrolled during an acute hospitalization.

CM *interventions* varied in nature and intensity (see Table 8). The focus of the interventions ranged from predominantly clinical management—including self-management education, monitoring of clinical parameters, and adjustment of medications—to a more comprehensive CM approach that included a strong element of service coordination and social support. All interventions employed telephone contacts, six included home visitation,[106-108, 111, 114, 115] and four held face-to-face clinic visits.[106, 107, 109, 114] Case managers were nurses in all interventions; some received supervision from physicians or more senior nursing staff. Most interventions employed protocols or algorithms to guide clinical management of CHF. Most studies evaluated the effect of CM as an isolated intervention, but some included CM as a component of a multidisciplinary team approach to discharge planning and disease management.[107, 111, 114, 115]

Table 8. Characteristics of case management interventions for patients with congestive heart failure (randomized trials)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contact (Average)	Case-load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
DeBusk 2004[105] Good	12	Phone	• Education • Clinical monitoring • Medication adjustment	9 hours	NR	Integrated	Yes	Nurses experienced in care management	Yes	Yes
Jaarsma 2008[106] Good	18	Home visits, phone, clinic	• Education • Clinical monitoring • PS support	40 hours	NR	NR	No	Nurses specializing in heart failure	Yes	Yes
Kasper 2002[107] Good	6	Phone, clinic, home visits	• Education • Clinical monitoring • Medication adjustment	8.5 visits (average 57 minutes each)	NR	Approved care plans, notified of test results	Yes	Nurses specializing in heart failure	NR	Yes
Laramee 2003[110] Fair	3	Phone	• Planning • Education • Clinical monitoring • Coordination of services • PS support	9 calls (5-45 minutes each)	65-89	Integrated for local physicians; others received CM progress reports	No	Cardiology nurse	No	NR
Peters-Klimm 2010[108] Good	12	Phone, home visits	• Education • Clinical monitoring	5-7 hours	NR	Integrated	No	Nurses	Yes	Yes
Pugh 2001[114] Poor	6	Clinic, phone, home visits	• Planning • Education • Clinical monitoring • Coordination of services	Minimum 5 visits (clinic or home), 8 calls	NR	Integrated	No	Nurses	NR	NR
Rich 1995[111] Fair	3	Phone, home visits	• Education • Clinical monitoring • PS support	NR	NR	NR	NR	Home care nurse	NR	NR
Rich 1993[115] Poor	3	Phone, home visits	• Education • Clinical monitoring • PS support	NR	NR	NR	NR	Home care nurse	NR	NR

Table 8. Characteristics of case management interventions for patients with congestive heart failure (randomized trials) (continued)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contact (Average)	Case-load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Riegel 2002[112] Fair	6	Phone	• Planning • Education • Clinical monitoring • Coordination of services	17 calls (16 hours total)	NR	Received calls and progress reports from CM	Supervision by cardiology nurse	RNs	Yes	Yes
Riegel 2006[113] Fair	6	Phone	• Education • Clinical monitoring • Coordination of services	22 calls	NR	Received calls and progress reports from CM	Supervision by cardiology nurse	Nurse	Yes	Yes
Sisk 2006[109] Good	12	Clinic, phone	• Education • Clinical monitoring	NR	NR	Integrated	Yes	RNs	Yes	Yes

CM = case management; NR = not reported; PS = psychosocial; RN = registered nurse

The *comparator* group in most studies received usual care without CM. What constituted usual care in most studies was a CHF-specific discharge plan for patients enrolled during a hospitalization with outpatient primary care followup that was not standardized. In a study from the Netherlands, outpatient followup care was provided by cardiologists.[106] That study also included a third arm, in addition to CM and usual care, in which patients received nurse-led CHF management that focused on clinical management alone (without coordinating functions) and was less intensive than the CM intervention.[106]

The primary *outcome* in all studies enrolling inpatients was hospital admission,[105-107, 110-113, 115] with some studies targeting the composite outcome of admission or death.[106, 107, 111] for two studies enrolling outpatients, the primary outcomes were all-cause hospitalizations[109] and health-related QOL.[108] Other outcomes included patient satisfaction,[108, 110, 112] patient adherence to self-care plans,[107, 108, 110] receipt of guideline-recommended CHF medications,[105, 107, 110] and the overall cost of care.[110-113] All studies examined multiple outcomes (see Table 9).

The *timing* and *setting* of CM interventions was in most of the studies related to the principal objective of preventing readmissions among patients hospitalized for CHF. Case managers typically engaged with patients prior to hospital discharge and followed them for 3 to 18 months, depending on the duration of CM stipulated in different study protocols.[105-107, 110-115] Two studies enrolled outpatients from community medical practices.[108, 109]

In one good-quality study, the authors reported a conflict of interest, indicating that the Division of Cardiology in which they worked had stock in and was entitled to royalties from the disease management company whose CM intervention they implemented and evaluated.[107] The company also provided funding for the study, which demonstrated multiple benefits of CM over usual care.

Key Points Related to Patients With Congestive Heart Failure

- CM does not reduce mortality among adults with CHF (strength of evidence: low). (See Appendix H. Strength of Evidence.)
- CM improves CHF-related QOL (strength of evidence: low).
- CM increases patient satisfaction (strength of evidence: moderate).
- CM increases patients' adherence to self-management behaviors recommended for patients with CHF (strength of evidence: moderate).
- CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

None of the included studies was explicitly designed to examine the impact of CM on mortality, although three trials included mortality as part of a composite primary outcome measure, usually coupled with rehospitalization.[106, 107, 111] Three other trials reported mortality rates without explicitly defining it as an outcome.[105, 112, 114] No study found a statistically significant improvement in either all-cause or CHF-related mortality, but all but one study[114] reported lower mortality rates in the CM group compared with controls (RR 0.74 to 0.88). The small number of studies, coupled with heterogeneity of the patient populations, CM interventions, and duration of followup, precluded pooling of data to derive a meaningful estimate of potential mortality reduction with CM. The consistency of relative risk across five studies, however, raises the possibility that CM may provide a survival benefit over usual care for patients with CHF. However, because none of the studies found a statistically significant mortality improvement, the overall impact on improvement appears to be low.

Quality of Life

Six studies examined the effect of CM on QOL, using a variety of CHF-specific instruments, including the Minnesota Living with Heart Failure Questionnaire,[107, 109] the Kansas City Cardiomyopathy Questionnaire,[108] and the Chronic Heart Failure Questionnaire.[111] Four of these studies also used global measures of functional status that are not specific to CHF: the Medical Outcomes Study SF-36[108, 109, 114] and the EuroQOL EQ-5D™.[113] Among these six studies, three found significant improvements in CHF-related QOL among patients receiving CM,[107, 109, 111] one of which also found improvements in overall functional status.[109] In the other three studies, QOL scores were similar in the CM and control groups, with minimal evidence of trends towards better QOL in either the CM or control groups. In the study showing improvements in overall functional status with CM, the improvement occurred in both physical and emotional domains of functioning.[109] Notably, in the one study that followed patients beyond the end of the intervention period, functional status declined in the CM group at a rate similar to that in the control group,[109] suggesting that the benefits of CM may not be durable unless the intervention is continued. Because of the heterogeneity of findings across the studies, the strength of evidence for the effect of CM on QOL was rated as low.

Patient Satisfaction

Three studies reported the impact of CM on patient satisfaction with care.[108, 110, 112] Two used general measures of patient satisfaction designed or adapted specifically for their studies and found modest but statistically significant improvements in satisfaction in the CM groups compared with controls.[110, 112] The third study used the Patient Assessment of Chronic Illness Care (PACIC) instrument and found significant improvements in patient ratings with CM.[108] Because of the consistency of positive findings across three studies, we judged the strength of evidence to be moderate that CM improves satisfaction among patients with CHF.

Quality of Care Outcomes

Four studies evaluated the impact of CM on indicators of quality of care for CHF. Three examined the use of appropriate pharmacotherapy (e.g., angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers and beta-blockers for patients with systolic heart failure).[105, 107, 110] One study showed improvements in the use of recommended medications with CM,[107] while the other two did not.[105, 110] Three studies examined adherence to self-care recommendations (e.g., low-sodium diet, monitoring weight).[107, 108, 110] All three found that patients' adherence to self-management recommendations improved with CM.[107, 108, 110] Because of the consistency of positive findings across these three studies, we judged the strength of evidence to be moderate that CM improves adherence to self care behaviors for CHF.

Resource Utilization Outcomes

Nine studies reported the impact of CM on all-cause hospitalization rates.[105-107, 109-113, 115] Results were mixed, with four studies showing lower hospitalization rates with CM[107, 109, 111, 112, 115] and five showing no difference between CM and controls.[105, 106, 110, 113-115] In the five studies showing no difference, the relative rates of hospitalization in CM compared with control groups ranged from 1.02 to 1.12. In the four studies reporting significantly lower hospitalization rates with CM,[107, 109, 111, 112] the relative rates ranged from 0.56 to 0.79, and absolute differences ranged from 19 fewer hospitalizations per 100 patients over a 12-month observation period[109] to 30 fewer hospitalization per 100 patients over a 3-month period.[111] Reductions in all-cause hospitalization rates were driven primarily by lower rates of hospitalization for CHF. Five studies examined the total number of hospital days during the study period, with one reporting fewer hospital days per patient in the CM compared with control group (3.9 vs. 6.2 days over a 3-month period),[111] and four reporting no difference.[107, 110, 112, 113]

We examined whether study quality was associated with the effects of CM interventions on inpatient utilization. Of the four studies that were rated as having the highest methodological quality,[105-107, 109] two[107, 109] found lower hospitalization rates and two[105, 106] found no decrease in hospitalization rates with CM. The study with the largest sample size (conducted in the Netherlands) found no reduction in hospital admissions.[106] We concluded that there is heterogeneity of results for this outcome. While CM may reduce hospitalization rates for patients with CHF, there presently is insufficient evidence to draw a conclusion about this effect.

Six studies estimated the impact of CM on the overall or hospital-related cost of care.[107, 110-114] Total costs were dominated by the cost of inpatient care, with estimated costs for CM interventions being comparatively small. Accordingly, three studies demonstrating reductions in hospitalization rates with CM also found reductions in cost,[111, 112] though in one study this difference was not significant.[107] The two studies that did not find improvements in hospitalization rates also did not find a positive or negative impact of CM on the cost of care.[110, 113]

We examined study characteristics, patient populations, and intervention components across studies to try to determine which elements might explain the mixed results for the impact of CM on various outcomes. Broadly speaking, three studies can be classified as “negative,” demonstrating no differences between CM and control groups across outcome measures.[105, 106, 113] Four studies can be considered “positive,” demonstrating improvements in QOL, hospitalization rates, and/or cost of care.[107, 109, 111, 112] Finally, two studies can be considered “intermediate,” showing some improvements in patient-reported measures of satisfaction and self-care but not in health outcomes or hospitalization rates.[108, 110] We omitted two small poor quality studies from this analysis.[114, 115]

Table 9. Characteristics and outcomes of studies of case management for patients with congestive heart failure (randomized trials)

Author Year Quality	Patient Population	NYHA Class[a]	Setting	Sample Size	Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
DeBusk 2004[105] Good	HMO members hospitalized with CHF, at low risk for poor outcomes	I/II: 50% III/IV: 50%	5 hospitals within large HMO (U.S.)	462	=	NR	=	=
Jaarsma 2008[106] Good	Adults hospitalized with CHF	II: 50% III: 46% IV: 4%	17 hospitals (Netherlands)	1,023	=	NR	NR	=
Kasper 2002[107] Good	Adults hospitalized for CHF, with risk factors for readmission	II: 36% III: 59%	2 university hospitals (U.S.)	200	↑ QOL	NR	↑ Appropriate medications, diet, achieving goal weight	↓ Hospitalizations
Laramee 2003[110] Fair	Adults with systolic dysfunction hospitalized for CHF, with risk factors for early readmission	I: 16% II: 43% III: 33% IV: 2%	One university hospital (U.S.)	287	NR	↑ Satisfaction	↑ Adherence to treatment regimen	=
Peters-Klimm 2010[108] Good	Adults with systolic dysfunction with $\geq$ 1 hospitalization during prior 2 years	I: 3% II: 65% III: 30% IV: 0.5%	29 small primary care practices (Germany)	199	=	↑ Satisfaction	↑ Self-care	NR
Pugh 2001[114] Poor	Patients 65 or older hospitalized for CHF	I: 4% II: 44% III: 45% IV: 7%	One university hospital, one community hospital (U.S.)	58	=	NR	NR	=
Rich 1995[111] Fair	Patients over 70 hospitalized with CHF, with risk factors for readmission	Mean NYHA class 2.4	One university hospital (U.S.)	282	↑ QOL	NR	NR	↓Hospitalizations, hospital days, cost
Rich 1993[115] Poor	Patients over 70 hospitalized with CHF, with risk factors for readmission	Mean NYHA class 2.7-3.0	One university hospital (U.S.)	98	NR	NR	NR	NR

Table 9. Characteristics and outcomes of studies of case management for patients with congestive heart failure (randomized trials) (continued)

Author Year Quality	Patient Population	NYHA Class[a]	Setting	Sample Size	Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
Riegel 2002[112] Fair	English- and Spanish-speaking adults hospitalized for CHF	I: 10% II: 18% III: 57% IV: 15%	2 hospitals (U.S.)	358	NR	↑ Satisfaction	NR	↓Hospitalizations, hospital days, cost
Riegel 2006[113] Fair	Hispanic adults hospitalized with CHF	II: 19% III: 46% IV: 35%	2 community hospitals (U.S.)	135	=	NR	NR	=
Sisk 2006[109] Good	Ethnically diverse, English- and Spanish-speaking adults with systolic dysfunction	I: 19% II: 22% III: 14% IV: 45%	Community general medicine, geriatrics, and cardiology practices (U.S.)	406	↑ QOL	NR	NR	↓Hospitalizations

CHF = congestive heart failure; HMO = health maintenance organization; NR = not reported; NYHA = New York Heart Association; QOL = quality of life; U.S. = United States

Note: ↑Higher with case management; = No difference; ↓Lower with case management.

[a] Totals may not add to 100% due to incomplete reporting or rounding.

Effectiveness of Case Management by Patient Characteristics

Case management is considered to be most appropriate for patients at high risk for poor outcomes. Three studies selected hospitalized patients who had features considered to put them at high risk for readmission.[107, 110, 111] Two of these studies showed lower hospitalization rates with CM,[107, 111] while the third demonstrated improvements in patient-reported outcomes.[110] Four other hospital-based studies enrolled either low-risk[105] or unselected patients[106, 112, 113] with CHF. Results were negative in three of these studies[105, 106, 113] and positive in one.[112]

In the three studies enrolling high-risk patients, high risk was defined as having one or more risk factors for readmission. The specific risk factors varied across the three studies. In two of them, a prior history of CHF was considered a risk factor in and of itself.[110, 111] All three studies included recent hospitalizations as a risk factor, though the specific criteria varied (e.g., four hospitalizations for any reason over the prior 5 years compared with one CHF hospitalization during the prior year). Two studies showing a positive impact of CM on readmission used clinical parameters (e.g., uncontrolled blood pressure) to select high-risk patients,[107, 111] while the other study, which found an impact on self-care but not on readmission, used mainly social and behavioral factors (e.g., knowledge deficits, potential for lack of adherence, living alone).[110]

Baseline hospitalization rates (those observed in control groups) can also be considered a proxy measure of risk within the sampled populations across studies. We calculated control-group hospitalization rates for each study reporting them and adjusted rates for the duration of followup. Three studies demonstrating a reduction in hospitalization rates with CM[107, 111, 112] had relatively high baseline rates of hospitalization (1.74 to 2.69 per person per year), while three negative studies[105, 106, 113] had relatively low rates (0.74 to 0.99 per person per year). A study with an intermediate baseline hospitalization rate (1.47 per person per year) showed no reduction in hospitalizations with CM but improvements in self-care and patient satisfaction.[110] These findings suggested a pattern of higher success with CM in populations at higher risk of hospitalization. One study did not fit this pattern. In that study,[109] CM successfully reduced hospitalization rates in a population with a relatively low baseline rate (0.89 per person per year). This study also differed from others in that patients were not hospitalized at the time of recruitment.[109]

There was no clearly discernible pattern in study outcomes based on whether the study sample included only patients with systolic heart failure or patients with either systolic or diastolic dysfunction. Likewise, functional status, as measured by New York Heart Association class did not appear to be associated with the impact of CM. The studies with the most class III and IV patients included one positive[109] and one negative study.[113]

Few studies specifically targeted vulnerable patient populations. One included predominantly ethnic minority patients with relatively poor functional status in a low-income, urban neighborhood (Harlem, New York City) and found improvements in both QOL and hospitalization.[109] Another study, however, enrolled Spanish-speaking patients in Southern California, also with poor functional status, and found no improvement with CM.[113] The authors of this latter study used a CM intervention that was essentially identical to one they used in an earlier study, in which they enrolled predominantly English-speaking patients and found significant reductions in hospitalization rates and cost with CM.[112] Linguistic and cultural factors may explain the difference in success in these two interventions. However, the populations in these two studies also differed in other ways, including more class IV heart failure patients in the unsuccessful study.

In two studies which found CM not to be superior to usual care for any outcome measure, the authors reported that the baseline quality of CHF care may have been sufficiently high such that there was minimal room for the CM intervention to improve quality of care and thereby result in better outcomes.[105, 106] These studies were conducted in a large HMO (Kaiser Permanente) with a strong quality improvement focus[105] and in a group of cardiology practices.[106] While it is possible that these settings may have resulted in control groups that received higher quality care than in other studies, we did not observe higher rates of appropriate pharmacotherapy in the control groups of those two studies, compared with other studies that reported superior outcomes with CM.

Overall, there were no consistent trends when examining patient subgroups in this set of studies. We concluded that patient characteristics do not appear to mediate the effects of CM for patients with CHF.

Effectiveness of Case Management by Intervention Characteristics

No studies included head-to-head comparisons of different models of CM. One study compared an intensive CM program with a more basic and less intensive disease management intervention.[106] Neither the CM nor the less intensive intervention was superior to the control group on any outcomes.

There were few discernible patterns in terms of intervention characteristics that predict successful CM interventions (Table 8). Interventions that were longer in duration did not produce more positive results, nor did the use of home visits, as opposed to telephone care alone or the amount of contact time. Only one study reported CM caseloads.[110] In most studies, CM functions were heavily weighted towards clinical activities, as opposed to coordinating functions; the specific CM functions employed did not track with intervention success, though few studies described CM functions with enough specificity to allow clear delineations in the nature and intensity of those functions. The ability of nurses to adjust medications was present in only two studies, one with negative and one with positive results.[105, 107]

The degree to which the care delivered by case managers was integrated with patients' usual care providers (usually primary care physicians or cardiologists) was not well described in most studies. Interventions that appeared to include higher levels of integration with usual care providers did not clearly produce better results than others. One study, however, reported significantly lower hospitalization rates among patients whose usual care providers were in the local vicinity where the case manager worked and with whom he or she had closer contact.[110] No such improvement in hospitalization rates was observed among patients with nonlocal providers.

The presence of physician supervision of case managers was not clearly associated with better outcomes. Two studies, however, that embedded case managers within teams that included other health professionals (e.g., cardiologist, social worker, dietitian) demonstrated better outcomes across multiple domains in the intervention compared with control group.[107, 111] Preintervention training for nurse CMs and care protocols to guide clinical management were not more prevalent in successful compared with unsuccessful CM interventions.

Population: Patients With Diabetes Mellitus

Diabetes mellitus (DM) is a significant health problem, currently estimated to affect 26 million Americans and approximately 27 percent of adults over age 65.[117] The prevalence of diabetes continues to rise, as do the associated increased risks of cardiovascular disease, end stage renal disease, neuropathy, and retinopathy. Considerable health care resources have been devoted to seeking mechanisms to optimize care as a strategy to diminish the morbidity and mortality associated with this chronic health condition. Diabetes is especially complex in that its management requires avid and persistent participation from both providers and patients. Desired patient behaviors often are complex, with permanent alterations of habits (diet and exercise) and complex medication regimens. The ability of case managers to work with patients to improve education and individual goal setting may positively impact patients' understanding of their diabetes and their self-directed care activities. Case manager involvement may also aid providers via improved tracking and implementation of systems to monitor glucose control and to obtain routine tests that screen for disease complications. Although the overall functional status of many patients with diabetes is relatively good, the rationale for CM is that they need assistance and training to improve both self-management skills and the overall coordination of their health care.

Description of Studies

We identified 12 studies in total, nine clinical trials and three observational studies, of adults with diabetes (see Appendix I, Evidence Table 9 and 10). Of the clinical trials, two were rated good,[118, 119]six were rated fair,[120-134] and one was rated poor[135] (see Appendix G). The study by Brown and colleagues was listed as poor quality due to unevenness of characteristics between groups at baseline as well as no reporting of withdrawals, attrition, or crossover between groups. Due to the poor quality of this study, its data will not be further included in this discussion and it is not incorporated in the tables within this chapter. All eight included trials were conducted in the United States and published between 2002 and 2009. Sample sizes of included trials ranged from 147 to 1,665 participants (total N = 3,776); notably, the majority of these studies were relatively small, with five of the eight having fewer than 400 participants.[118, 120, 123, 125-127, 136] Of the three observational studies, two were rated fair[137, 138] and one was rated good.[139, 140] All three observational studies utilized a retrospective cohort design, were conducted in the United States, included a total patient population of greater than 1,000 (range 1,076 to 5,925), and were published between 2005 and 2009. Study duration ranged from 12 months to 5 years. Only one study examined outcomes at 5 years,[130] however, and 10 of the 11 included studies limited their followup or retrospective analysis to 2 years or less.

The *populations* examined by the 11 included studies varied significantly. The mean age of participants ranged from 48 to 71. There was notable heterogeneity in racial/ethnic backgrounds, as some trials limited their patient populations to African Americans,[121, 122] American Indians/Alaskan Natives,[137, 138] or Latinos.[120] Five trials examined only individuals with type II diabetes.[118, 120, 121, 123, 124, 126, 127, 136] The trials also exhibited different levels of complexity defined by differences in disease severity (measured as mean hemoglobin A1c [HgA1c] and duration of DM).[118, 120, 122, 125-127, 136] Population complexity also varied between studies due to different degrees of socioeconomic disparity in that five of the eight trials included populations of lower socioeconomic status[120-124, 126-130] and four studies documented a low educational level in the majority of their included population.[120, 121, 123, 124, 126] One of the eight trials documented that a large percentage utilized medical assistance programs or were uninsured.[122]

The intensity of the CM *intervention* was similar in seven of the 11 studies, in that face-to-face interaction was the primary mode of CM delivery supplemented with telephone contact[118, 120, 122, 125-127, 136, 138, 139] (see Table 10). One study, rated good quality, included two face-to-face visits but relied primarily on telephone contact for most of the CM intervention.[119] Unfortunately, very few trials reported adherence to the CM intervention or the number of case manager interactions/visits achieved, making true intervention intensity difficult to assess. Case managers for the included studies were primarily nurses, although some were registered dietitians[118, 126, 127, 136] or social workers.[139] The *comparator* group for each study was defined as usual care, which uniformly referred to care by a patient's primary care or usual care provider. Targeted *outcomes* in the included studies included patient health, patient satisfaction, quality of care, and resource utilization (see Tables 11 and 12). Patient health outcomes included hard endpoints (i.e., mortality and QOL) as well as a number of intermediate measures such as HgA1c, cholesterol management, blood pressure control, and weight/body mass index (BMI) among others. Quality of care measures included eye and foot examinations, medication adherence, and glucose self-monitoring. Resource utilization measures included ED utilization, hospitalizations, primary care utilization, and a cost analysis. The *timing* of the CM intervention was mentioned by only one trial, which limited their population to individuals with a new diagnosis of type II diabetes (within 6 months of enrollment).[120] The *settings* for the CM intervention was conducted in an outpatient clinic setting in eight of the eleven studies,[118, 120, 121, 123, 124, 126, 127, 136, 138, 139] while the setting in the remaining three studies was unclear.

Table 10. Characteristics of case management interventions for patients with diabetes (randomized trials)

Author Year Quality	Duration	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Case-load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Babamoto 2009[120] Fair	12 months recruitment, 6 months followup	FTF visits and phone	• Assessment • Develop treatment plan • Resource referral	NR	53 patients per CM	Integrated	NR	RN	NR	Yes (protocol)
California Medi-Cal Type 2 Diabetes Study Group 2004[126] Pettitt 2005[127] Fair	36 months	FTF visits and phone	• Identified barriers • Develop treatment plan • Education	NR	NR	Integrated	Yes	RN or RD	NR	Yes (protocol and algorithm)
Gary 2003[122] Fair	2 years enrollment, 2 years followup	FTF visits with phone	• Educate • Resource referral Feedback to MDs	NR	NR	Integrated	Yes	RN	NR	NR
Gary 2009[123] Gary 2004[121]; Gary 2005[124]; Fair	20 months enrollment, 30 months followup	FTF visits	• Assessment • Develop treatment plan • Titrate insulin	NR	269	Integrated	NR	RN	6 weeks	NR
Ishani 2011[119] Good	12 months	FTF visits and phone	• Set goals for lifestyle modification • Improve home glucose and blood pressure monitoring • Improve blood pressure, glucose, and LDL lipid control	Median 15 attempted Median 10 successful	NR	Not integrated	NR	RN	NR	Yes (algorithm to guide medication changes)

Table 10. Characteristics of case management interventions for patients with diabetes (randomized trials) (continued)

Author Year Quality	Duration	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Case-load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Krein 2004[125] Fair	18 months	FTF visits and phone as needed	• Monitor home glucose and BP • Reminders about screening tests • Med adjustment	Goal of 3/year	120	NR	NR	NP	2-day training	Yes (algorithm)
Shea 2002[128] Shea 2006[129] Shea 2009[130] Palmas 2010[131] Trief 2006[132] Trief 2007[133] Izquierdo[134] Fair	2 years initially; 5 years overall	Exclusively phone	• Monitoring blood glucose and BPs • Confer with endocrinology if med adjustment felt needed • Resource referral	NR	200	Integrated	Yes	Unclear	NR	NR
Wolf 2004[118] Wolf 2007[136] Good	12 months	FTF and phone	• Review labs • Establish and adjust goal • Education	NR	72	NR	Yes	RD	NR	NR

BP = blood pressure; CM = case management; FTF = face-to-face; MD = medical doctor; NP = nurse practitioner; NR = not reported; PS = psychosocial; RD = registered dietitian; RN = registered nurse; SW = social worker

Key Points Related to Patients With Diabetes

- CM does not reduce mortality among adults with diabetes (strength of evidence: low). (See Appendix H. Strength of Evidence.)
- CM improves glucose control among adults with diabetes (strength of evidence: low).
- CM does not improve lipid management or weight/BMI in patients with diabetes (strength of evidence: moderate).
- CM does not reduce hospitalization rates among adults with diabetes (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Mortality

One study, a clinical trial rated as fair quality, examined 5-year mortality in adults with diabetes who were exposed to a CM intervention.[130] This study did not find a mortality benefit from this CM intervention after 5 years (hazard ratio for mortality 1.01, 95% confidence interval [CI] 0.82 to 1.24).

Quality of Life

Two clinical trials examined differences in QOL among adults exposed to CM.[118, 120] These trials utilized similar CM intervention techniques but found discordant results (one positive study in favor of CM and one negative study).[118, 120] The positive study observed differences in seven of nine examined categories in a standard scale commonly used to assess QOL.[118] There is insufficient evidence to draw a conclusion about the effect of CM on QOL among people with diabetes.

Changes in Hemoglobin A1c

All of the eight included clinical trials examined differences in glucose control over time, measured by HgA1c, and the majority identified no difference in this intermediate outcome with CM intervention (see Table 11).[118, 119, 122, 123, 125, 126, 129, 130, 136] The intervention setting and duration were similar in six of these trials (see Table 11). One good-quality trial[119] found statistically significant improvement in HgA1c to less than 8 percent in the CM group compared with usual care. Two fair quality trials[126, 129, 130] found statistically significant declines in HgA1c in the CM groups compared with usual care. One trial, also rated as fair quality, provided information on within-group change in HgA1c over time and identified a possible benefit of CM for HgA1c improvement by this metric. Four trials, three fair quality and one good quality, found no significant difference between CM and usual care groups.[118, 122, 123, 125] Three observational studies also examined changes in HgA1c between CM and control groups. Two of these three studies, one rated good quality and one rated fair quality, found improvement in HgA1c among individuals exposed to CM while the third study found no significant difference between groups.[137-139] Taken together, this evidence suggests that CM intervention improves glucose control in patients with diabetes, but there is marked heterogeneity of results for this outcome. The strength of evidence for the conclusion of a positive effect on glucose control is low.

Additional Intermediate Health Outcomes

Seven clinical trials and one observational study examined a cholesterol-related outcome—change in total cholesterol, triglyceride levels, low-density lipoprotein (LDL) cholesterol, or high-density lipoprotein (HDL) cholesterol[118, 119, 122, 123, 125, 126, 129, 130, 139] (See Table 12). Of these, the vast majority identified no benefit of CM for improving measures of cholesterol control. Limited improvement was identified in two studies[122, 129, 130] with regards to two specific measures (LDL and triglyceride levels). The most commonly measured outcome was LDL level, and only one trial[129, 130] showed a benefit of CM for improving this outcome. Because of the consistently negative findings in the other studies, we concluded that there is moderate evidence that CM does not improve lipid measures, when compared with usual care.

Changes in blood pressure were predominantly examined as changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP) (see table 12). The one exception is the trial by Ishani and colleagues, which examined both components of blood pressure together with goal to reach less than 130/80 mmHg; this trial found a significant improvement in blood pressure in CM compared with usual care (p=0.047). One fair quality study also identified benefit of CM for hypertension control.[128-130] Five trials (all fair quality) examined changes in SBP and DBP and the majority (four of the five) identified no benefit or excess harm of CM for SBP management.[122, 123, 125, 126] In total, three of the seven studies which examined blood pressure control identified a benefit of CM including one good-quality study, compared with four studies (all fair quality) which did not. Because of the inconsistency of these results, the evidence is insufficient to discern whether CM leads to improved control of hypertension in people with diabetes.

Four trials examined changes in BMI and none of these identified a benefit of CM[120, 122, 123), 126] (see Table 12). Two trials, one good quality[118] and one fair quality,[126] examined change in weight and describe discordant results. In total, five trials found no benefit in BMI/weight adjustment with CM intervention, while one did find a benefit.

Patient Satisfaction

Krein et al. assessed "general satisfaction" of individuals who received CM compared with usual care and found significantly greater satisfaction among patients in the CM group (p=0.04).[125]

Quality of Care Outcomes

Quality of care was examined via process measure outcomes. Process measure outcomes include those tests or examinations that are recommended to help curb disease severity or to follow/manage other disease manifestations. In the case of diabetes, this ranged from screening examinations for diabetes-related illness (i.e., neuropathy, nephropathy, or retinopathy) to prescription of appropriate medication regimens such as aspirin and angiotensin converting enzyme inhibitor use. The majority of the available quality of care outcomes were examined by a single study. Two studies (one trial and one observational study), both rated as fair, examined the frequency of patient receipt of recommended dilated eye examinations among adults with diabetes but identified discordant results.[125, 138] While the trial was negative (no significant improvement in CM group),[125] the observational study found improved regularity of eye examinations in the CM intervention group.[138] Similarly, these same studies examined patterns of medication use and again the trial was negative and the observational study was positive (observed significantly more aspirin use in the CM arm).

Resource Utilization Outcomes

Resource utilization outcomes can include analysis of trends or frequency with which the examined population utilized the health care system. In the case of diabetes, CM might be expected to improve hospitalization rates, both via influence on glucose control (e.g., hypoglycemia, hyperglycemia) and via improvement in diabetes-related complications such as cardiovascular disease and peripheral neuropathy. CM could similarly influence ED visits, primary care provider appointments, and overall costs of health care. Four studies examined resource utilization outcomes.[118, 120, 121, 125]

Two trials,[120, 123] both rated as fair quality, examined differences in rates of ED utilization and had opposing findings. One identified fewer ED visits in the CM intervention group, whereas the other found no significant difference in ED visits between groups. These two studies varied significantly by CM intervention strategy and patient populations (see Table 10).[120, 123]

Two trials[123, 125] examined rates of hospitalizations. Despite some design differences between studies (see Table 11), results of these two studies for this outcome were both negative (no significant benefit of CM in decreasing rates of hospitalization). This conclusion was rated as having low strength of evidence, due to the small number of studies.

Table 11. Characteristics and outcomes of studies of case management for patients with diabetes (randomized trials)

Author Year Quality	Patient Population	Setting	Sample Size	Health Outcome: Lower HgA1c	Resource Utilization (Hospitalizations/ ED Visits)	Quality of care (Eye Examinations/ Medication Adherence)
Babamoto 2009[120] Fair	Age 18+, inner-city Latinos with incident DM-II	Primary care clinic	318	↑(statistical analysis not provided)	↑ ED visits	↑ Medication adherence
Gary 2003[122] Fair	Age 35-75, inner-city African-Americans with DM-II	Outpatient clinic	186	=	NR	NR
Gary 2009[123] Gary 2004[121] Gary 2005[124] Fair	Age 25+, inner-city African-Americans with DM-II	Primary care clinic	542	=	↑ Hospitalizations	NR
Ishani 2011[119] Good	Veterans with diabetes	NR	431	↑	NR	NR
Krein 2004[125] Fair	Age 18+; prescription for oral hypoglycemic, insulin, or glucose monitoring in year prior with HgA1c >7.5%	NR	209	=	= Hospitalizations	= Eye exams
California Medi-Cal Type 2 Diabetes Study Group 2004[126] Pettit 2005[127] Fair	Age 18+ with DM-II, with HgA1c >7.5%	Primary care clinic	317	↑	NR	NR
Shea 2002[128] Shea 2006[129] Shea 2009[130] Palmas 2010[131] Trief 2006[132] Trief 2007[133] Izquierdo[134] Fair	Age 55+, on Medicare, with DM, living in underserved area	2 remote telephone bank locations	1,417	↑	NR	NR
Wolf 2004[118] Wolf 2007[136] Good	Age 20+,DM-II, BMI ≥27	Outpatient clinic	147	=	= ED visits	NR

BMI = body mass index; DM = diabetes mellitus; ED = emergency department; HgA1c = glycated hemoglobin; NR = not reported

Note: ↑Better with case management; = No difference; ↓Worse with case management.

Table 12. Intermediate health outcomes among trials of case management for diabetes mellitus[a]

Author Year Quality	Lipids[b]	Blood Pressure[b]	Body Mass Index[b]	Weight/Waist[b]
Babamoto 2009[120] Fair	NR	NR	BMI: =	NR
Gary 2003[122] Fair	LDL: ↓ Triglycerides: ↑	DBP: ↑ (P>0.05) SBP: ↓	BMI: ↓	NR
Gary 2009[123] Fair	LDL: = HDL: = TC: =	SBP: = DBP: =	BMI: =	NR
Ishani 2011[119] Good	LDL: = (p=0.017)	BP: ↑ (p=0.047)	NR	NR
Krein 2004[125] Fair	LDL: =	SBP: = DBP: =	NR	NR
California Medi-Cal Type 2 Diabetes Study Group 2004[126] Fair	LDL: = HDL: = TC: = Triglycerides: =	SBP: = DBP: =	BMI: =	Weight: =
Shea 2006[129]; Shea 2009[130] Fair	LDL: ↑ (p<0.05)	SBP: ↑ (p=0.024) DBP: ↑ (p<0.001)	NR	NR
Wolf 2004[118] Good	LDL: = HDL: = TC: = Triglycerides: =	NR	NR	Weight: ↑ (p<0.001) Waist: ↑ (p<0.001)

BMI = body mass index; DBP = diastolic blood pressure; HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein cholesterol; NR = not reported; SBP = systolic blood pressure; TC = total cholesterol

[a] This table reports those health outcomes that were examined by two or more trials.

[b] = No difference between CM and usual care; ↑CM superior to usual care; ↓CM inferior to usual care.

Effectiveness of Case Management by Patient Characteristics

Several studies examined specific patient subgroups of people with diabetes. By far the most common subpopulation examined was that of patients with type II diabetes (examined by 5 of 10 studies).[118, 120-124, 126, 136] All five of these studies (four rated as fair and one rated as poor quality) examined HgA1c and BMI as outcomes. The results of these five studies, however, did not differ from the three studies that did not examine this patient subgroup.

Two trials limited their patient populations to urban, inner-city patient populations,[120, 122] and two trials examined CM among African-American adults with diabetes.[122-124] All three of these studies were rated as fair quality, and all examined BMI as an outcome. CM was not associated with improved BMI in any of these studies. The two clinical trials of African-American adults with diabetes[122-124] also did not find an effect of CM on other physiologic outcomes (e.g., HgA1c, SBP, and HDL cholesterol). Two observational studies limited their populations to American Indians/Alaskan Natives with diabetes.[137, 138] These studies both examined change in HgA1c but had discordant results. Wilson et al.[138] observed significant improvement in HgA1c among individuals who received the CM intervention, while Curtis et al. did not. Two other patient populations (Latinos and adults living in under-served areas) were each examined by only one study.[120, 128-130] Overall, there was minimal evidence suggesting that CM is more effective for improving outcomes for diabetes in any subpopulation.

Effectiveness of Case Management by Intervention Characteristics

Only one observational study evaluated different CM strategies head-to-head.[137] This study included three intervention arms which differed in intensity: usual care by primary care provider alone (least intensive), primary care provider and nurse case manager combined intervention (intermediate intensity), and primary care provider and nurse case manager intervention which allowed case managers to alter medications (most intensive). Interpretation of results from this study was challenging because of the distribution of patients among the study arms. Although the total population for this study was large (n=2300), the vast majority (98 percent) of participants were in either the least intensive (usual care) or intermediate intensity CM arm, with only 60 patients included in the high intensity CM group. Because of the small sample size in the high intensity arm, the precision of the results is low. This study identified no benefit of CM for HgA1c between arms but did observe a statistically significant increase in hypoglycemic events in the most intensive arm (p=0.035). However, this is based upon a single hypoglycemic event in the most intensive arm.

CM strategies employed by the included studies overall were quite variable (see Table 10). There were no consistent similarities in CM strategies among trials with positive results. Only one trial[128-130] reported results which consistently showed a benefit of CM in diabetes (to improve HgA1c, LDL, and blood pressure). That trial, rated as fair quality, was the only trial to utilize solely telephone interactions between case manager and participant. One other trial found a significant improvement in HgA1c with CM utilized a strategy of both face-to-face and telephone interactions by care managers. Of note, this trial only identified a positive result for HgA1c improvement but did not find that CM improved other health outcomes.[126]

Population: Patients With Cancer

The goals of CM for patients with cancer are generally to support and navigate patients through intensive and complex treatment regimens (e.g., surgery, chemotherapy, and radiation); to manage symptoms (e.g., pain, dyspnea, nausea, and fatigue) associated with cancer or its treatment; to maintain patients' physical, mental, and emotional well-being and independence in the context of serious illness and often debilitating treatment; and to help patients, families, and caregivers plan for and cope with the psychosocial and emotional burden imposed by the diagnosis, treatment, and prognosis of cancer. Many CM activities in the setting of cancer care overlap with other interventions such as hospice and palliative care services. What differentiates CM is that comprehensive care coordination is usually the primary focus, while hospice and palliative care interventions tend to focus primarily on symptom management.[141]

Description of Studies

We found six clinical trials of CM for patients with cancer (see Appendix I, Evidence Table 11). Of these, four were rated fair quality[18, 142-144] and two poor quality[145, 146] (see Appendix G). Sample sizes of the included trials ranged from 203 to 335 patients (total N for all studies = 1,406). The earliest included study was published in 1989 and the most recent in 2006. No observational studies were identified for this category of patients.

The *populations* in which CM interventions were tested varied substantially across studies. Two studies evaluated CM for patients with breast cancer,[143, 146] two for patients with lung cancer,[144, 145] and two for patients with a variety of cancer types.[142] Patients ranged in age from 21 to 85 years old, although the mean ages reported by the majority of the studies ranged from 55 to 72 years old. One study recruited only patients meeting criteria for being homebound.[145]

None of the other five studies explicitly targeted patients with functional limitations or specified complex care needs beyond the vulnerability and complexity inherent in undergoing treatment for and coping with cancer. Some studies were conducted in patient populations with high levels of comorbidity[144] or low socioeconomic status.[142]

CM *interventions* across the six studies shared some common elements but varied in both content and implementation (see Table 13). In all six studies, case managers performed a variety of functions, including developing management plans; addressing the psychosocial and emotional needs of patients and their families or caregivers; educating them about cancer and its treatment; assessing, monitoring, and treating symptoms; and coordinating care and making referrals. CM functions were deployed mainly through home visits, face-to-face encounters in a clinic setting, and telephone calls. The duration of CM interventions, as implemented in each trial, ranged from 3 months to 2 years. The intensity of CM also varied, from multifaceted and comprehensive CM that included home visits, telephone calls, and accompanying the patient to doctor visits[143] to lighter interventions involving primarily telephone calls to evaluate and coordinate simple care needs.[18] In most cases, case managers were nurses with specialized training in cancer care. Although protocols and care scripts were used in some interventions, case managers had the flexibility to individualize care according to specific patient needs in all studies.

Table 13. Characteristics of case management interventions for patients with cancer (randomized trials)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Case-load	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Engelhardt 2006[142] Fair	6	In-person (clinic NR)	• Planning • PS support • Coordination	6	NR	NR	NR	RN, NP, or SW	Yes	Yes
Goodwin 2003[143] Jennings-Sanders 2003,[147] 2005[148] Fair	12	Home visits, clinic, phone	• Planning • Education • PS support • Coordination	24	50-60	Integrated	NR	RNs with prior CM experience	Yes	Yes
McCorkle 1989[145] Poor	6	Phone, home visits	• Planning • Education • Clinical monitoring • Coordination	7 (average 34 minutes per call)	NR	Referred patients to program	NR	NR	NR	NR
Moore 2002[144] Fair	12	Home visits, phone	• Education • Clinical monitoring • PS support • Coordination	8	NR	Assessed by CMs for complications	NR	Oncology APNs	NR	Yes
Mor 1995[18] Fair	6	Phone, clinic	• Clinical monitoring • Education • PS support • Coordination	36 (average 23 minutes per contact)	50	Integrated	Yes	Clinical nurse specialists in lung cancer	Yes	Yes
Ritz 2000[146] Poor	24	Phone, home visits, clinic	• Planning • Education • Clinical monitoring • Coordination	23 hours per patient	50-60	Integrated	NR	APNs	NR	NR

APN = advanced practice nurse; CM = case management; NP = nurse practitioner; NR = not reported; PS = psychosocial; RN = registered nurse; SW = social worker

The *comparator* group in most CM trials was described as usual, standard, or conventional medical care. In most studies, the nature of usual care was not explicitly described. One study of patients undergoing lung cancer treatment in the United Kingdom described usual care as outpatient visits in the post-treatment period and then at 2-3 month intervals.[144] Another study of patients with lung cancer compared CM both with a "standard" home care intervention carried out by a multidisciplinary team (without a case manager) and with usual outpatient care.[145]

Targeted *outcomes* in CM trials (see Table 14) included health outcomes such as QOL, functional status, cancer-related symptoms, and survival;[18, 143-146] patient and caregiver satisfaction with care;[142-144] receipt of specific treatments and services considered to represent high-quality cancer care;[142-144] utilization of resources not considered to represent high-quality care (e.g., hospitalization, ED visits);[18, 144, 145] and the overall cost of care.[142, 144, 146]

The *timing* of CM interventions varied across studies. In four studies, case managers primarily supported and coordinated the care of patients undergoing treatment for cancer.[18, 143, 144, 146] CM began before initial treatment in two studies[143, 146] and after treatment in two studies.[18, 144] The other two studies included trials that enrolled patients at different stages in the course of their illness and focused more generally on addressing patients' care needs related to cancer.[142, 145]

The *settings* for CM interventions included managed care organizations,[142, 146] VAMCs,[142] community hospitals and clinics,[18, 143] home care organizations,[142, 145] and cancer care centers.[144] Five studies were conducted in the United States and one in the United Kingdom.[144]

Key Points Related to Patients With Cancer

- CM is effective in improving selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall QOL or survival (strength of evidence: low). (See Appendix H. Strength of Evidence.)
- CM improves patient satisfaction with care (strength of evidence: moderate).
- CM is effective in increasing the receipt of appropriate (i.e., guideline-recommended) cancer treatment (strength of evidence: moderate).
- CM does not affect overall health care utilization or cost among cancer patients (strength of evidence: low).
- Greater intervention intensity and duration, integration of CM with patients' usual care providers, and greater structuring of interventions through preintervention training and care protocols enhance the effectiveness of CM (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Quality of Life/Health Outcomes

Overall QOL and survival were generally not improved by CM in any of the studies that examined those outcomes.[18, 144, 145] CM was effective, however, in improving outcomes that were directly targeted by the intervention. For instance, using an intervention intended to help women recover after breast cancer surgery, Goodwin et al. found that CM was effective in restoring normal ipsilateral arm function compared with usual care (93 vs. 84 percent).[143]

Similarly, two studies in which case managers provided symptom management and psychosocial support for patients with lung cancer demonstrated improvements in symptoms and psychosocial or emotional functioning.[144, 145] However, in one of these studies, significant improvements were found in only three of 36 prespecified outcome measures,[144] raising the possibility that the improvements resulted by chance rather than as a result of CM. Another study found no differences in symptoms or functional outcomes with CM.[18] In one study, patients receiving CM had declining perceived health status over the course of the study, while control patients' perceived health status steadily improved,[145] even in the presence of greater symptom distress and worse functioning. This seemingly contradictory finding may have indicated, as suggested by the authors, that education and monitoring by case managers instilled more realistic evaluations of health status among homebound patients with lung cancer.[145] Due to the inconsistent findings and changes that were sometimes of small magnitude, the strength of evidence for the effect of CM on these outcomes was rated as low.

Patient Satisfaction

Of four studies that analyzed various aspects of patient experience with the care they received,[18, 142-144] three found CM to be superior to usual care. Two studies found that CM increased patients' (and caregivers') satisfaction with care.[142, 144] Another CM intervention improved breast cancer patients' sense of having a choice in their treatment.[143] The fourth study showed no difference in perceived unmet needs[18] among patients receiving CM compared with controls. A study examining the effect of CM on patients who had died found that CM increased the proportion of cancer patients dying at home rather than in an institution.[144] Whether or not home deaths reflected patients' and families' preferences was not reported in this study. Due to the consistency of findings across three of these studies, the effect of CM on patient satisfaction was rated as having moderate strength.

Quality of Care Outcomes

Three studies examined the effect of CM on the use of health care services considered to represent high-quality care.[142-144] All three found that CM improved the use of recommended services. An intervention specifically targeting the use of advanced directives succeeded in increasing the number of completed advanced directives.[142] Other studies demonstrated increased use of use of breast-conserving surgery (with lymph node dissection and radiation treatment) for women with early-stage breast cancer[143] and the early use of radiation as adjunctive therapy for lung cancer.[144] The strength of evidence for this outcome was rated as moderate because of the consistent findings across the studies.

Resource Utilization Outcomes

Five studies examined the impact of CM on resource utilization (including hospitalizations, ED visits, medical visits, and testing) and overall cost of care[18, 142, 144-146] and found no reduction in overall cost of care. One study found that CM reduced the number of radiographic studies patients underwent but did not affect referrals, hospitalization rates, or the overall cost of care.[144] Other studies similarly demonstrated no difference between CM and controls in utilization of services.[18, 142, 145, 146] In general, the estimated cost of the CM interventions was small. Thus, the cost of implementing CM had a minimal impact on the overall cost of care, which was driven mainly by the cost of hospitalizations. We rated the overall strength of evidence for these outcomes as low. Although there were consistently negative results across all the studies, the sample sizes were not large and the studies may not have been sufficiently powered for these outcomes.

Table 14. Characteristics and outcomes of studies of case management for patients with cancer (randomized trials)

Author Year Quality	Cancer Type(s)	Patient Population	Setting	Sample Size	Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
Engelhardt 2006[142] Fair	Multiple[a]	Any patient with cancer, or COPD or CHF with recent hospitalizations	3 VAMCs, 2 MCOs, home care organization (U.S.)	275	NR	↑ Satisfaction	↑ Advanced directive completion	=
Goodwin 2003[143] Jennings-Sanders 2003,[147] 2005[148] Fair	Breast	Women ≥ 65 with newly diagnosed cancer	13 community hospitals, 2 public hospitals (U.S.)	335	↑ Arm function after surgery	↑ Satisfaction	↑ Breast-conserving surgery with radiation therapy	NR
McCorkle 1989[145] Poor	Lung	Homebound patients	Home care program (U.S.)	166	↑ Improved symptoms, functional status ↓ Perceived health	NR	NR	=
Moore 2002[144] Fair	Lung	Patients completing initial cancer treatment	Cancer hospital, 3 outpatient cancer centers (U.K.)	203	↑ Improved symptoms, emotional functioning	↑ Satisfaction	↑ Radiation therapy	↑ Fewer x-rays
Mor 1995[18] Fair	Multiple	Patients starting chemotherapy	2 hospital-based clinics, 8 private oncology practices (U.S.)	257	=	=	NR	=
Ritz 2000[146] Poor	Breast	Women ≥ 21 with newly diagnosed cancer	Integrated health care system (U.S.)	141	↑ Less uncertainty about illness	NR	NR	=

CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; MCO = managed care organization; NR = not reported; U.K. = United Kingdom; U.S. = United States; VAMC=Veterans Affairs Medical Center

Note: ↑Better with case management; = No difference; ↓Worse with case management.

[a] Studies may have examined multiple outcomes within an outcome category.

Effectiveness of Case Management by Patient Characteristics

CM is a high-intensity intervention that is most often deployed for patients with complex care needs. While cancer and its treatment may in and of themselves create complex care needs, it is possible that the utility of CM is greatest among high-risk or vulnerable patient subgroups. In our review, only one study explicitly targeted a high-risk group (homebound patients with lung cancer). This study did not show a stronger effect of CM than other studies.[145] Three studies evaluated whether measures of vulnerability or level of care needs predicted the success of CM within their study samples. In one study, patients were stratified into three groups based on a statistical model of predicted unmet needs.[18] This study found no differences in any outcomes for any subgroups. Two other studies, however, both using CM for women undergoing treatment for breast cancer, found that CM was primarily effective in women with lower levels of social support, as indicated by being unmarried or living alone.[143, 146] CM was most effective in this population of women in terms of ensuring use of appropriate services[143] and improving QOL.[146] Overall, these subgroup analyses were limited and had inconsistent results. Thus, there was insufficient evidence to draw conclusions about subgroups of patients with cancer.

Effectiveness of Case Management by Intervention Characteristics

No studies included head-to-head comparisons of different models of CM. One study compared a specialized home care CM program for cancer patients with a standard home care program delivered by a multidisciplinary team.[145] In that study of homebound lung cancer patients, both home care programs produced similar outcomes in terms of symptoms, functional status, and hospitalization rates. However, the study was poor quality and did not clearly specify the differences in activities and functions performed by the different home care models.

The CM interventions described in the included studies varied widely in their implementation. We analyzed this variation in an attempt to discern the features of successful compared with unsuccessful CM interventions. Heterogeneity in the outcome measures used across studies precluded a quantitative analytic approach (e.g., meta-regression). Our findings therefore derived from a qualitative synthesis of the six included studies.

Two studies reported on interventions that demonstrated significant improvements in multiple outcomes, including health outcomes, patient experience, and quality and utilization of care.[143, 144] Another intervention was successful in achieving more focused improvements in targeted outcomes, including patient satisfaction and advanced directive completion.[142] There were several features that, while not unique to these successful interventions, in the aggregate appeared to distinguish them from others (Table 13). Specifically, the interventions reported by Goodwin et al. and Moore et al. represented more intensive forms of CM, in that they included more contacts and were sustained over a longer period of time than most others. They also explicitly included integration between the case managers and the patients' usual care providers. Finally, those interventions, as well as the one reported by Engelhardt et al., appeared to be more structured, as indicated by explicit descriptions of pre-intervention training for case managers and the use of care protocols to guide CM activities.

Aside from CM intensity, integration with primary care, and structure, we found no discernible pattern indicating that other aspects of CM—including modes of contact or principal CM functions—influenced effectiveness. It should be noted, however, that the specificity with which authors described the core functions performed by case managers was variable, which limited our ability to evaluate whether specific core functions influenced CM effectiveness. Likewise, no studies provided information on the average caseload of case managers at any given time, and only one explicitly reported the degree to which case managers received supervision from a physician. Most case managers were nurses, and most had flexibility for individualizing care plans, limiting our ability to comment on the value of these intervention components. Overall, because of the limited number of studies, the strength of evidence for the influence of intervention characteristics on patient outcomes (programs with higher intensity and better integration being associated with better quality/satisfaction outcomes) was rated as low.

Population: Patients With Serious Chronic Infections

HIV and mycobacterium tuberculosis (TB) are serious infectious agents that, when inadequately treated, can be fatal. Both require treatment with multiple drugs and for long durations of time. For HIV, treatment must be continued indefinitely. Both are infectious, and treatment can reduce the chance of transmitting the infection to others. Thus, effective treatment of these infections is a clinical and public health priority. Treatment requires engagement by the infected person and adherence to regimens that are complex and can be associated with unpleasant side effects. Problems such as low health literacy, unstable living situations, and substance abuse can be important barriers to carrying out treatment plans. For both of these infections, a variety of public health programs have been tried to improve medication adherence and thereby to enhance clinical outcomes.

Description of Studies

Studies of Case Management for People With HIV

We identified five randomized trials and six observational studies of CM programs for people infected with HIV (see Appendix I, Evidence Tables 12 and 13). Of the five randomized trials, two were rated fair quality[149, 150] and three were rated poor[151-153] (see Appendix G). Four of the trials were conducted in the United States and one in Canada.[151] The earliest included study was published in 1992 and the most recent in 2007. Sample sizes ranged from 57 to 250 participants (total N = 736).

Of the six observational studies, one was rated good quality,[154] two were rated fair,[155, 156] and three were rated poor.[157-159] All six observational studies were conducted in the United States, and the majority included a relatively small number of participants (sample sizes of 51, 78, 132, 280, 588, and 988). One study was published in 1991.[155] The other five studies were published between 2000 and 2009.

All 11 of these studies targeted low income populations except for one observational study restricted to women.[157] The majority of participants in each study were male (54 to 93 percent). In three of the studies the majority (70 percent or more) of participants were Caucasian.[151, 153, 155] In six studies, 49 to 90 percent of participants were African American or Latino. One study evaluated CM services specific to American Indians, Alaska Natives, and Native Hawaiians.[159] The average age of study participants was 35–45 years. One study targeted homeless and marginally housed individuals[154] and three studies specifically included current intravenous drug use or other substance abuse as study eligibility criteria.[149, 152, 157]

Studies of Case Management for People With Tuberculosis

We identified two randomized trials (see Appendix I, Evidence Table 12), both of which were rated fair quality (see Appendix G). One was conducted in the United States and published in 2006[160, 161] and one was conducted in Taiwan and published in 2007.[162] Sample sizes, respectively, were 520 and 114 (three study arms). We also identified two observational studies (see Appendix I, Evidence Table 13). One was rated good quality[163] and one was rated poor.[164] Both studies utilized a retrospective cohort design and were of similar sample size (n=343 and n=369). One was conducted in the United States and published in 2002[163] and one was conducted in Taiwan and published in 2006.[164] One of the trials restricted enrollment to individuals with latent tuberculosis infection.[160] The other three studies examined programs serving patients with active TB infection. The majority of participants in both U.S. studies were nonwhite and male; in one of the U.S. studies, more than 30 percent were substance abusers and more than 40 percent had concurrent infection with HIV; eligibility for the other U.S. study included spending the previous night in a homeless shelter. Participants in the Taiwan studies were mostly male with a mean age range of 53 to 68; socioeconomic status was not reported.

Approach to Case Management for Chronic Infections

CM *interventions* in all of the studies focused on linking individuals to needed services, including medical, mental health, social, and drug treatment services (see Table 15). The programs generally included counseling and education components. The TB programs tended to have a greater emphasis on the coordination and monitoring of medications. In one of the HIV programs,[153] the participants were housebound patients with AIDS, and the case managers had caseloads of only 12 or less. Mode of case manager/client contact (reported in three studies) was either strictly face-to-face or in combination with telephone contact. The disciplines of the case managers were usually nurses or counselors. The length of the interventions was 6 months in all of the TB studies and 6 to 12 months in the HIV studies.

While one of the trials was a head-to-head comparison of less intensive to more intensive CM for TB treatment,[162] the rest of the studies used a usual care comparison group. The control groups generally had access to all the same services as the intervention groups (community-based services, or usual clinic or in-home care), but acquired them through self-direction or without the assistance or involvement of a designated case manager.

Table 15. Characteristics of case management interventions for patients with HIV/AIDS or tuberculosis (randomized trials)

Author Year Quality	Duration (Months)	Mode(s) of Contact	Main CM Functions	Contacts (Average)	Caseload	Role of Usual Care Provider	Supervision by Physician	Profession	Pre-intervention Training	Use of Protocols or Scripts
Hsieh 2008[162] Fair	6	Clinic and home visits	• Education • Coordination • Monitoring	Group 1: DOT daily for 2 months; weekly home visits for 6 months; Group 2:monthly home visit for 6 months	NR	Integrated	Yes	NR	NR	No
Husbands 2007[151] Poor	6	NR	• Assessment • Self-management support • Coordination	NR	NR	Not integrated	No	NR	Yes	No
McCoy 1992[152] Poor	12	Unclear	• Assessment • Education • Coordination	NR	30 - 35	Not integrated	No	BS health educators, no social work training	Yes	No
Nickel 1996[153] Poor	30	In-home care	• Assessment • Planning • Coordination • Monitoring	Weekly phone, monthly visit while receiving in-home care	NR	Integrated	Yes	Nurses specialized in HIV care	NR	No
Nyamathi 2006[160] Fair	6	In-person	• Education • Self-management support • Coordination	1-hour weekly	NR	Integrated	Yes	Nurse	Yes	No
Sorensen 2003[149] Fair	12	Phone, in-person contact	• Education • Self-management support • Coordination	44 contacts per year	20	Not integrated	Yes	Para-professionals certified as chemical dependency counselors	Yes	No
Wohl 2006[150] Sansom 2008[165] Fair	6	In clinic	• Assessment • Self-management support • Coordination	14 weekly contacts	NR	Integrated	NR	"Trained case manager"	NR	No

BS = bachelor of science; CM = case management; DOT = directly observed therapy; NP = nurse practitioner; NR = not reported; RN = registered nurse; SW = social worker

The patient-centered *outcomes* included in these studies (see Table 16) often were measures of response to antibiotic treatment. All of the TB studies used measures of successful suppression of the infection. Two of the HIV studies[150, 154] included viral load or CD4 count as outcome measures. Other patient-centered outcomes included measures of mental health, QOL, and risk behaviors. Quality of care outcomes included and medication adherence rates and receipt of community services. Resource utilization measures included outpatient and ED utilization, hospitalization rates, and overall program costs.

The *settings* for these CM programs included HIV/AIDS service organizations,[151, 152, 159] public health clinics,[150, 163] public hospitals,[149, 156, 162, 164] and homeless shelters.[160] All of these studies were conducted in large metropolitan areas.

Key Points Related to Patients With Serious Chronic Infections

- CM does not improve survival among patients with HIV infection (strength of evidence: low). (See Appendix H. Strength of Evidence.)
- Short-term CM management programs that emphasize medication adherence improve rates of successful treatment for TB in vulnerable populations (strength of evidence: moderate).
- Evidence is insufficient to determine whether CM improves antiviral treatment of HIV infection.

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

Two clinical trials of HIV patients included survival as a primary outcome. A fair quality trial[149] reported 16 percent mortality at 18 months and a poor quality clinical trial of patients with AIDS reported 50 percent mortality at 6 months.[153] Neither study found a significant difference in mortality between the CM and control groups.

Some clinical trials in HIV populations also measured psychological distress[149, 151] and quality of well-being.[153] Changes in these measures showed little difference between the CM and control groups. One fair quality observational study[156] found that CM counseling on mental health issues had a positive relationship with client QOL, and one poor quality observational study found improvement in self-reported QOL after CM program enrollment.[159] Due to the overall small changes found in these studies, this evidence was judged as insufficient to conclude whether CM affects measures of QOL in these populations.

Quality of Care Outcomes

The studies of populations with TB had CM programs in which the case manager emphasized adherence to drug treatment regimens, and these programs generally found higher rates of successful treatment with CM. The study with the best methodological quality was a good quality interrupted-time-series evaluation.[163] Using a measure of achieving adequate treatment, a successful outcome was achieved for 69 percent of patients during the time period in which conventional directly observed therapy (DOT) was used. This rate increased from 81 percent to 86 percent in successive time periods in which CM was added to DOT. These rates stayed consistent over four successive 6-month time periods, suggesting that this finding was not due to a time trend unrelated to the use of CM. Higher rates of treatment completion with CM were also observed in two fair quality clinical trials of patients with TB.[160, 162] A poor quality observational study compared a population of TB patients receiving CM with a population in a different health system. Treatment success was 87 percent in the CM group and 73 percent in the comparison group.[164]Due to the consistently positive findings in these studies, we concluded that the overall strength of evidence is moderate that CM programs emphasizing medication adherence improve rates of successful treatment of TB.

In a fair quality clinical trial, HIV patients were randomized to CM, directly observed antiretroviral administration, or usual care.[150] Viral load dropped in all three groups, without significant differences among the programs. The CM used in this trial was of moderately high intensity (weekly contacts by case manager) and was not found to bring significant improvement in self-reported medication adherence.[150] In a good quality cohort study, the quantity of CM was used as a predictor variable in a multivariate analysis.[154] The quantity of CM had a moderate association with rise in the CD4 count but was not associated with drops in viral load. Due to the small number of studies, the evidence is insufficient to conclude whether CM has an effect on the quality of treatment for HIV.

Other quality measures have included (for HIV patients) behaviors associated with viral transmission. CM has not been demonstrated to improve viral transmission behaviors.[149, 152]

Resource Utilization Outcomes

Because the studies in this clinical category often include vulnerable and underserved populations, the CM programs focus on facilitating and increasing provider visits. However, CM generally had little effect on the rate of clinic visits. While CM was associated with increased clinic visits in a poor quality observational study of HIV patients,[157] the visit rates were not significantly changed in a fair quality clinical trial[150, 165] and a good quality observational study.[154] In a fair quality clinical trial of an HIV population, hospitalization rates were lower in the CM group than in the usual care group, but ED visits were not significantly different.[165] However, in a good quality observational study, receiving CM was not associated with either ED or inpatient utilization.[154] The study finding a reduction of hospitalizations also found lower overall health care costs in the CM group.[165] A poor quality clinical trial[151] also found lower (but not significant) overall costs in the CM group. Due to the small number of studies and inconsistent findings, the evidence about the effect of CM on measures of utilization was judged to be insufficient in these populations.

Table 16. Characteristics and outcomes of studies of case management for patients with HIV/AIDS or tuberculosis (randomized trials)

Author Year Quality	Patient Population	Disease	Setting	Sample Size	Health Outcomes	Patient Experience	Quality of Care	Resource Utilization, Cost
Hsieh 2008[162] Fair	Individuals with TB infection (Taiwan)	TB	Hospital-to-community	96	↑ Sputum conversion, chest x-ray improvement, treatment success	NR	↑ Adherence to medication and. treatment completion	NR
Husbands 2007[151] Poor	HIV+, receiving services from AIDS service organization	HIV/AIDS	AIDS service organization	79	NR	= QOL, physical and mental health, social functioning, risk-behavior *Subgroup analyses: very depressed* ↑ Physical and mental health, social functioning, lower risk behaviors	NR	= Direct cost health and social services
McCoy 1992[152] Poor	Low income, HIV+, IV drug users	HIV+	County public health AIDS program	140	NR	NR	NR	NR
Nickel 1996[153] Poor	AIDS patients referred to home care	AIDS	Home health care	57	NR	= QOL	NR	NR
Nyamathi 2006[160] Fair	Homeless, with latent TB infection	Latent TB	Health care clinic serving low-income	494	NR	NR	↑ Adherence to treatment, TB knowledge	NR
Sorensen 2003[149] Fair	HIV+, substance abusers	HIV/AIDS	Hospital	160	NR	= Substance use, physical and psychological status, quality of living situation ↑ Lower risk behaviors	= Treatment services received	
Wohl 2006[150] Sansom 2008[165] Fair	HIV+, receiving care through public health HIV clinics	HIV/AIDS	Public health clinic	194	= Viral load, CD4+ cell, opportunistic Infection	NR	= Medication adherence	↑ Hospital days = ED visits ↑ Net program cost

CM = case management; IV = intravenous; ED = emergency department; NR = not reported; OP = outpatient; QOL = quality of life; TB = tuberculosis
Note: ↑Better with case management; = No difference; ↓Worse with case management.

Effectiveness of Case Management by Patient Characteristics

Because all of the studies in this clinical category had relatively small sample sizes, there were few subgroup analyses. The influence of CM on patient outcomes applies only to the limited populations that were studied. As previously stated, this group of studies included mostly underserved and impoverished populations.

Effectiveness of Case Management by Intervention Characteristics

One fair quality clinical trial for TB patients had a head-to-head comparison of two levels of intensity of CM (weekly home visits vs. monthly home visits).[162] The sample size was small (32 participants per study arm). The measure of treatment success was significantly higher in the group that received weekly visits. A good quality observational study of HIV patients[154] measured intensity of CM by frequency of contact with case managers. However, the highest-frequency category could still be less often than monthly. The intensity of CM was evaluated for a large number of possible outcomes. The only outcome that showed a positive association with CM intensity was improvement in CD4 count. Due to the small number of studies and inconsistent results, the evidence was judged to be insufficient for drawing conclusions about variation by intervention characteristics.

Population: Patients With Other Medical Problems

CM can be adapted to a wide variety of community settings and clinical problems. While the clinical categories described earlier in this report captured most of the studies of CM, there were 15 additional studies that do not fall into those categories, nine trials[28, 166-177] and six observational studies.[178-183] These additional studies related to three care coordination themes. The first is coordinating services for low income individuals who often have serious problems with access to clinical services. The second theme is patient education and coordination of services following hospital discharge for acutely disabling medical conditions (stroke and renal failure requiring dialysis).The third theme is case management that focuses on self-care for patients with obstructive lung disease. In general, these studies had findings that were consistent with the results described earlier in this report.

Description of Studies

Of the nine randomized trials of CM programs for clinical populations different from those already described in this report (see Appendix I, Evidence Table 14), six were good quality,[28, 166, 167, 168, 169, 170, 172, 173, 177] one was fair quality,[174] and two were rated poor[175, 176] (see Appendix G). Six were conducted in the United States,[28, 166-170, 175, 176] two were conducted in Canada,[172, 177]and the remaining trial was conducted in Hong Kong.[174] These trials were published between 2002 and 2012. Of the observational studies (See Appendix I, Evidence Table 15) two were rated as having fair quality methods,[180, 182] and the other four were rated as poor quality.[178, 179, 181, 183] Six of the studies (two trials[166, 169] and four observational studies[178-181]) examined low income populations, although the nature of the CM programs was quite variable across these studies. Four clinical trials examined patients undergoing home peritoneal dialysis[174] or patients undergoing rehabilitation after a stroke.[175-177] Three clinical trials[28, 170, 172] and one observational study[183]examined patients with chronic obstructive pulmonary disease (COPD), while one observational study examined adults with bronchial asthma.[182]

A good quality clinical trial evaluated a CM program for patients followed in primary care clinics operated by a county health department in California.[166, 167] Patients were eligible for the study if they had DM, coronary artery disease, peripheral vascular disease, cerebrovascular disease, hypertension, or elevated cholesterol and/or triglyceride levels. Of the 419 participants, mean age was 56 years, 65 percent were female, 63 percent were Hispanic, and 38 percent were employed. Sixty-three percent had type 2 diabetes. In the intervention group, CM was performed by a team consisting of a registered nurse and a dietician. The case managers used protocols that focused on lifestyle modifications and the intervention lasted 15 months. The control group received the usual model of primary care provided in the four participating clinics. The primary outcome was a measure of risk factors for atherosclerosis (the Framingham risk score).

The second clinical trial that focused on a low income population examined homeless patients who were recruited at the time of an acute hospitalization in the United States.[169] The participants had a wide variety of chronic medical conditions. The intervention included CM for up to 18 months, and the intervention group patients also were provided placement in stable housing. The control group received no specific services following hospital discharge, but there were other CM services available in the community. The outcomes were counts of hospitalizations and ED visits. This study design makes it difficult to discern the unique effects of CM, in that there was an important cointervention (placement in permanent housing) that was not available to the control group.

The fair quality observational study examined a group of patients followed in a California safety net clinic who had high rates of emergency department use or hospital stays over a one-year period.[180] A group who were assigned to case management services was compared with a group who did not receive such services, but assignment to groups was not randomized or otherwise controlled. The non-CM group had a significantly lower comorbidity score than the CM group. The three poor quality observational studies were all conducted in the United States and evaluated CM programs for low-income people.[178, 179, 181] The first evaluated 492 uninsured adults, 70 percent of whom were female (mean age 35 years).[179] CM was provided by a team consisting of a registered nurse and social worker. There was no comparison group and the primary outcome was ED visit rates (measured 6 months prior to starting CM and 6 months after completing CM). Mean duration of CM was 179 days. The second observational study evaluated 159 patients who received services from a CM program designed for low-income patients with epilepsy.[178] Mean age was 41 years, and 58 percent were male. Two-thirds were uninsured, 59 percent were unemployed, and none had yearly incomes greater than $5,000. Self-reported estimates of seizure control and ED visits were assessed by a questionnaire administered after completing the CM program. A third study using a pre-post design enrolled 53 patients who had used the ED five times or more in 12 months.[181] Study subjects were assigned to a social worker case manager who was responsible for providing and coordinating all needed services. Hospital service utilization and cost and psychosocial outcomes, including homelessness and access to care, were measured at 12 months.

A fair quality clinical trial conducted in Hong Kong evaluated a 6-week CM program for patients who perform home peritoneal dialysis.[174] The 85 study participants were recruited during an acute hospitalization. The outcome data were derived from patient questionnaires administered at 6 and 12 weeks after hospital discharge.

One good quality and two poor-quality clinical trials evaluated CM programs for patients who had recently undergone acute rehabilitation following a stroke. The good-quality trial was performed in Canada among 190 people hospitalized for an acute stroke. They were randomized at hospital discharge to a short-term (6-week) CM program or to a comparison group that received only instructions on how to make an appointment with a primary care provider.[177] The case managers were nurses with geriatrics experience. The primary outcomes were physical functioning and healthcare utilization. Another randomized trial evaluated utilization outcomes of 28 stroke patients who were being discharged from an inpatient rehabilitation service in New York.[175] The case managers were social workers, and the program focused on ameliorating barriers to ongoing rehabilitation. Control group patients received usual care without the services of the social workers. The outcomes were measures of utilization over 3 months. The third trial also enrolled patients (N=96) who were being discharged from an inpatient stroke unit.[176] The case managers were advanced practice nurses. The CM focused on coordination between neurology consultants and the primary care physicians. Patients in the control group did not receive these coordination services. The outcome measures included functional status, QOL, and measures of stroke-related quality of medical care (all measured at 3 months after hospital discharge).

Three good quality clinical trials examined programs for patients with COPD. All three programs emphasized training patients in self management, including self-administration of medications (steroids and/or antibiotics) for acute exacerbations.[28, 170, 172] One of the trials was conducted in Canada.[172] The other two trials were conducted at Veteran Affairs (VA) medical centers in the United States.[28, 170] Study participants in each trial had severe COPD, with mean values of the forced expiratory volume in one second (FEV1) ranging from 1.0 to 1.2 liters across the trials. Outcomes measured in all the trials included mortality, number of hospital admissions or time to first hospital admission, number of acute exacerbations, and other health status and quality of life measures.

All three of these trials emphasized self-management of symptoms. In the Canadian trial,[172] eight hour-long educational sessions were conducted weekly in the intervention participant’s home for the first two months. The case manager (either a nurse or respiratory therapist) made follow-up phone calls weekly during the 8-week educational period and then monthly for the remainder of the 1 year study. In one of the VA studies,[170] intervention group patients received a single 1- to 1.5-hour educational session and monthly calls from a case manager. In the other VA study,[28] the educational program consisted of 4 weekly 90-minute sessions and followup phone calls from the case manager once per month for 3 months and then every 3 months thereafter.

A poor quality observational study conducted in New Zealand evaluated 16 patients with severe COPD (mean FEV1 0.64 liters) who were enrolled in a program in which a registered nurse provided weekly telephone calls and monthly in-home visits.[183] Hospitalization rates were compared with a control group of 16 patients followed at a different hospital.

A fair quality observational study evaluated a case management program for adults with a clinical diagnosis of bronchial asthma.[182] Nurses conducted case management by telephone. Rates of unscheduled outpatient visits and hospitalizations over 24 months were compared with a baseline period.

Key Points Related to Other Populations

- Evidence is insufficient to assess the effect of CM programs on mortality among patients with severe COPD. (See Appendix H. Strength of Evidence.)
- CM programs that serve populations that have COPD or are homeless reduce ED visits (strength of evidence: low).

Detailed Analysis: Effectiveness of Case Management by Outcome

Patient-Centered Outcomes

In general the studies included in this category had short durations of followup. They also included diverse populations and used a variety of outcome measures. Of the good quality clinical trials, three (all in populations of patients with COPD) examined mortality rates. In two studies, cumulative mortality was measured at one year after enrollment.[170, 172] In both the mortality rate was less than 12 percent and was slightly lower in the CM groups. The third trial was stopped early because of a finding of a higher mortality rate in the CM arm of the trial.[28] With a mean follow-up of 250 days, mortality was 13 percent in the CM group and 5 percent in the control group. When cause of death was assessed, mortality attributable to COPD was also higher in the CM group. Due to the heterogeneity in mortality rates across these three trials, the overall evidence is insufficient to conclude whether CM affects mortality in the population of patients with severe COPD. These trials also included measures of symptom status and QOL, but there generally were only small changes in these measures.

One trial conducted in a low-income population measured a variety of cardiac risk factors.[166, 167] In this trial the mean Framingham risk score was one point lower in the intervention group at 15 months. The major contributor to the difference between groups was better achievement of blood pressure goals in the intervention group. Because there no other similar studies, there is insufficient evidence from this single study to conclude whether CM is effective for this clinical goal.

Two of the three clinical trials of patients with recent strokes measured patient-centered outcomes. [176, 177] The good quality trial measured physical functioning and found no difference between the CM and control groups at 6 months of follow-up.[177] The second study, which had poor methodological quality, had a small sample size and used multiple outcome measures, suggesting that some changes may have been due to chance. The study found small improvements in QOL in the CM group but no differences in functional status or blood pressure control.[176]

Studies in two other clinical settings also found improvements in patient-centered outcomes with CM. In the trial of CM for patients undergoing home peritoneal dialysis, patients in the CM group had small improvements in several measures of functioning and satisfaction compared with patients in the control group.[174] The observational study of patients with seizures found a reduction in self-reported seizure rates.[178] However, there was no comparison group in this study and it is possible that part of this change was due to regression to the mean. Due to the small number of studies, the evidence was judged insufficient to draw conclusions about the influence of CM on physical functioning or seizure rates.

Resource Utilization Outcomes

Many of the studies in this category reported on utilization of health care services, with ED visits being the most commonly measured type of utilization. Three of the good quality trials had ED visits as a primary outcome.[169, 170, 172] Compared with the usual care group, homeless CM patients had, on average, about one fewer ED visit per year, but this group also received housing assistance in addition to CM. In a trial of patients with COPD, the group receiving CM had half as many ED visits over one year (0.21 visits/year in CM group vs. 0.42 visits/year in the comparison group).[170] In another COPD trial ED visit rates were higher, but visits attributable to exacerbations of pulmonary symptoms were significantly lower in the CM group.[172] A good quality trial of CM following stroke found no difference between CM and control groups in ED visit rates during the 6 weeks that patients received CM. However, in the following 6 months, 16percent of patients who had received CM and 23percent of control-group patients made ED visits.[177] Two fair quality observational studies compared ED utilization rates for patients who received CM.[180, 182] CM was associated with reductions in rates of ED use when compared with a group of patients matched by race and age[180] and when compared with usage by the same patients in a historical time period.[182] Four other studies that were rated as poor quality[175, 178, 179, 181] also found lower ED visit rates in patient groups who received CM. Due to the consistency of findings across studies, it was concluded that there is a low strength of evidence that CM leads to fewer ED visits in these populations.

Five good quality trials of CM examined hospitalization rates as a utilization outcome. Three were studies of patients with COPD,[28, 170, 172] one was a study of stroke patients, and one was a study of CM for homeless people.[169] All three of the COPD trials found lower hospitalization rates in the groups receiving CM, with this result being statistically significant in two.[170, 172] In the trial of CM conducted among homeless people, the hospitalization rates did not differ significantly between the CM and control groups, but patients in the CM group had about three fewer hospital days per year. However, this difference in length of hospital stays may be due to the housing assistance provided as a cointervention to the CM group.[169] The trial of stroke patients did not find a significant effect of CM on hospitalization rates.[177] A poor quality observational study of patients with COPD also found that a group receiving CM had shorter lengths of stay but no difference from a comparison group in the hospitalization rates.[183] Due to the inconsistency of findings for hospitalization rates, the evidence was rated as insufficient for this outcome.

Effectiveness of Case Management by Patient Characteristics

Although four of the studies in this category[166, 169, 178, 179] addressed CM for low income individuals, the populations were quite diverse, ranging from homeless people to patients who were followed regularly in safety net clinics. The outcome measures in these studies were diverse, and the only outcome that was measured in multiple studies was ED visits. This measure improved in all the studies, so the utilization outcome did not appear to be influenced by any particular patient characteristics. The other outcomes in these studies are different enough that it is not possible to draw conclusions based on patient subgroups. The studies of CM for COPD did not perform comparisons by sub-groups with differing severity of lung disease, although most participants in these trials had severe disease.[28, 170, 172]

Effectiveness of Case Management by Intervention Characteristics

The studies in this category tended to examine CM programs that were tailored to the patient populations (i.e., cardiac risk factor reduction, management of home dialysis, management of respiratory symptoms, or coordination of care for the uninsured) and the outcomes were specific to each type of program. The main difference that can be examined is length of CM. In the studies of CM for COPD or for low income people,[28, 166, 169, 170, 172, 178, 179] the CM was continued for 6 to 18 months. In the four other studies (of home dialysis[174] and stroke[175, 176, 177]) the CM lasted 3 months or less. Nevertheless, there were no clear trends in outcomes based on CM duration within these ranges.

Summary and Discussion

Case management (CM) is a strategy for improving the delivery of clinical services to patients with complex needs. It has been studied in a wide variety of patient populations, and the programs have usually been tailored to the needs of those specific populations. In surveying the many different programs described in the studies included in this review, the types of patients who potentially could benefit from CM generally fell into four categories:

- Patients with life-threatening chronic diseases that can be improved with proper treatment such as cancer, congestive heart failure (CHF), or tuberculosis infection.
- Patients with progressive, debilitating, and often irreversible diseases for which supportive care can enhance independence and quality of life (QOL), such as the frail elderly or patients with dementia.
- Patients who have slowly progressive chronic diseases for which self-management can improve health and functioning, such as diabetes mellitus.
- Patients for whom serious social problems impair their ability to manage disease, such as the homeless.

For all of these clinical categories, health care resources generally are available but may be inaccessible or poorly coordinated. Case managers can help to surmount these problems, but the role of the case manager is complex. Depending on the organization and strategy of CM programs, the case manager can play distinctly different roles:

- A care provider who helps patients improve their self-management skills and/or helps caregivers to be more effective in helping and supporting patients.
- A collaborative member of the care delivery team who promotes better communication with providers and advocates for implementation of care plans.
- A patient advocate who evaluates patient needs and works to surmount barriers that inhibit access to clinical services.

There are multiple strategies for fulfilling these roles, and CM programs are often complex and difficult to replicate. Organizationally, programs can be freestanding or imbedded in clinical settings (usually primary care or specialty practices). Case managers can interact with patients in their homes, in clinics, or by telephone. Case managers can have caseloads of hundreds or only a few dozen. Case managers can follow prespecified protocols or can develop personalized care plans based on patient assessments. Case managers can work independently or can function as a member of a CM team. The studies of CM use a variety of approaches to describe their programs, and full specification of the program's content often is not possible. Acknowledging this heterogeneity of study populations, interventions, and outcomes, we sought to discern the conditions under which CM was effective or ineffective.

Limitations of the Evidence Base

Many important questions about case management have not been answered by the body of evidence that is available. For example, there is a surprising lack of evidence about the effectiveness of case management for facilitating the delivery of multidrug treatment regimens to patients with HIV infection. We found few studies of this population that used outcome measures that met the criteria defined for this review. Thus, we concluded that the evidence for this outcome is insufficient. Another important unanswered question pertains to the comparison of different delivery models for CM and role definitions for case managers. The multiplicity of roles and variability of day-to-day activities means that evaluations of CM can never fully specify the content of the intervention. Furthermore, few organizations have the potential scope (in terms of patient base and clinical resources) to conduct evaluations that directly compare different CM approaches. Thus, nearly all evaluations have compared a customized CM program with a "usual care" model in which patients receive no CM services. Synthesizing the evidence about CM requires indirect comparisons among different types of clinical programs. Because the published studies have not compared case managers with differing qualifications, there is no evidence about the efficacy of specialized training programs or case manager certification.

Despite these extensive methodological challenges, the evidence base about CM is still very useful. This review included 70 randomized trials that have been conducted in a variety of patient populations, and a smaller number of good quality observational studies also have been reported. The total number of participants in these studies approaches 100,000. The majority of these studies have given good descriptions of the patient populations, making it possible to organize the evidence by population groupings (as was done in this report). In some cases, there has been enough similarity in patient populations that indirect comparisons of different types of programs can be made with moderate confidence.

Most of the individual clinical trials of CM have had modest sample sizes (less than 500 participants per intervention arm). This size limitation has been a barrier to the analysis of patient subgroups, and many of the trials have not reported results by subgroup. Consequently, analyses of subgroup results are mostly based on indirect comparisons. In fact, the available evidence permits all conclusions about subgroup comparisons to have only a low strength of evidence. Furthermore, for some of the outcomes of interest (particularly resource utilization outcomes in several population groups), the conclusions generally had only a low strength of evidence.

The broad scope of the review and the high heterogeneity of included studies, particularly heterogeneity in the nature of the interventions and the outcomes evaluated, constrained our ability to assess applicability in great detail. The bodies of evidence for each of the Key Questions had good general applicability for the patient populations as generally defined by each disease/condition. However, because of heterogeneity in the inclusion criteria among studies of CM for particular diseases/conditions and limited descriptions of subgroups, we were not able to assess applicability for the many possible specific patient subgroups of potential interest within the disease/condition-based population groups. The unique characteristics and circumstances of so many of the diverse CM interventions and the variety of particular outcomes that they evaluated made even a general assessment of applicability related to these domains of populations, interventions, comparators, outcomes, timing, and setting (PICOTS) impractical.

Another important limitation of our review is that we examined only studies that met our definition of CM, and in most cases the CM program was not compared with other types of care management interventions. Some of the outcomes achieved by CM may have been achievable using less intensive, more focused interventions. CM typically involves nurses or other health professionals performing multiple functions to meet patients' needs. Our review did not address whether the outcomes achieved by successful CM interventions could have been achieved with more narrowly tailored interventions, targeting the specific deficits in care most likely to cause poor outcomes. However, the published research does not provide a model for how such targeted interventions would be designed. One approach that has been widely deployed is disease management programs, which generally use telephone-based interactions with patients to address specific treatments and self-care measures for individual chronic diseases. While assessment of disease management programs is beyond the scope of this review, recent evaluations suggest that these narrow disease-focused interventions are often ineffective.[13] Overall, we were able to draw conclusions only with a low strength of evidence for the relationships between characteristics of the CM intervention and any clinical outcomes (Key Question 3).

Case managers vary in their experience and training, and there is a very limited evidence base about the expertise of case managers in any of the CM programs that have been studied.

While most studies included registered nurses as the case managers, there are no good quality studies that have compared the outcomes achieved by registered nurses with case managers from other disciplines. Many of the programs that have been studied provided CM via a team (such as a nurse and a social worker), and the distinctive roles of the team members were not well described. Because of the lack of studies providing comparisons of differing skill sets, it is not possible to answer important questions about the necessary qualifications and training of case managers.

Conclusions

The main findings of this review are summarized in Table 17, below, and Appendix H provides details about how the estimates of the strength of the evidence were derived. Due to heterogeneity in the characteristics of case management (CM) interventions and the limitation of small sample sizes in many studies, the strength of evidence for the conclusions often is only low or moderate. This applies to statements about both positive effects and the lack of effect on outcomes. However, in some cases there were consistent findings in large clinical trials of uniform populations. In such cases, the evidence statements were assigned high strength of evidence ratings. Table 17 does not summarize outcomes for which there is insufficient evidence to draw a conclusion. For some patient populations there were few studies that examined certain outcomes. In other cases (such as results about hospitalization rates in people with diabetes), the findings were highly heterogeneous across the studies, leading to a conclusion that the evidence was insufficient.

The cumulative evidence about CM is sufficient to draw several conclusions that apply to specific patient populations. Because CM programs generally are customized to the patient groups served, it usually is not possible to apply the results to other patient populations. In this review, we found that, on balance, CM had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. The most positive findings are that CM improves the quality of care, particularly for patients with serious illnesses that require complex treatments (cancer and tuberculosis). For a variety of medical conditions, CM improves medication adherence and self-management skills. CM also improves quality of life (QOL) in some populations (congestive heart failure [CHF] and cancer) and tends to improve satisfaction with care. For the caregivers of patients with dementia, targeted CM programs improve levels of stress, burden, and depression.

The available evidence has not demonstrated that CM programs decrease resource utilization and lead to resultant cost savings. For general populations of patients who receive CM for chronic diseases, there is a high strength of evidence that the programs do not reduce Medicare expenditures. However, the impact of CM may have beengreatest when the CM was targeted towards patients with the highest previous levels of health care utilization. The implication of this finding is that those with the greatest need for assistance with clinical management and care coordination, patients with low levels of social support, and/or patients at highest risk for poor outcomes might be more likely to benefit from CM. CM may be best suited for only the highest risk patients, who are most likely to benefit from high intensity engagement that addresses a wide variety of needs. It may have more limited impact for patients with more focused (less complex) care needs. While the effectiveness of CM may depend on selection of the appropriate target population, the published studies suggest that this type of careful case selection is difficult to implement.

The results of trials across different clinical conditions suggested that CM effectiveness was greater when the intervention was more prolonged, included more patient contact, and included face-to-face (rather than telephone only) interactions. This finding validates the premise that the relationship between case manager and patient is likely to be a key ingredient for successful CM interventions. CM also appears to be most effective when the case manager works closely with patients' usual care providers (usually primary care physicians) and/or collaborates with a physician (or multidisciplinary team of health care providers) with expertise in managing the targeted medical condition. This finding suggests that CM may be most effective when case managers are embedded within a collaborative, team-based intervention model. Finally, there also is some evidence that CM is successful in achieving outcomes when the intervention includes specific training modules and protocols that are tailored towards those outcomes. This suggests that the breadth and flexibility of CM may need to be complemented by focused efforts—including specific training, guidelines, and protocols—to achieve explicitly targeted outcomes.

Consistency With Previous Systematic Reviews

We identified no prior systematic reviews that evaluated studies of CM across multiple disease categories, and most prior systematic reviews used definitions of CM that differed from that used in this review. One recent systematic review of CM among patients with cancer used a CM definition and study inclusion criteria similar to ours.[184] That review focused on whether CM optimizes cancer care pathways. Of the seven studies included in that systematic review, six were included in our review. We excluded one study that was included in that review because it was a short-term intervention (4 weeks) intended to manage patients in the postoperative period after cancer surgery.[185] The authors of the prior systematic review concluded that the heterogeneity of CM studies made it impossible to comment on the effectiveness of CM in cancer care.[184] They also concluded that the poor specification around CM implementation (i.e., the "black box" nature of CM studies) precluded an analysis of effective elements of CM.

Other prior systematic reviews evaluated interventions that include some components of the CM models examined in this report. These prior reviews evaluated community-based interventions for CHF and diabetes. A recent Cochrane Collaboration review examined interventions including structured telephone support and telemonitoring for patients with CHF.[186] While that review included some of the studies in our review that involved a telephone care component, the majority of the studies did not involve CM. Five other reviews examined "care management"[187] and "disease management"[188-191] interventions for patients with CHF. While these reviews included many of the studies included in our review, they also included other studies of primarily nurse-led interventions that did not meet our criteria for being considered CM. There was significant heterogeneity in the nature and duration of the interventions examined in these reviews. Nevertheless, meta-analysis demonstrated a significant reduction in hospitalization rates with disease management in three of the reviews[188-190] and a reduction in all-cause mortality in two reviews.[188, 190] All of these reviews included largely the same group of individual studies. Gohler et al. also conducted a meta-regression of 36 disease management studies and found that rehospitalization rates were significantly lower in interventions that involved multidisciplinary teams and in those that included face-to-face contact with patients, as opposed to telephone contact alone.[188] Windham et al. conducted a qualitative analysis of differences in outcomes among studies of care management for CHF.[187] They found that 15 of 32 studies demonstrated improved outcomes with care management and 15 showed nonsignificant trends towards improvement. Common elements observed in successful interventions included more frequent clinical monitoring, collaboration between a physician and nurse in delivering the intervention, and patient education in self-management skills.[187] Yu et al. similarly reviewed 21 clinical trials of CHF disease management interventions and compared and contrasted "effective" and "ineffective" interventions. They found that effective interventions were characterized by: an in-hospital phase of care, intensive patient education, self-care support, optimization of medical regimens, and ongoing surveillance and management of clinical deterioration.[191]

In considering the potential impact of CM on care for patients with diabetes, there have been six systematic reviews of related interventions.[192-197] All used substantially different definitions of CM than was used in this report.

Table 17. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a: In adults with chronic medical illness and complex care needs, is case management effective in improving *patient-centered outcomes*, including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?	**Older adults with one or more chronic diseases**	***Mortality.*** CM programs that serve patients with one or more chronic diseases **do not** reduce overall mortality (9 studies).	High
Key Question 1a	**Older adults with one or more chronic diseases**	***Functional status.*** CM programs that serve patients with one or more chronic diseases **do not** result in clinically important improvements in functional status (3 studies).	High
Key Question 1a	**Frail elderly**	***Mortality.*** CM **does not** affect mortality in frail elders (5 studies).	Low
Key Question 1a	**Frail elderly**	***Nursing home admissions.*** CM programs that serve frail elderly patients **do not** decrease nursing home admissions (2 studies).	Low
Key Question 1a	**Dementia**	***Mortality.*** Patients with dementia who receive services from CM programs **do not** have lower mortality rates (12 studies).	High
Key Question 1a	**Dementia**	***Problematic behavioral symptoms.*** CM programs that serve patients with dementia **do not** reduce problematic behavioral symptoms.	Moderate
Key Question 1a	**Dementia**	***Caregiver depression and strain (burden).*** CM programs that serve patients with dementia **do** reduce depression and strain among caregivers (13 studies).	Moderate
Key Question 1a	**Dementia**	***Time to nursing home placement.*** CM programs that serve patients with dementia and have duration of no longer than 2 years **do not** confer clinically important delays in time to nursing home placement (9 studies).	Moderate
Key Question 1a	**Congestive heart failure**	***Mortality.*** CM programs that serve adults with CHF **do not** reduce mortality (6 studies).	Low
Key Question 1a	**Congestive heart failure**	***Patient satisfaction.*** CM programs that serve patients with CHF **do** increase patient satisfaction (3 studies).	Moderate

Table 17. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1a	**Congestive heart failure**	***Quality of life.*** CM programs that serve patients with CHF **do** improve CHF-related quality of life (6 studies).	Low
Key Question 1a	**Diabetes mellitus**	***Glucose management*.** CM programs that serve adults with diabetes **do** improve glucose management (12 studies).	Moderate
Key Question 1a	**Diabetes mellitus**	***Lipids, BMI/weight*.** CM programs that serve adults with diabetes **do not** improve measures of lipid management or BMI/weight. (8 studies).	Moderate
Key Question 1a	**Diabetes mellitus**	***Mortality*.** CM programs that serve adults with diabetes **do not** reduce mortality (1 study).	Low
Key Question 1a	**Diabetes mellitus**	***Glucose control.*** CM improves glucose control among adults with diabetes.	Low
Key Question 1a	**Cancer**	***Satisfaction with care*.** CM programs that serve patients with cancer **do** improve satisfaction with care (4 studies).	Moderate
Key Question 1a	**Cancer**	***Cancer-related symptoms, functioning, quality of life, survival*.** CM **does** improve selected cancer-related symptoms and functioning (physical, psychosocial, and emotional) but not overall quality of life or survival (8 studies).	Low
Key Question 1a	**HIV**	***Mortality*.** CM programs that serve adults with HIV infection **do not** improve survival (2 studies).	Low
Key Question 1b: In adults with chronic medical illness and complex care needs, is case management effective in improving *quality of care*, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?	**Older adults with one or more chronic diseases**	***Patient perception of care coordination*.** CM programs that serve patients with one or more chronic diseases **do** increase patients' perceptions of the coordination of their care (2 studies).	High
Key Question 1b	**Dementia**	***Clinical guideline adherence*.** CM programs that focus on clinical guideline measures for care of dementia **do** increase adherence to those measures (1 study).	Low
Key Question 1b	**Congestive heart failure**	***Self-management behaviors*.** CM **does** increase patients' adherence to self-management behaviors recommended for patients with CHF (3 studies).	Moderate

Table 17. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 1b	**Cancer**	***Appropriate treatment*.** CM programs that serve patients with cancer **do** increase the receipt of appropriate (i.e., guideline-recommended) cancer treatment (2 studies).	Moderate
Key Question 1b	**Tuberculosis**	***Treatment success*.** Short-term CM programs that emphasize medication adherence **do** improve rates of successful treatment for tuberculosis in vulnerable populations (4 studies).	Moderate
Key Question 1c: In adults with chronic medical illness and complex care needs, is case management effective in improving *resource utilization*, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?	**Older adults with one or more chronic diseases**	***Medicare expenditures*.** CM programs that serve patients with one or more chronic diseases **do not** reduce Medicare expenditures (3 studies).	High
Key Question 1c	**Older adults with one or more chronic diseases**	***Hospitalization rates*.** CM programs that serve patients with one or more chronic diseases **do not** reduce overall rates of hospitalization (17 studies).	Moderate
Key Question 1c	**Frail elderly**	***Hospitalization rates.*** CM **does not** decrease acute hospitalizations in the frail elderly (11 studies).	Low
Key Question 1c	**Dementia**	***Health care expenditures*.** CM **does not** change total health care expenditures for patients with dementia (6 studies).	Moderate
Key Question 1c	**Diabetes**	***Hospital readmission rates*.** CM **does not** reduce hospitalization rates among adults with diabetes.	Low
Key Question 1c	**Cancer**	***Health care expenditures*.** CM programs that serve patients with cancer **do not** affect overall health care utilization and cost of care (5 studies).	Low
Key Question 1c	**Other medical problems**	***Emergency department visits.*** CM programs that serve populations that have chronic obstructive pulmonary disease (COPD) or are homeless **do** reduce emergency department visits (3 studies).	Low

Table 17. Summary evidence table: Outpatient case management for adults with medical illness and complex care needs (continued)

Key Question	Condition/ Disease	Conclusion	Strength of Evidence
Key Question 2: Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?	**Older adults with one or more chronic diseases**	***Disease burden*.** CM programs that serve patients with one or more chronic diseases are more effective for reducing hospitalization rates among patients with greater disease burden (2 studies).	Low
Key Question 3: Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?	**Older adults with one or more chronic diseases**	***Personal contact*.** CM programs that serve patients with one or more chronic diseases are more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians (4 studies).	Low
Key Question 3	**Dementia**	***Duration*.** CM programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than 2 years are more effective for delaying nursing home placement than programs providing services for 2 years or less (1 study).	Low
Key Question 3	**Congestive heart failure**	***Integration with multidisciplinary team.*** CM is more effective in improving outcomes among CHF patients when case managers are part of a multidisciplinary team of health care providers.	Low
Key Question 3	**Cancer**	***Intensity, integration, training, protocols*.** CM programs that serve patients with cancer are more effective when the CM is more intensive, better integrated with patients' usual care providers, and employs preintervention training and care protocols (3 studies).	Low

CM = case management; BMI = body mass index; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease

Note: this table does not include statements for which the evidence was insufficient to draw a conclusion.

Future Research

The existing evidence base includes a large number of randomized trials comparing case management (CM) with "usual care." While the components of usual care were quite variable across studies, in some cases (particularly the Medicare Coordinated Care Demonstration [MCCD] trial)[32] the studies had large sample sizes and good overall methodological quality, and there is unlikely to be a high yield in continuing to repeat such studies. Instead, future clinical research needs to address the gaps in the current evidence base. These gaps include:

- Lack of effective risk assessment tools for choosing candidates for CM. Some published trials[29] have used existing tools but no studies have compared tools or rigorously examined patient subgroups to learn which patients achieve the greatest benefits from CM. The factors included in better risk profiles could include:
    - Demographics including age, gender, and ethnicity
    - Living situation and ability to meet basic living needs
    - Access to primary care and other health care services
    - Social support
    - Health care utilization profiles
    - Clinical risk factors for adverse outcomes.
- Lack of understanding of the length of time to continue CM. Nearly all trials have set seemingly arbitrary durations of the intervention (often 1 to 2 years). It is not known when the benefits of the intervention have been achieved. Some of the negative results may be due to the CM being too short. This is particularly important if developing an effective long-term relationship between the patient and case manager affects the program's success.
- Imprecision about the intensity of CM. Existing trials have infrequently examined whether patient outcomes are influenced by the frequency of case manager contact, the length and content of the contacts, and the approach to followup of problems.

Other examples of CM elements that should be explicitly described in future research include:

- Training received by case managers
- Case manager experience
- Specific functions of case managers and the distribution of effort devoted to different activities
- Modes of contact (clinic visits, home visits, telephone calls)
- Average caseload
- Relationship to other health care providers
- Use of protocols, guidelines, and information technology.

CM typically involves case managers providing both direct clinical support and coordination for patients, as well as education and empowerment to enable patients to better manage their own conditions and coordinate their own care. Better specification of intervention components and population characteristics would contribute to greater understanding of when interventions should emphasize direct support compared with patient education.

Many CM interventions employed more than one case manager, but few studies examined the effectiveness of CM delivered by different case managers. CM is a human intervention, and the effectiveness of CM may vary substantially according to the skills, experience, and personality of the person delivering the intervention. Understanding how much variability there is from one case manager to another would provide valuable information about the degree to which CM can be standardized and the importance of choosing individuals to implement CM.

As discussed above, future research should compare CM with other interventions designed to achieve similar outcomes, particularly interventions that are less intensive or more narrowly focused and may thereby achieve desired outcomes more efficiently. Such studies would help determine in which situations CM adds value over potentially less costly interventions.

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Acronyms and Abbreviations

AD	Alzheimer's disease
ADL	Activities of daily living
AHRQ	Agency for Healthcare Research and Quality
APN	Advanced practice nurse
BMI	Body mass index
BP	Blood pressure
BS	Bachelor of science
CER	Comparative effectiveness review
CG	Caregiver
CHF	Congestive heart failure
CHW	Community health worker
CM	Case management
CMS	Centers for Medicare and Medicaid Services
COPD	Chronic obstructive pulmonary disease
DBP	Diastolic blood pressure
DM	Diabetes mellitus
DOT	Directly observed therapy
ED	Emergency department
EHC	Effective Health Care Program
EPC	Evidence-based Practice Center
FFS	Fee-for-service
FTF	Face-to-face
GDS	Global Deterioration Scale
GRACE	Geriatric Resources for Assessment and Care of Elders
HBPC	Home-based Primary Care
HDL	High-density lipoprotein cholesterol
HgA1c	Hemoglobin A1c
HMO	Health maintenance organization
IADL	Instrumental activities of daily living
IV	Intravenous
LDL	Low-density lipoprotein cholesterol
LPN	Licensed practical nurse
MADDE	Medicare Alzheimer's Disease Demonstration and Evaluation
MCCD	Medicare Coordinated Care Demonstration
MCO	Managed care organization
MMSE	Mini-mental State Examination
MSW	Master of social work
NP	Nurse practitioner
NPI	Neuropsychiatric inventory
NR	Not reported
NYHA	New York Heart Association
NYU	New York University
OP	Outpatient
PACE	Program for All-Inclusive Care of the Elderly

PCP	Primary care provider
PICOTS	Populations, interventions, comparators, outcomes, timing, and setting
PS	Psychosocial
QOL	Quality of life
RD	Registered dietitian
RN	Registered nurse
SBP	Systolic blood pressure
SF-36	Short form (36) Health Survey
SNF	Skilled nursing facility
SW	Social worker
TB	Tuberculosis
TC	Total cholesterol
TEP	Technical Expert Panel
TOO	Task Order Officer
U.K.	United Kingdom
U.S.	United States
VAMC	Veterans Affairs Medical Center

Appendix A. Definitions of Case Management

Source	**Definition**
AARP http://healthtools.aarp.org/galecontent/case-management	Case management assigns the administration of care for an outpatient individual with a serious mental illness to a single person (or team); this includes coordinating all necessary medical and mental health care, along with associated supportive services. Case management tries to enhance access to care and improve the continuity and efficiency of services. Depending on the specific setting and locale, case managers are responsible for a variety of tasks, ranging from linking clients to services to actually providing intensive clinical or rehabilitative services themselves. Other core functions include outreach to engage clients in services, assessing individual needs, arranging requisite support services (such as housing, benefit programs, job training), monitoring medication and use of services, and advocating for client rights and entitlements.
American Nurses Association (ANA) http://www.nursingworld.org	Management directed toward serious conditions likely to require numerous providers and involve costly care. Case managers handle each case individually, identifying the most cost-effective treatments for extremely resource-intensive conditions, such as accidents, AIDS, cancer, major trauma, prematurity, and strokes. *Huntington, J., (January 6, 1997). "Glossary for Managed Care" Online Journal of Issues in Nursing Vol. 2. No. 1. Available: www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol21997/No1Jan97/GlossaryforManagedCare.aspx.* Nursing case management is a dynamic and systematic collaborative approach to providing and coordinating health care services to a defined population. It is a participative process to identify and facilitate options and services for meeting individuals' health needs, while decreasing fragmentation and duplication of care, and enhancing quality, cost-effective clinical outcomes. The framework for nursing case management includes five components: assessment, planning, implementation, evaluation and interaction. *Definition attributed to American Nurses Credentialing Center in* White P, Hall ME. Mapping the literature of case management nursing. J Med Libr Assoc. 2006 Apr;94(2 Suppl):E99-106. PubMed PMID: 16710470.

Source	Definition
California Department of Health Services http://www.ccah-alliance.org/providermanual/PM_5.htm	Guiding the course of resolution of a personal medical problem (including the ‘problem’ of the need for health education, screening or preventive services) so that the recipient is brought together with the most appropriate provider at the most appropriate times, in the most appropriate setting. The objectives of case management of Member medical care are as follows: • To foster continuity of care and longitudinal Provider/Member relationships for Members in Santa Cruz and Monterey Counties. • To coordinate the care of members in order to achieve satisfactory care results. • To contribute to the reduction of the use of hospital emergency rooms as a source of non-emergency, first-contact and urgent medicine by Members. • To reduce unnecessary referral to specialty providers by Members. • To discourage medically inappropriate use of pharmacy and drug benefits by Members. • To facilitate Member understanding and use of disease prevention practices and early diagnostic services. • To provide a structure for Physicians to manage services to Members by means of the following: o Selection of Referral Physicians for quality of care, and adherence to the case management system and to cost effective delivery of services. o Measurement of individual and group Primary Care Physician performance on the basis of quality of care data.
Case Management Leadership Coalition (CMLC), 2004 http://www.cmsa.org/PolicyMaker/NewsEvents/PressReleases/tabid/272/ctl/ViewPressRelease/mid/1004/PressReleaseID/19/Default.aspx	Case managers work with people to get the health care and other community services they need, when they need them, and for the best value.
Case Management Society of America (CMSA), 2002 http://www.cmsa.org/consumer/tabid/61/default.aspx	Case management is a collaborative process of assessment, planning, facilitation, and advocacy for options and services to meet an individual’s health needs through communication and available resources to promote quality cost-effective outcomes.

Source	Definition
Center for Medicare/Medicaid Services (CMS) http://www.cms.gov/SpecialNeedsPlans/Downloads/SPMeasuresUpdate.pdf	Case management is the coordination of care and services provided to members to facilitate appropriate delivery of care and services. The organization implements case management for members. The goal of complex case management is to help members regain optimum health or improved functional capability, in the right setting and in a cost-effective manner. It involves comprehensive assessment of the member's condition; determination of available benefits and resources; and development and implementation of a case management plan with performance goals, monitoring and follow-up. Distinguishing features of case management • Degree and complexity of illness or condition is typically severe • Level of management necessary is typically intensive • Amount of resources required for member to regain optimal health or improved functionality is typically extensive
Commission of Case Manager Certification (CCMC), 2004 http://www.cmbodyofknowledge.com/CaseManagementKnowledge/tabid/159/Default.aspx	Case management is a collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates options and services required to meet an individual's health needs, using communication and available resources to promote quality, cost-effective outcomes.
Robert Wood Johnson Foundation, Research Synthesis Report No. 19 (12/2009) http://www.thenationalcouncil.org/galleries/default-file/Care%20Management%20Synthesis%20Report.pdf	Care management is a set of activities designed to assist patients and their support systems in managing medical conditions and related psychosocial problems more effectively, with the aim of improving patients' health status and reducing the need to medical services. The goals of care management are to improve patients' functional health status, enhance coordination of care, eliminate duplication of services, and reduce the need for expensive medical services.

Appendix B. Exact Search Strings

Database: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R)
1947 to August Week 3 2010 (Updated 8/16/2011)
Search Strategy:
----
1 exp Patient Care Planning/ (48371)
2 ((manag$ or oversee$ or supervis$ or coordin$) adj5 ((patient$ adj3 care) or (case or cases))).mp. (36118)
3 1 and 2 (8866)
4 limit 3 to English language (8356)
5 limit 4 to "all adult (19 plus years)" (2594)
6 limit 5 to yr="2002 -Current" (1491)
7 limit 5 to yr="1902 - 2001" (1103)

Database: EBM Reviews - Cochrane Central Register of Controlled Trials
<2nd Quarter 2010> (Updated 8/16/2011)
Search Strategy:
----
1 case manag$.ti,hw,kw. (597)

Database: EBM Reviews - Cochrane Database of Systematic Reviews
<2005 to August 2010> (Updated 8/16/2011)
Search Strategy:
----
1 case manag$.ti,kw. (9)
2 case manag$.oh,tw. (106)
3 1 or 2 (106)

Database: EBM Reviews - Database of Abstracts of Reviews of Effects
<3rd Quarter 2010> (Updated 8/16/2011)
Search Strategy:
----
1 case manag$.ti,kw,tw. (86)

Database: CINAHL Plus with Full Text
1937-December 15, 2010 (Updated 8/16/2011)
Search Strategy:

S25 S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 (2474)
S24 S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23

S23	S3 and S14
S22	S3 and S13
S21	S3 and S12
S20	S3 and S11
S19	S3 and S10
S18	S3 and S7
S17	S3 and S6
S16	S3 and S5
S15	S3 and S4
S14	(MH "Attitude of Health Personnel+")
S13	(MH "Professional-Patient Relations+")
S12	(MH "Disease Attributes+")
S11	(MH "Emergency Medical Services+")
S10	S8 or S9
S9	(MH "Hospitalization+")
S8	(MH "Hospitals+")
S7	(MH "Mortality+")
S6	(MH "Attitude to Health")
S5	(MH "Quality of Life")
S4	(MH "Outcome Assessment") OR (MH "Nursing Outcomes")
S3	S1 or S2
S2	(MH "Case Managers")
S1	(MH "Case Management")

Database: ClinicalTrials.gov
November 29, 2011
Search Strategy:
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"case management" OR "case manager" OR "care coordination" OR "self-management support" OR "individual service coordination" OR "care management" OR "care managers" | Recruitment: Closed Studies, Exclude Unknown checked | Age Group: Adult, Senior (221)

WHO International Clinical Trials Registry Platform (ICTRP)
(http://apps.who.int/trialsearch/AdvSearch.aspx)
November 29, 2011
Search Strategy:
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Search Terms in the Title Field: case management OR care coordination OR self-management support OR case manager OR individual service coordination OR care management OR care managers | Recruitment Status: ALL (144)

Appendix C. Inclusion and Exclusion Criteria

Abstract Level Eligibility Criteria

Study Characteristic	Inclusion/Exclusion
Population	Include: all ages >18; adults with medical illnesses and complex care needs Exclude: Mental health only
Interventions	Include: case management, care coordination, care management and disease management programs and others that may have elements of case management (e.g., coordination, medical monitoring) Exclude: disease management without care coordination, low intensity telephonic and short duration interventions, screening interventions
Comparators	Include: Usual care or other model of case management
Outcomes	Include: Relevant outcome measured (patient, resource utilization, or process measurement outcomes as listed in Key Questions.
Timing/Duration	Include: Duration >30 days
Setting	Include: Outpatient settings (i.e., primary care, specialty care, and home care)
Study Design	Include: Randomized trial, cohort, case control, systematic review, meta-analysis

Full-Text Eligibility Criteria

Study Characteristic	Inclusion/Exclusion
Population	Include: all ages >18; adults with medical illnesses and complex care needs Exclude: Mental health only
Interventions	Include: case management, care coordination, care management and disease management programs and others that may have elements of case management (e.g., coordination, medical monitoring) Exclude: disease management without care coordination, low intensity telephonic and short duration interventions, screening interventions
Comparators	Include: Usual care or other model of case management
Outcomes	Include: Patient (health) outcomes, resource utilization (e.g., hospitalizations, primary care visits), or process measurement outcomes (e.g. medication adherence)
Timing/Duration	Include any study duration >30 days
Setting	Include all outpatient settings (e.g., primary care) Exclude: Inpatient, hospital-based case management

Appendix D. Included and Excluded Studies

Included Studies

1. Allen KR, Hazelett S, Jarjoura D, et al. Effectiveness of a postdischarge care management model for stroke and transient ischemic attack: a randomized trial. J Stroke Cerebrovasc Dis. 2002;11(2):88-98. PMID: 17903862.
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12. Bourbeau J, Collet JP, Schwartzman K, et al. Economic benefits of self-management education in COPD. Chest. 2006 Dec;130(6):1704-11. PMID: 17166985.
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15. Brodaty H, Mittelman M, Gibson L, et al. The effects of counseling spouse caregivers of people with Alzheimer disease taking donepezil and of country of residence on rates of admission to nursing homes and mortality. Am J Geriatr Psychiatry. 2009 Sep;17(9):734-43. PMID: 19705519.
16. Brown SA, Garcia AA, Winter M, et al. Integrating education, group support, and case management for diabetic Hispanics. Ethn Dis. 2011;21(1):20-6. PMID: 21462725.
17. California Medi-Cal Type 2 Diabetes Study Group. Closing the gap: effect of diabetes case management on glycemic control among low-income ethnic minority populations: the California Medi-Cal type 2 diabetes study. Diabetes Care. 2004 Jan;27(1):95-103. PMID: 14693973.
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Excluded Studies

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1015. Wolfe GS. HIV/AIDS: developing a disease management program. Remington Report. 1997 Jul-Aug;5(4):34-9. **Exclusion reason: Wrong intervention**

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1022. Wright K, Ryder S, Gousy M. Community matrons improve health: patients' perspectives. British Journal of Community Nursing. 2007 Oct;12(10):453-9. PMID: 18073645. **Exclusion reason: Wrong outcome**

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1025. Yarmo D, Scanlan N, Edge V, et al. Embracing the continuum of care: an Australian private hospital's experience. Journal of Case Management. 1998 Fall;7(3):127-34. PMID: 10703378. **Exclusion reason: Wrong intervention**

1026. Yau DCN, Leung ACT, Yeoh C-S, et al. Global case management: Hong Kong. Care for the hospital-discharged frail elders by nurse case managers: a process evaluation of a longitudinal case management service project. Lippincott's Case Management. 2005 Jul-Aug;10(4):203-12. PMID: 16056117. **Exclusion reason: Wrong outcome**

1027. Yordi C, DuNah R, Bostrom A, et al. Caregiver supports: outcomes from the Medicare Alzheimer's disease demonstration. Health Care Financing Review. 1997;19(2):97-117. PMID: 10345408. **Exclusion reason: Wrong outcome**

1028. Yordi CL. Case management in the social health maintenance organization demonstrations. Health Care Financing Review. 1988 Dec; Spec No:83-8. PMID: 10312977. **Exclusion reason: Wrong outcome**

1029. Yoshie S, Saito T, Takahashi M, et al. Effect of work environment on care managers' role ambiguity: an exploratory study in Japan. Care Management Journals. 2008;9(3):113-21. PMID: 18847095. **Exclusion reason: Wrong outcome**

1030. Young HM, Haight K. Case management in a retirement community. Nursing Administration Quarterly. 1993;17(3):34-8. PMID: 8502420. **Exclusion reason: No original data**

1031. Young S. Professional relationships and power dynamics between urban community-based nurses and social work case managers: advocacy in action. Professional Case Management. 2009 Nov-Dec;14(6):312-20. PMID: 19935349. **Exclusion reason: Wrong outcome**

1032. Young T, Busgeeth K. Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS. Cochrane Database of Systematic Reviews. 2010(5)PMID: 20091575. **Exclusion reason: Wrong intervention**

1033. Yu DS, Thompson DR, Lee DT. Disease management programmes for older people with heart failure: crucial characteristics which improve post-discharge outcomes. Eur Heart J. 2006 Mar;27(5):596-612. PMID: 16299021. **Exclusion reason: Background**

1034. Yuan LP, Manderson L, Ren MY, et al. School-based interventions to enhance knowledge and improve case management of schistosomiasis: a case study from Hunan, China. Acta tropica. 2005 Nov-Dec;96(2-3):248-54. PMID: 16202594. **Exclusion reason: Wrong intervention**

1035. Zaller ND, Holmes L, Dyl AC, et al. Linkage to treatment and supportive services among HIV-positive ex-offenders in Project Bridge. Journal of Health Care for the Poor & Underserved. 2008 May;19(2):522-31. PMID: 18469423. **Exclusion reason: Wrong population**

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1037. Zander K. Nursing case management: resolving the DRG paradox. Nursing Clinics of North America. 1988 Sep;23(3):503-20. PMID: 3138667.**Exclusion reason: No original data**

1038. Zander K, Warren C. Issues and interventions. Converting case managers from MD/service to unit-based assignments: a before and after comparison. Lippincott's Case Management. 2005 Jul-Aug;10(4):180-4. PMID: 16056113.**Exclusion reason: Wrong setting**

1039. Zausig YA, Grube C, Boeker-Blum T, et al. Inefficacy of simulator-based training on anaesthesiologists' non-technical skills. Acta Anaesthesiologica Scandinavica. 2009 May;53(5):611-9. PMID: 19419355.**Exclusion reason: Wrong intervention**

1040. Zawadski RT, Eng C. Case management in capitated long-term care. Health Care Financing Review. 1988 Dec; Spec No:75-81. PMID: 10312976.**Exclusion reason: No original data**

1041. Zazworsky D. Project targets patients in Latino community. Patient Education Management. 2007 Oct;14(10):117-8.**Exclusion reason: No original data**

1042. Zerull L, Cohen EL. Nurse case management in a rural community. Nurse case management in the 21st century. 1996:133-9.**Exclusion reason: Wrong setting**

1043. Ziebarth D. Parish nursing used in a multidisciplinary team approach to case manage Emergency Department's high utilization patients. Wisconsin Parish Nurse Coalition. 2009 May;8(2):6-7. **Exclusion reason: No original data**

1044. Zimmer JG, Eggert GM, Treat A, et al. Nursing homes as acute care providers. A pilot study of incentives to reduce hospitalizations. Journal of the American Geriatrics Society. 1988 Feb;36(2):124-9. PMID: 3276766. **Exclusion reason: Wrong intervention**

1045. Zink MR. Episodic case management in home care. Home Healthcare Nurse. 2005 Oct;23(10):655-62. PMID: 16217216. **Exclusion reason: No original data**

1046. Zurovac D, Larson BA, Skarbinski J, et al. Modeling the financial and clinical implications of malaria rapid diagnostic tests in the case-management of older children and adults in Kenya. American Journal of Tropical Medicine & Hygiene. 2008 Jun;78(6):884-91. PMID: 18541764. **Exclusion reason: Wrong intervention**

1047. Zwarenstein M, Goldman J, Reeves S. Interprofessional collaboration: effects of practice-based interventions on professional practice and healthcare outcomes. Cochrane Database of Systematic Reviews. 2009 Jul 8(3):CD000072. PMID: 19588316. **Exclusion reason: Wrong population**

1048. Zwarenstein M, Reeves S, Straus SE, et al. Case management: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews. 2009(1). **Exclusion reason: No original data**

Appendix E. Defining Complex Care Needs

Source	Description/Definition
American Geriatrics Society	Persons whose conditions require complex continuous care and frequently require services from different practitioners in multiple settings.
Robert Wood Johnson Foundation, Research Synthesis Report NO. 19 (12/2009): Care management of patients with complex care needs	Usually patients who are Medicare beneficiaries with multiple chronic conditions, frequent hospitalizations, and limitations on their ability to perform basic daily functions due to physical, mental and psychosocial challenges. Patients with complex health care are patients at the far end of a population-wide spectrum ranging from health individuals to people with serious medical problems and high utilization of heath care services.
Scottish Executive, Department of Health Ministries (Report 2007)	Terms linked to the concepts of 'complex' and 'multiple' needs and include: 'multiple disadvantage', 'multiple disabilities', 'multiple impairment', 'dual diagnosis', 'high support needs', 'complex health needs', and 'multiple and complex needs.' People identified as having multiple and complex needs may include: • People with mental health problems, including 'severe and lasting' problems • Those disadvantaged by age and transitions – young and older people • Those fleeing abuse and violence – mainly women and refugees • Those culturally and circumstantially disadvantaged or excluded – minority, ethnic groups; travelling people • People with a disability, including profound, severe or long term impairment or disability and those with sensory disabilities with 'additional needs' • People who present challenging behaviors to services, for example in schools, within residential services/ hostels or in their own neighborhoods • People who are multiply disadvantaged by poverty, poor housing, poor environments or rural locations which mean they are distant from services • People who have a 'dual diagnosis' of mental ill health and substance misuse, or of other combinations of medically defined conditions. • People who are 'marginal, high risk and hard to reach', who may be involved in substance misuse, offending and at risk of exclusion

Appendix F. Quality Assessment Methods

Individual studies were rated as “good,” “fair” or “poor” as defined below:[1-3]

Studies rated “good” have the least risk of bias and results are considered valid. Good quality studies include clear descriptions of the population, setting, interventions, and comparison groups; a valid method for allocation of patients to treatment; low dropout rates, and clear reporting of dropouts; appropriate means for preventing bias; appropriate measurement of outcomes, and reporting results.

Studies rated “fair” are susceptible to some bias, but it is not sufficient to invalidate the results. These studies do not meet all the criteria for a rating of good quality because they have some deficiencies, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems. The “fair” quality category is broad, and studies with this rating vary in their strengths and weaknesses: the results of some fair-quality studies are *likely* to be valid, while others are only *probably* valid.

Studies rated “poor” have significant flaws that imply biases of various types that may invalidate the results. They have a serious or “fatal” flaw in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting. The results of these studies are at least as likely to reflect flaws in the study design as the true difference between the compared drugs.

For Controlled Trials:

Each criterion was given an assessment of yes, no, or unclear.

1. Was the assignment to the treatment groups really random?

Adequate approaches to sequence generation:
    Computer-generated random numbers
    Random numbers tables
Inferior approaches to sequence generation:
    Use of alternation, case record numbers, birth dates or week days
Randomization reported, but method not stated
Not clear or not reported
Not randomized

2. Was the treatment allocation concealed?

Adequate approaches to concealment of randomization:

- Centralized or pharmacy-controlled randomization (randomization performed without knowledge of patient characteristics).
- Serially-numbered identical containers
- On-site computer based system with a randomization sequence that is not readable until allocation
- Sealed opaque envelopes

Inferior approaches to concealment of randomization:

- Use of alternation, case record numbers, birth dates or week days
- Open random numbers lists
- Serially numbered non- opaque envelopes
- Not clear or not reported

3. Were the groups similar at baseline in terms of prognostic factors?
4. Were the eligibility criteria specified?
5. Were outcome assessors and/or data analysts blinded to the treatment allocation?
6. Was the care provider blinded?
7. Was the patient kept unaware of the treatment received?
8. Did the article include an intention-to-treat analysis, or provide the data needed to calculate it (i.e., number assigned to each group, number of subjects who finished in each group, and their results)?
9. Did the study maintain comparable groups?
10. Did the article report attrition, crossovers, adherence, and contamination?
11. Is there important differential loss to followup or overall high loss to followup?

For Cohort Studies:

Each criterion was given an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?
2. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?
3. Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?
4. Were outcome assessors and/or data analysts blinded to treatment?
5. Did the article report attrition?
6. Did the study perform appropriate statistical analyses on potential confounders?
7. Is there important differential loss to followup or overall high loss to followup?
8. Were outcomes pre-specified and defined, and ascertained using accurate methods?

For Case-control Studies

Each criterion was given an assessment of yes, no, or unclear.

1. Did the study attempt to enroll all (or a random sample of) cases using pre-defined criteria?
2. Were the controls derived from the same population as the cases, and would they have been selected as cases if the outcome was present?
3. Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?
4. Did the study report the proportion of cases and controls who met inclusion criteria that were analyzed?
5. Did the study use accurate methods for identifying outcomes?
6. Did the study use accurate methods for ascertaining exposures and potential confounders?
7. Did the study perform appropriate statistical analyses on potential confounders?

Appendix G. Quality Assessment of Randomized Trials and Observational Studies

Table G-1. Quality Assessment of Randomized Trials

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Allen 2002[4]	Yes	Yes	Yes	Yes	No	No, No, No, No	No	No	Yes	Poor	Private Foundation
Applebaum 2002[5]	No	No	Yes	Yes	Not reported	Yes, No, No, No	Yes	No	Yes	Fair	Robert Wood Johnson Foundation
Babamoto 2009[6]	Yes	No	Yes	Yes	Yes	Yes, No, No, No	No	No	Yes	Fair	Pfizer Foundation and Pfizer Health Solutions
Bernabei 1998[7]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	National Research Council of Italy

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Boult 2011[8] Wolff 2010[9] Boult 2008[10] Boyd 2010[11]	Yes	Yes	Yes	Yes	Yes	Yes, No, Yes, No	Yes	Yes	Yes	Good	Agency for Healthcare Research and Quality, National Institute on Aging, The John A. Hartford Foundation, Jacob and Valeria Langeloth Foundation, Kaiser-Permanente Mid-Atlantic, Johns Hopkins HealthCare, Roger C. Lipitz Center for Integrated Health Care
Bourbeau 2003[12] Bourbeau 2006[13]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	Boehringer Ingelheim Canada; Fonds de la Recherche en Sante du Quebec
Brown 2011[14]	No	No	No	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Poor	National Institute of Diabetes and Digestive and Kidney Diseases
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]	Yes	Yes	Yes	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Fair	State of California Medi-Cal Managed Care Division; Centers for Disease Control and Prevention

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Callahan 2006[17]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	Agency for Healthcare Research and Quality
Chien 2008[18]	No	No	Yes	Yes	Yes	No, No, No, No	Yes	Yes	Yes	Fair	Nethersole School of Nursing, Hong Kong
Chow 2010[19]	Yes	Yes	Yes	Yes	No	No, No, No, No	Yes	Yes	Yes	Fair	Council of Hong Kong
Chu 2000[20]	No	No	Yes	Yes	No	No, No, No, No	Yes	Yes	Yes	Poor	Home care agency
Claiborne 2006[21]	No	No	No	Yes	No	No, Yes, No, No	Yes	No	Yes	Poor	Not reported
Clark 2004[22]	No	No	Unclear	Yes	No	Yes, No, No, No	No	No	Yes	Poor	Private foundations
DeBusk 2004[23]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	NIH
Eggert 1991[24] Zimmer 1990[25]	No	No	Yes	Yes	No	No, No, No, No	Yes	Yes	Yes	Poor	Robert Wood Johnson Foundation
Eloniemi-Sulkava 2001[26]	Yes	Yes	Yes	Yes	Yes	No, No, No, No	Yes	Yes	Yes	Good	Social Insurance Institution, Finland, and the Alzheimer Foundation of Finland
Eloniemi-Sulkava 2009[27]	Yes	Yes	Yes	Yes	No	No, No, No, No	Yes	Yes	Yes	Good	Research grants received from Finnish Slot Machine Association.
Engelhardt 2006[28]	Yes	No	Yes	Yes	Unclear	Yes, Yes, No, No	No	Yes	Yes	Fair	Foundations (RWJF, Fox/Samuels, Cummings)

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Fan 2012[29]	Yes	No	Yes	Yes	Yes	Yes, Yes, Yes, Yes	Yes	Yes	Yes	Good	Veterans Affairs
Fitzgerald 1994[30]	No	No	Yes	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Fair	Veterans Affairs
Gagnon 1999[31] Schein 2005[32]	Yes	No	Yes	Yes	Yes	No, No, No, No	Not reported	Yes	Yes	Fair	Not reported
Gary 2003[33]	Yes	Yes	No	Yes	Yes	Yes, No, Yes, No	Yes	No	Yes	Fair	National Institutes of Health
Gary 2004, 2005, 2009[34-36]	Yes	Yes	Yes	Yes	Yes	Yes, No, Yes, No	Yes	No	Yes	Fair	National Institutes of Health, Hopkins General Clinical Research Center
Goodwin 2003[37] Jennings-Sanders 2003, 2005[38, 39]	No	No	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Fair	U.S. Public Health Service
Hsieh 2008[40]	No	No	Yes	Yes	No	No, No, No, No	Yes	Yes	Yes	Fair	Not reported
Husbands 2007[41]	Yes	Yes	Yes	Yes	No	No, No, No, No	No	No	Yes	Poor	Wellesley Central Health Corp and the CLEAR Unit (Canada)
Ishani 2011[42]	Yes	Yes	Yes	Yes	No	Yes, No, Yes, No	Yes	Yes	Yes	Good	US Department of Veterans Affairs
Jaarsma 2008[43]	Yes	No	Yes	Yes	Yes	Yes, Yes, Yes, No	Yes	Yes	Yes	Good	Netherlands Heart Foundation
Jansen 2011[44] Jansen 2005[45]	Yes	Yes	Yes	Yes	Yes	Yes, No, Yes, Yes	Yes	Yes	Yes	Good	Netherlands Organization for Health Research and Development

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Kasper 2002[46]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	CardioContinuum (congestive heart failure disease management company)
Krein 2004[47]	Yes	No	Yes	Yes	Yes	Yes, No, Yes, No	Yes	No	Yes	Fair	Veterans Affairs
Kristensson 2010[48]	Yes	No	Yes	Yes	No	Yes, Yes, Yes, No	No	Yes	Yes	Good	The Swedish Research Council
Lam 2010[49]	No	No	Yes	Yes	No	Yes, No, Yes, No	Yes	Yes	Yes	Fair	Hong Kong Health and Health Services Research Fund
Laramee 2003[50]	No	No	No	Yes	No	Yes, No, No, No	Yes	Unclear	Yes	Fair	Novartis
Latour 2006[51] Latour 2007[52]	Yes	Yes	Yes	Yes	No	Yes, No, No, No	No	Yes	Yes	Fair	Dutch Health Insurance Council
Leung 2004a[53]	No	No	Yes	Yes	No	No, No, No, No	Unclear	Yes	Yes	Fair	Not reported
Leung 2004b[54]	No	No	No	No	No	No, No, No, No	Unclear	Unclear	No	Poor	Not reported
Ma 2009[55] Berra 2007[56] Ma 2006[57]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	National Institutes of Health
Marshall 1999[58] Long 2000[59] Long 2002[60]	Yes	Yes	Yes	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Good	Garfield Memorial Fund

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Martin 2004[61]	Yes	No	Yes	Yes	Yes	Yes, No, Yes, No	Yes	Yes	Yes	Good	Coventry Health Care, Inc; Merck & Co, Inc.
Mayo 2008[62]	Yes	Yes	Yes	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Good	Canadian Institute of Health Research
McCorkle 1989[63]	No	No	No	Yes	Unclear	Yes, No, No, No	No	Unclear	Yes	Poor	Grant: NU-01001, HRSA
McCoy 1992[64]	No	No	No	Yes	No	No, No, No, No	No	No	Yes	Poor	HRSA
Mittelman 2006[65] Mittelman 2004a[66] Mittelman 2004b[67] Roth 2005[68]	Yes	Yes	Yes	Yes	No	Yes, Yes, Yes, Yes	Yes	Yes	Yes	Good	Not reported
Mittelman 2008[69] Brodaty 2009[70]	Yes	Yes	Yes	Yes	Yes	Yes, No, Yes, No	Yes	Yes	Yes	Good	Pfizer; New York University Alzheimer's Disease Center
Moore 2002[71]	No	Yes	Yes	Yes	Unclear	Yes, No, No, No	No	Yes	Yes	Fair	National Health Service, National Cancer Program
Mor 1995[72]	No	No	Yes	Yes	Unclear	Yes, No, Yes, No	Yes (at 3 months) No (at 6 months)	Yes	Yes	Fair	Not reported
Newcomer 1999a, 1999b, 1999c[73-75] Miller 1999[76] Shelton 2001[77] MADDE	No	No	Yes	Yes	No	No, No, No, No	Unclear	No	Yes	Poor	Health Care Financing Administration

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Newcomer 2004[78]	No	Yes	Yes	Yes	No	No, No, No, No	Not reported	Yes	Yes	Fair	California Healthcare Foundation; Sharp Healthcare; PacifiCare; Pfizer
Nickel 1996[79]	No	No	Yes	Yes	No	No, No, No, Yes	No	No	Yes	Poor	National Institute for Nursing Research
Nyamathi 2006, 2007[80, 81]	No	No	No	Yes	No	Yes, No, Yes, No	Yes	Yes	Yes	Fair	National Institute on Drug Abuse
Peikes 2009[82] Oliva 2010[83]	Yes	Yes	Yes	Yes	Unclear	Yes , No, No, No	Yes	Yes	Yes	Good	Centers for Medicare & Medicaid Services (CMS)
Peters-Klimm 2010[84]	Yes	Yes	Yes	Yes	No	Yes, No, Yes, No	Yes	Yes	Yes	Good	German Ministry of Education and Research
Pugh 2001[85]	No	No	Yes	Yes	No	No, No, No, No	Yes	Yes	Yes	Poor	Not reported
Rice 2010[86] Dewan 2011[87]	Yes	No	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	Veterans Affairs research grants
Rich 1993[88]	Yes	Yes	No	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Poor	American Heart Association
Rich 1995[89]	No	No	No	Yes	No	Yes, No, No, No	Yes	Yes	Yes	Fair	National Institutes of Health
Riegel 2002[90]	No	No	Yes	Yes	Unclear	Yes, No, No, No	Yes	Unclear	Yes	Fair	Pfizer
Riegel 2006[91]	No	No	No	Yes	No	Yes, No, No, No	Yes	No	Yes	Fair	American Hospital Association
Ritz 2000[92]	No	No	No	Yes	Unclear	Yes, No, No, No	Yes (at 1 year) No (at 2 years)	Unclear	Yes	Poor	Not reported

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Rubenstein 2007[93]	Yes	No	Yes	Yes	Yes	Yes, No, No (re CM intervention adherence)/ Yes (for those who complied with recommended referrals), No	Yes	Yes	Yes	Good	Veterans Affairs: Health Services Research & Development; Los Angeles Geriatric Educational and Clinical Center
Sadowski 2009[94]	Yes	Yes	Yes	Yes	Yes	Yes, Yes, Yes, No	Yes	Yes	Yes	Good	Private foundations
Schore 1999, 1997, 2011[95-97]	Yes	Yes	Yes	Yes	No	Yes, No, Yes, No	Yes	Yes	Yes	Good	Health Care Financing Administration
Shea 2002, 2007, 2009[98-100] Palmas 2010[101] Trief 2006, 2007[102, 103] Izquierdo 2007[104]	Yes	No	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Fair	Supported by Cooperative Agreement 95-C-90998 from the Centers for Medicare and Medicaid Services
Sisk 2006[105]	Yes	Yes	Yes	Yes	Yes	Yes, No, No, No	Yes	Yes	Yes	Good	Agency for Healthcare Research and Quality
Sorensen 2003[106]	No	No	Yes	Yes	Yes	Yes, No, No, No	Yes	No	Yes	Fair	National Institute on Drug Abuse

Author Year	Randomization Adequate?	Allocation Concealment Adequate?	Groups Similar at Baseline (Intervention and Control)?	Eligibility Criteria Specified?	Outcome Assessors Masked?	Reporting of Attrition, Crossovers, Adherence, and Contamination?	Dropout Rate <20 Percent	Intention-to-treat Analysis?	Appropriate Statistical Analyses	Quality Rating	Funding
Vickrey 2006[107] Duru 2009[108]	Yes	Yes	Yes	Yes	Yes	Yes, Yes, Yes, No	No	Yes	Yes	Good	California HealthCare Foundation, State of California, Department of Aging, State of California, Department of Health Services, Alzheimer's Disease Education Initiative, Archstone Foundation, State of California, Department of Health Services
Wohl 2006[109] Sansom 2008[110]	Yes	Yes	Yes	Yes	Yes	Yes, Yes, Yes, Yes	No	Yes	Yes	Fair	Centers for Disease Control and Prevention; and University wide AIDS Research Program grant
Wolf 2004, 2007[111, 112]	Yes	Unclear	Yes	Yes	Not reported	Yes, No, Yes, No	No	Yes	Yes	Good	American Dietetic Association; National Institute of Diabetes and Digestive and Kidney Diseases; University of Virginia General Clinical Research Center

Table G-2. Quality Assessment of Observational Studies

Author Year	Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?	Were outcome assessors and/or data analysts blinded to treatment?	Did the article report attrition?	Did the study perform appropriate statistical analyses on potential confounders?	Is there important differential loss to follow-up or overall high loss to followup?	Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality Rating
Andersen 2007[113]	Unclear	Yes	Yes	No	No	No	Yes	Yes	Poor
Bird 2007[114] Bird 2010[115]	Yes	Yes	Yes	No	No	No	Not reported	Yes	Fair
Bouey 2000[116]	Yes	NA	No	No	No	No	Yes	Yes	Poor
Challis 2002[117]	No	Yes	Yes	No	Yes	No	No	Yes	Fair
Chi 2004[118]	No	Yes	Yes	No	Yes	No	Yes	Yes	Fair
Creason 2001[119]	No	Not reported	No	No	No	No	No	Yes	Poor
Curtis 2009[120]	Unclear	No	Yes	Unclear	No (N/A)	Yes	No	Yes	Fair
Dorr 2005[121] Dorr 2007[122]	Yes	Yes (CM/control) No (Registry)	Yes	No	No (N/A)	Yes	No	Yes	Good
Dorr 2008[123]	No	Yes	Yes	No	No	Yes	No	Yes	Good
Duke 2005[124]	No	Not relevant	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Poor
Fleishman 1991[125]	No	NA	Yes	No	Yes	Yes	No	Yes	Fair
Fletcher 2009[126]	Yes	Yes	No	No	No	No	No	Yes	Poor
Gravelle 2007[127]	Yes	Unclear	Yes	No	No	Yes	Unclear	Yes	Fair
Hammer 2001[128]	No	NA	No	No	No	No	No	Yes	Poor
Hebert 2003[129]	No	Not reported	No	No	No	No	Unclear	No	Poor
Huws 2008[130]	Yes	Not reported	No	No	No	No	No	Yes	Poor
Jowers 2000[131]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Fair
Keating 2008[132]	Yes	No	No	No	No	No	Unclear	Yes	Poor

Author Year	Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?	Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?	Were outcome assessors and/or data analysts blinded to treatment?	Did the article report attrition?	Did the study perform appropriate statistical analyses on potential confounders?	Is there important differential loss to follow-up or overall high loss to followup?	Were outcomes pre-specified and defined, and ascertained using accurate methods?	Quality Rating
Kruse 2010[133]	Yes	Yes	No	No	No	No	No	Yes	Fair
Kushel 2006[134]	Yes	Unclear	Yes	No	Yes	Yes	No	Yes	Good
Lehrman 2001[135]	Yes	NA	Yes	No	No	No	Unclear	Yes	Poor
Lin 2006[136]	Yes	Unclear	Yes	No	Yes	No	No	Yes	Poor
Lu 2006[137]	Yes	Yes	Unclear	No	N/A	Yes	NA	Yes	Fair
Luzinski 2008[138]	No	NA	No	No	No	No	Unclear	No	Poor
Mangura 2002[139]	Yes	No	Yes	No	Yes	Yes	No	Yes	Good
Morales-Asencio 2008[140]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Fair
Moran 2008[141]	Yes	NR	No	No	No	No	MR	Yes	Poor
Okin 2000[142]	No	N/A	No	No	No	No	No	Yes	Poor
Onder 2007 2008[143, 144]	Yes	Yes	No	No	No	Unclear	No	Yes	Poor
Picariello 2008[145]	Yes	No	Yes	No	No	Yes	No	Yes	Fair
Poole, 2001	Yes	No	Yes	No	No	No	No	Yes	Poor
Pugh 2009[146]	Yes	Yes	No	No	Yes	Yes	No	Yes	Fair
Schifalacqua 2000, 2004[147, 148]	Yes	NA	No	No	No	No	Unclear	No	Poor
Schraeder 2008[149]	Yes	Yes	Yes	Unclear	No	Yes	Unclear	Yes	Fair
Shah 2011[150]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Fair
Specht 2009[151]	Yes	No	Yes	No	Yes	Yes	Yes	Yes	Poor
Tatum 2008[152]	Unclear	NA	Yes	No	Unclear	No	Unclear	Unclear	Poor

Author Year	**Did the study attempt to enroll all (or a random sample of) patients meeting inclusion criteria, or a random sample (inception cohort)?**	**Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?**	**Did the study use accurate methods for ascertaining exposures, potential confounders, and outcomes?**	**Were outcome assessors and/or data analysts blinded to treatment?**	**Did the article report attrition?**	**Did the study perform appropriate statistical analyses on potential confounders?**	**Is there important differential loss to follow-up or overall high loss to followup?**	**Were outcomes pre-specified and defined, and ascertained using accurate methods?**	**Quality Rating**
Wetta-Hall 2007[153]	No	Yes	Yes	No	Yes	No	Yes	Yes	Poor
Wilson 2005[154]	No	Yes	Yes	Unclear	No	Yes	No	Yes	Fair

Appendix H. Strength of Evidence

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Table H-1. Strength of evidence for key outcomes in case management for older adults with one or more chronic diseases

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 5 trials Fitzgerald 1994[30] Latour 2006[51] Martin 2004[61] Newcomer 2004[78] Peikes 2009[82] 4 observational studies Bird 2010[115] Dorr 2008[123] Kruse 2010[133] Onder 2007[143]	Good	Consistent	Direct	Precise	35,797	Case management programs that serve patients with one or more chronic diseases do not reduce overall mortality.	High
Functional outcomes 3 trials Martin 2004[61] Newcomer 2004[78] Peikes 2009[82]	Good	Consistent	Direct	Precise	27,639	Case management programs that serve patients with one or more chronic diseases do not result in clinically important improvements in functional status.	High
Patient's perception (ratings) of care coordination 2 trials Peikes 2009[82] Wolff 2010[9]	Good	Consistent	Direct	Precise	19,252	Case management programs that serve patients with one or more chronic diseases increase patients' perceptions of the coordination of their care.	High

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Hospitalizations 7 trials Boult 2011[8] Fitzgerald 1994[30] Latour 2006[51] Martin 2004[61] Newcomer 2004[78] Peikes 2009[82] Schore 1999[95] 10 observational studies Bird 2007[114] Dorr 2008[123] Duke 2005[124] Keating 2008[132] Kruse 2010[133] Luzinski 2008[138] Moran 2008[141] Oliva 2010[83] Onder 2008[144] Schifalacqua 2000[147]	Good	Inconsistent	Direct	Precise	44,909	Case management programs that serve patients with one or more chronic diseases do not reduce overall rates of acute care hospitalizations.	Moderate
Nursing home admissions 4 trials Boult 2011[8] Latour 2006[51] Martin 2004[61] Newcomer 2004[78] 2 observational studies Onder 2008[144] Picarello 2008[145]	Fair	Inconsistent	Direct	Imprecise	15,212	Case management programs that serve patients with one or more chronic diseases reduce rates of nursing home admission.	Insufficient

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Medicare expenditures 2 trials Martin 2004[61] Peikes 2009[82] 1 observational study Luzinski 2008[138]	Good	Consistent	Direct	Imprecise	24,960	Case management programs that serve patients with one or more chronic diseases do not reduce Medicare expenditures.	High
Patient characteristics 1 trial Peikes 2009[82] 1 observational study Dorr 2008[123]	Fair	Consistent	Direct	Imprecise	21,834	Case management is more effective for reducing hospitalization rates among patients with greater disease burden.	Low
Intervention characteristics 4 trials Martin 2004[61] Newcomer 2004[78] Peikes 2009[82] Schore 1999[95]	Good	Consistent	Direct	Imprecise	30,021	Case management is more effective for preventing hospitalizations when case managers have greater personal contact with patients and physicians.	Low

Table H-2. Strength of evidence for key outcomes in case management for the frail elderly

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 4 trials Applebaum 2002[5] Bernabei 1998[7] Leung 2004[53] Rubenstein 2007[93] 1 observational study Morales-Asencio 2008[140]	Fair	Consistent	Direct	Precise	1,751	CM does not affect mortality in frail elders.	Low
Hospitalizations 7 studies Applebaum 2002[5] Bernabei 1998[7] Gagnon 1999[31] Leung 2004[53] Leung 2004[54] Marshall 1999[58] Rubenstein 2007[93] 4 observational studies Fletcher 2009[126] Hammer 2001[128] Hebert 2003 [129] Schraeder 2008[149]	Fair	Inconsistent	Direct	Precise	3,895	CM does not decrease acute hospitalizations in the frail elderly.	Low
Nursing home admissions 2 trials Applebaum 2002[5] Bernabei 1998[7]	Fair	Consistent	Direct	Imprecise	496	CM does not decrease nursing home admissions in the frail elderly.	Low
Costs of care 3 trials Applebaum 2002[5] Bernabei 1998[7] Marshall 1999[58] 3 observational studies Chi 2004[118] Fletcher 2009[126] Hammer 2001[128]	Fair	Inconsistent	Direct	Imprecise	1,802	CM does not affect the costs of care for the frail elderly.	Insufficient

Table H-3. Strength of evidence for key outcomes in case management for patients with dementia

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 10 trials Callahan 2006[17] Chien 2008[18] Chu 2000[20] Eggert 1991[24] Eloniemi-Sulkava 2001[26] Eloniemi-Sulkava 2009[27] Jansen 2011[44] Miller 1999[76] Mittelman 2006[65] Vickrey 2006[107] 2 observational studies Challis 2002[117] Specht 2009[151]	Good	Consistent	Direct	Precise	12,852	Patients with dementia who receive services from CM programs do not have lower mortality rates	High
Nursing home placement rates 8 trials Callahan 2006[17] Chu 2000[20] Eggert 1991[24] Eloniemi-Sulkava 2001[26] Eloniemi-Sulkava 2009[27] Mittelman 2006[65] Mittelman 2008[69] Newcomer 1999a[73] 1 observational study Challis 2002[117]	Fair	Inconsistent	Direct	Precise	9,534	No delay in NH placement at 24 months	Moderate

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Caregiver burden 8 trials Callahan 2006[17] Chien 2008[18] Chu 2000[20] Jansen 2011[44] Lam 2010[49] Mittelman 2006[65] Newcomer 1999a[73] Vickrey 2006[107] 2 observational studies Challis 2002[117] Specht 2009[151]	Fair	Consistent	Direct	Precise	9,421	Reduction in CG burden at 12 months	Moderate
Caregiver depression 3 trials Callahan 2006[17] Mittelman 2006[65] Mittelman 2008[69]	Good	Inconsistent	Direct	Precise	3,321	Reduction of CG depression at 2 years	Moderate
Guideline adherence 1 trial Vickrey 2006[107]	Fair	Consistent	Direct	Imprecise	354	Case management programs that focus on clinical guideline measures for care of dementia increase adherence to those measures	Low
Hospitalizations/ ED visits 2 trials Callahan 2006[17] Chien 2008[18] Clark 2004[22] 1 observational study Challis 2002[117]	Good	Inconsistent	Direct	Imprecise	347	No change in hospitalization rates at 12 mo.	Insufficient

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Health care expenditures 5 trials Eggert 1991[24] Eloniemi-Sulkava 2009[27] Mittelman 2006[65] Newcomer 1999a[73] Vickrey 2006[107] 1 observational study Challis 2002[117]	Good	Consistent	Direct	Imprecise	6,798	Case management does not reduce health care expenditures for patients with dementia.	Moderate
Intervention characteristics 1 trial Mittelman 2006[65]	Fair	Consistent	Direct	Imprecise	406	Case management programs that serve patients with dementia who have in-home spouse caregivers and continue services for longer than two years are more effective for delaying nursing home placement than programs providing services for 2 years or less.	Low
Outpatient visits 3 trials Callahan 2006[17] Clark 2004[22] Jansen 2011[44] 1 observational study Challis 2002[117]	Good	Inconsistent	Direct	Imprecise	358	CM does not change the use of physician visits for patients with dementia.	Insufficient

Table H-4. Strength of evidence for key outcomes in case management for patients with congestive heart failure

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 6 trials Debusk 2004[23]; Jaarsma 2008[43] Kasper 2002[46] Pugh 2001[85] Rich 1995[89] Riegel 2002[155]	Good	Consistent	Direct	Imprecise	2,383	Case management programs that serve adults with CHF do not reduce mortality.	Low
Quality of life 6 trials Kasper 2002[46] Peters-Klimm 2010[84] Pugh 2001[85] Rich 1995[89] Riegel 2006[91] Sisk 2006[105]	Good	Inconsistent	Direct	Imprecise	1,280	Case management programs that serve patients with CHF improve CHF-related quality of life.	Low
Patient satisfaction 3 trials Laramee 2003[50] Peters-Klimm 2010[84] Riegel 2002[155]	Fair	Consistent	Direct	Imprecise	844	Case management programs that serve patients with CHF increase patient satisfaction.	Moderate
Patient adherence to self-management behaviors 3 trials Kasper 2002[46] Laramee 2003[50] Peters-Klimm 2010[84]	Good	Consistent	Direct	Imprecise	686	Case management increases patients' adherence to self-management behaviors recommended for patients with CHF.	Moderate
Guideline adherence 3 trials Debusk 2004[23] Kasper 2002[46] Laramee 2003[50]	Good	Inconsistent	Direct	Imprecise	949	CM does not increase the use of recommended medications for CHF	Insufficient

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
All-cause hospitalizations 10 trials Debusk 2004[23] Jaarsma 2008[43] Kasper 2002[46] Laramee 2003[50] Pugh 2001[85] Rich 1993[88] Rich 1995[89] Riegel 2002[155] Riegel 2006[91] Sisk 2006[105] 1 observational study Creason 2001[119]	Good	Inconsistent	Direct	Imprecise	3,540	Case management reduces hospitalization rates among CHF patients.	Low

Table H-5. Strength of evidence for key outcomes in case management for patients with diabetes mellitus

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 1 trial Shea 2009[100]	Poor	Unknown (single study)	Direct	Precise	1,417	No mortality benefit identified	Low
Quality of life 2 trials Babamoto 2009[6] Wolf 2004[111]	Poor	Inconsistent	Indirect	Imprecise	465	No quality of life benefit identified	Insufficient
Improvement in HgA1c 9 trials Babamoto 2009[6] Brown 2011[14] California Medi-Cal 2004[15] Gary 2003[33] Gary 2009[36] Ishani 2011[42] Krein 2004[47] Shea 2002[98] Wolf 2004[111] 3 observational studies Curtis 2009[120] Dorr 2005[121] Wilson 2005[154]	Good	Inconsistent	Indirect	Precise	12,994	CM improves HgA1C levels.	Moderate
Improvement in blood pressure 5 trials California Medi-Cal 2004[15] Gary 2009[36] Ishani 2011[42] Krein 2004[47] Shea 2002[98]	Fair	Inconsistent	Indirect	Imprecise	2,916	No clear benefit identified	Insufficient

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Improvement in LDL cholesterol 6 trials California Medi-Cal 2004[15] Gary 2009[36] Ishani 2011[42] Krein 2004[47] Shea 2002[98] Wolf 2004[111]	Good	Inconsistent	Indirect	Precise	3,063	No effect on LDL levels.	Moderate
Improvement in HDL cholesterol 3 trials California Medi-Cal 2004[15] Gary 2009[36] Wolf 2004[111]	Fair	Consistent	Indirect	Precise	1,006	No benefit identified	Moderate
Improvement in total cholesterol 3 trials California Medi-Cal 2004[15] Gary 2009[36] Wolf 2004[111]	Fair	Consistent	Indirect	Precise	1,006	No benefit identified	Moderate
Improvement in triglycerides 2 trials California Medi-Cal 2004[15] Gary 2003[33] Wolf 2004[111]	Fair	Inconsistent	Indirect	Imprecise	650	No benefit identified	Low
Improvement in BMI/weight 5 trials Babamoto 2009[6] Brown 2011[14] California Medi-Cal 2004[15] Gary 2009[36] Wolf 2004[111]	Fair	Inconsistent	Indirect	Precise	1,407	No effect of CM on BMI or weight	Moderate
Emergency department visits 2 trials Babamoto 2009[6] Gary 2009[36]	Poor	Inconsistent	Direct	Precise	860	No clear benefit identified	Insufficient

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Hospitalizations 2 trials Gary 2009[36] Krein 2004[47]	Poor	Consistent	Direct	Imprecise	751	No reduction in hospitalizations	Low

Table H-6. Strength of evidence for key outcomes in case management for patients with cancer

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Cancer-related symptoms 4 trials Goodwin 2003[37] McCorkle 1989[63] Moore 2002[71] Mor 1995[72]	Fair	Inconsistent	Direct	Imprecise	921	Case management improves selected cancer-related symptoms and functioning (physical, psychosocial, and emotional).	Low
Quality of life 4 trials McCorkle 1989[63] Moore 2002[71] Mor 1995[72] Ritz 2000[92]	Fair	Inconsistent	Direct	Imprecise	796	Case management does not improve overall quality of life or survival.	Low
Patient satisfaction with care 4 studies Engelhardt 2006[28] Goodwin 2003[37] Moore 2002[71] Mor 1995[72]	Fair	Consistent	Direct	Imprecise	1030	Case management programs that serve patients with cancer improve satisfaction with care.	Moderate
Patient receipt of appropriate treatment 2 trials Goodwin 2003[37] Moore 2002[71]	Fair	Consistent	Direct	Imprecise	538	Case management programs that serve patients with cancer increase the receipt of appropriate (i.e., guideline-recommended) cancer treatment.	Moderate
Overall cost and health care utilization 5 trials Engelhardt 2006[28] McCorkle 1989[63] Moore 2002[71] Mor 1995[72] Ritz 2000[92]	Fair	Inconsistent	Direct	Imprecise	1042	Case management programs that serve patients with cancer have little effect on overall health care utilization and cost of care.	Low

Outcome, Number of Studies	**Quality (Good, Fair or Poor)**	**Consistency (Consistent or Inconsistent)**	**Directness (Direct or Indirect)**	**Precision (Precise or Imprecise)**	**Number of Subjects**	**Summary of Findings**	**Strength of Evidence**
Intensity, integration, training, protocols 3 trials Goodwin 2003 Moore 2002 Engelhardt 2006	Fair	Consistent	Indirect	Imprecise	813	CM programs that serve patients with cancer are more effective when the CM is more intensive, better integrated with patients' usual care providers, and employs preintervention training and care protocols.	Low

Table H-7. Strength of evidence for key outcomes in case management for patients with serious chronic infections

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 2 trials Nickel 1996[79] Sorenson 2003[106]	Poor	Consistent	Direct	Imprecise	247	CM does not improve survival among patients with HIV infection	Low
Quality of life 3 trials Husbands 2007[41] Nickel 1996[79] Sorenson 2003[106] 2 observational studies Bouey 2000[116] Pugh 2009[146]	Poor	Inconsistent	Indirect	Imprecise	506	CM results in improvements in QOL measures in the HIV/AIDS population.	Insufficient
TB treatment 2 trials Hsieh 2008[40] Nyamathi 2006[80] 2 observational studies Lin 2006[136] Mangura 2002[139]	Fair	Consistent	Direct	Precise	1,302	Short-term CM management programs that emphasize medication adherence improve rates of successful treatment for TB in vulnerable populations.	Moderate
HIV treatment 1 trial Wohl 2006[109] 1 observational study Kushel 2006[134]	Fair	Inconsistent	Direct	Imprecise	474	Evidence is insufficient to determine whether CM improves antiviral treatment of HIV infection.	Insufficient
Risk behaviors 2 trials McCoy 1992[64] Sorenson 2003[106]	Poor	Inconsistent	Indirect	Imprecise	300	Evidence is insufficient to determine whether CM reduces risk behaviors.	Insufficient
Cost of care 2 trials Husbands 2007[41] Wohl 2006[109]	Fair	Inconsistent	Indirect	Imprecise	273	CM lowers overall health care costs in the HIV/AIDS population.	Insufficient

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Clinic appointment rates 1 trial Wohl 2006[109] 2 observational studies Andersen 2007[113] Kushel 2006[134]	Fair	Inconsistent	Indirect	Imprecise	525	No clear benefit.	Low
Intervention characteristics 1 trial Hsieh 2008[40] 1 observational study Kushel 2006[134]	Fair	Inconsistent	Direct	Imprecise	376	Evidence is insufficient to determine whether more frequent visits by a case manager are associated with higher rates of clinical improvement in HIV and TB infections.	Insufficient

Table H-8. Strength of evidence for key outcomes in case management for patients with other medical problems

Outcome, Number of Studies	Quality (Good, Fair or Poor)	Consistency (Consistent or Inconsistent)	Directness (Direct or Indirect)	Precision (Precise or Imprecise)	Number of Subjects	Summary of Findings	Strength of Evidence
Mortality 3 trials Bourbeau 2003[12] Fan 2012[29] Rice 2010[86]	Good	Inconsistent	Direct	Imprecise	1,250	Evidence is insufficient to assess the effect of CM on mortality among patients with severe COPD.	Insufficient
Physical functioning 3 trials Mayo 2008[62] Allen 2002[4] Chow 2010[19]	Fair	Inconsistent	Direct	Imprecise		Evidence is insufficient to assess the effect of CM on physical functioning in patients who have had a stroke or are receiving peritoneal dialysis.	Insufficient
ED visits 3 trials Bourbeau 2003[12] Mayo 2008[62] Rice 2010[86] Sadowski 2009[94]	Good	Consistent	Direct	Imprecise	1,419	CM reduces ED visits for those with COPD and in the homeless population.	Low
Hospitalizations 3 trials Bourbeau 2003[12] Fan 2012[29] Mayo 2008[62] Rice 2010[86]	Good	Inconsistent	Direct	Imprecise	1,449	CM reduces hospitalizations for acute clinical exacerbations.	Insufficient

Appendix I. Evidence Tables

Evidence Table 1. Trials of Case Management for Older Adults with One or More Chronic Diseases

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Boult 2011[8] Boult 2008[10] Boyd 2010[11] Wolff 2010[9] (Good)	To measure the effect of guided care teams on multi morbid older patients' use of health services.	≥65 years or older and at high risk of using health services heavily during the following year, as estimated by the claims based hierarchical condition category predictive model in the highest quartile.	NR	Cluster randomized trial, 20 months	Mean age: 77.5 years Age range: 66-106 55% Female 51% White 55% reported have inadequate finances	81% Hypertension; 19% CHF; 21% COPD, asthma or emphysema; 49% diabetes; 27% cancer (not skin)	42% self-reported fair/poor health, 4.3 average of chronic conditions

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Fitzgerald 1994[30] (Fair)	Assess the efficacy of case managers to increase outpatient general internal medicine primary care contacts and reduce subsequent hospital readmissions and emergency department visits among men discharged from the hospital. Hypothesized that patients with case manager intervention would have more post discharge general medicine clinic visits and fewer subsequent nonelective hospital admissions and days of hospitalization than patients with usual care.	Male Discharged from general medicine services between 11/01/1988 and 10/31/1990; 45+ years; received primary care in the hospital's clinics; lived in the primary service area of the hospital; access to a telephone	Lived outside the primary service area; considered terminally ill.	Randomized trial, followed up to 12 months	Age: intervention 64.4±7.7 comparator 64.6±7.7 p=0.76 Race % white: intervention 82% comparator 82% p=0.99 Family income ≥ $14,000/year %: intervention 31% comparator 24% p=0.12	COPD, hypertension, diabetes, heart disease, alcohol dependency	Number of comorbidities, high risk for rehospitalization.

Author, Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of Intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Description of Factors of Complex Care Needs**
Latour 2006[51] Latour 2007[156] (Fair)	To determine the impact of post-discharge, nurse-led, home-based, case management intervention on the resource utilization, quality of life and health outcomes.	Admitted to the departments of internal medicine, gastroenterology, pulmonology, and/or cardiology; admitted at least once (≥2 nights) in the previous 5 years; resident of the municipality of Amsterdam; age ≥ 18 years; able to speak Dutch or English.	Discharged to non-independent living accommodation; had a MMSE score of ≤ 21 (and no relative who help completing questionnaires); or planned readmissions (e.g., chemotherapy visits).	Randomized trial, 24 weeks	Age Mean: 64 years 50% Female Race: NR	General medical outpatients 1) Endocrine, 6.8% Circulation, 30.6% Respiratory,17% GI, 20.4% Note: determined by medical ICD-9 codes 2) Mean total depression score: 7 (Did not report those with depression diagnosis)	NR
Martin 2004[61] (Good)	To examine the effect of population- based disease management and case management on resource use, self-reported health status, and member satisfaction within an HMO, Medicare Plus Choice. Implemented the Senior Life Management Program.	≥65 years, signed consent on their health plan enrollment form to participate, and continuously enrolled with the health plan for all of 1999.	NR	Randomized controlled open trial of case management and population-based disease management, 18 months Note: 38.5% (1640 patients) evaluate for CM.	Mean age: 73 years 53% Female Race: NR	Medicare beneficiaries ≥65 years 1) NR 2) NR	NR

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Newcomer 2004[78] (Fair)	To report the effectiveness of a program intended to complement the primary care of high-risk geriatric patients using nurse case managers. Hypothesis was that those in ECM would have lower utilization and expenditures and higher health status than those in usual care	Active PacifiCare member as of 1/1/2000; age ≥ 80 years or age ≥ 65 with at least one qualifying condition (i.e., COPD, CHF, coronary disease, diabetes) and receiving care from a Sharp Health Care clinic.	Living in nursing home, Alzheimer's facility, or hospice; end-stage renal diseases; histories of organ transplants at the time of baseline data collection; using VA or other military-connected health care benefits	Randomized trial, 12 months Article reports of the Elders in Managed Care Program of one site.	Age: 70% ≥ 80 years Gender: 60% female Race: 88% White Education: 23% more than high school Income: 70% ≤ $20,000/year	High-risk elderly 1) Coronary Artery Disease: 66% Diabetes: 25% 2) Depression: 7%	# of chronic conditions: a) at least 2 =7% b) 3 or more =2%
Peikes 2009 (a)[82] Site: Carle - Integrated Delivery System (Good)	MCCD- comparison of 15 programs describing to determine whether care coordination programs improved quality of care for chronically ill Eligible-fee-for-service Medicare beneficiaries and reduced hospitalizations/ expenditures	Medicare beneficiaries (primarily > 65 years old) covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program.	End-stage renal disease, long-term nursing home, unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.), excluded patients with ESRD.	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 86% ≥ 65 years Gender: 47.5% male Race: 3.7% Black/Non-Hispanic Medicaid: 5.3% Education: 14% less than high school	CAD 45.5% CHF 27.7% Diabetes 28.5% COPD 21.1% Cancer 20.8% Stroke 13.5% 1) Depression 13.1% 2) Dementia 5.1%	Rural location Hospitalization within the year before random assignment for target diagnosis or other diagnosis Medicaid (proxy for poverty): 5%

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Peikes 2009 (b)[82] Site: CorSolutions - Provider of disease Care/Coordinated Care/QI services (Good)	See above	Medicare beneficiaries (primarily > 65 years old)covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease Long-term nursing home Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 72.8% ≥ 65 years Gender: 38.1% male Race: 30.5% Black/Non-Hispanic Medicaid: 27.9% Education: 36.3% less than high school	CAD 83.5% CHF 96.4% Diabetes 55% COPD 49.8% Cancer 16.9% Stroke 40.1% 1) Dementia 12.3% 2) Depression 21.9%	Hospitalization within the year before random assignment for target diagnosis or other diagnosis Medicaid (proxy for poverty): 28%
Peikes 2009 (c)[82] Site: Washington University - Academic Medical Center (Good)	See above	Medicare beneficiaries (primarily > 65 years old)covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 63.5% ≥ 65 years Gender: 45.3% male Race: 36.8% Black/Non-Hispanic Medicaid:19.1 % Education: 25.3% less than high school	CAD 54.8% CHF 41.5% Diabetes 42.2% COPD 31.4% Cancer 35.9% Stroke 23.7% 1) Dementia 11.5% 2) Depression 23.4%	Hospitalization within the year before random assignment for target diagnosis or other diagnosis Medicaid (proxy for poverty):19%
Peikes 2009 (d)[82] Site: Avera - Community Hospital (Good)	See above	Medicare beneficiaries (primarily > 65 years old)covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	Age < 65 years End-stage renal disease Long-term nursing home SM: unable to learn self management (serious mental illness or dementia Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 80% ≥ 65 years Gender:52 % male Race: 0.1% Black/Non-Hispanic Medicaid:8.2 % Education: 34% less than high school	CAD 75.4% CHF 96.7% Diabetes 40% COPD 42.5% Cancer 23.7% Stroke 21.1% 1) Dementia 4% 2) Depression 14.5%	Rural location Medicaid (proxy for poverty): 8%

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Peikes 2009 (e)[82] Site: CenVaNet - Provider of disease Care/Coordinated Care/QI services (Good)	See above	Medicare beneficiaries (primarily > 65 years old) covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	Age < 65 years End-stage renal disease SM: unable to learn self management (serious mental illness or dementia Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 87% ≥ 65 years Gender: 56.5% male Race: 14.9% Black/Non-Hispanic Medicaid: 8.2% Education: 34% less than high school	CAD 73.4% CHF 47.8% Diabetes 50.7% COPD 27.9% Cancer 27.7% Stroke 26.4% 1) Dementia 4.8% 2) Depression 10.9%	Medicaid (proxy for poverty): 5%
Peikes 2009 (f)[82] Site: Charlestown - Retirement Community (Good)	See above	Medicare beneficiaries (primarily > 65 years old) covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease Long-term nursing home Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 56.5% ≥ 65 years Gender: 34.5% male Race: 0.5% Black/Non-Hispanic Medicaid: 0% Education: 10.2% less than high school	CAD 54.9% CHF 43.4% Diabetes 25.1% COPD 36.4% Cancer 32.3% Stroke 32% 1) Dementia 8.4% 2) Depression 18.7%	Medicaid (proxy for poverty): 0%

Author, Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of Intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Description of Factors of Complex Care Needs**
Peikes 2009 (g)[82] Site: Health Quality Partners - Provider of disease Care/Coordinated Care/QI services (Good)	See above	Medicare beneficiaries (primarily > 65 years old) covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	Age < 65 years End-stage renal disease Long-term nursing home SM: unable to learn self management (serious mental illness or dementia Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 93% ≥ 65 years Gender: 39.7% male Race: 0.8% Black/Non-Hispanic Medicaid: 1.8% Education: 1.6% less than high school	CAD 34% CHF 10.6% Diabetes 24.3% COPD 12.8% Cancer 22.2% Stroke 14.2% 1) Dementia 1.8% 2) Depression 8.3%	Hospitalization within the year before random assignment for target diagnosis or other diagnosis Medicaid (proxy for poverty): 2% rural location
Peikes 2009 (h)[82] Site: Medical Care Development - Community Hospital (Good)	See above	Medicare beneficiaries (primarily > 65 years old) covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease SM: unable to learn self management (serious mental illness or dementia Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 82.4% ≥ 65 years Gender: 50.6% male Race: 0% Black/Non-Hispanic Medicaid: 20.7% Education: 32% less than high school	CAD 78.3% CHF 48.5% Diabetes 41.6% COPD 31.8% Cancer 19% Stroke 17.3% 1) Dementia 2.3% 2) Depression 16.9%	Medicaid (proxy for poverty): 21%

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Peikes 2009 (i)[82] Site: Mercy Medical Center - Community Hospital (Good)	See above	Medicare beneficiaries (primarily > 65 years old)covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease Long-term nursing home Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age:78.6 % ≥ 65 years Gender: 54.6% male Race: 0.1% Black/Non-Hispanic Medicaid:11.6 % Education: 29.7% less than high school	CAD 64.1% CHF 60.1% Diabetes 33.3% COPD 52.9% Cancer 23.6% Stroke 26.1% 1) Dementia 6.3% 2) Depression 24.2%	Hospitalization within the year before random assignment for target diagnosis or other diagnosis Rural location Medicaid (proxy for poverty): 12%
Peikes 2009 (j)[82] Site: Qmed - Provider of disease Care/Coordinated Care/QI services (Good)	See above	Medicare beneficiaries (primarily > 65 years old)covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 86.5% ≥ 65 years Gender: 44.5% male Race: 5.1% Black/Non-Hispanic Medicaid:13.7 % Education: 19.7% less than high school	CAD 48.6% CHF 18.1% Diabetes 25.5% COPD 14.3% Cancer 19.8% Stroke 14% 1) Dementia 1.6% 2) Depression 9.5%	Hospitalization within the year before random assignment for target diagnosis or other diagnosis Medicaid (proxy for poverty): 14%
Peikes 2009 (k)[82] Site: Georgetown - Academic Medical Center (Good)	See above	Medicare beneficiaries (primarily > 65 years old)covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease Long-term nursing home Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 82.6% ≥ 65 years Gender: 44.8% male Race: 63% Black/Non-Hispanic Medicaid: 21.3% Education: NA	CAD 80.9% CHF 96.1% Diabetes 54.8% COPD 40% Cancer 23.9% Stroke 28.3% 1) Dementia 12.2% 2) Depression 14.3%	Hospitalization within the year before random assignment for target diagnosis or other diagnosis Medicaid (proxy for poverty): 21%

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Peikes 2009 (I)[82] Site: Quality Oncology - Provider of disease Care/Coordinated Care/QI services (Good)	See above	Medicare beneficiaries (primarily > 65 years old) covered by FFS/traditional Medicare and had one or more of the chronic conditions targeted by the program	End-stage renal disease Long-term nursing home Unusually complex (human immunodeficiency virus/AIDS, transplant recipient or candidate, or terminally ill.)	Randomized trial - coordinated care program treatment vs. usual care, 3 years	Age: 80.1% ≥ 65 years Gender: 45.5% male Race: 8.5% Black/Non-Hispanic Medicaid:13.7 % Education: NA	CAD 46% CHF 18% Diabetes 25.1% COPD 32.2% Cancer 94.3% Stroke 14.2% 1) Dementia 5.7% 2) Depression 10.9%	Medicaid (proxy for poverty): 14%

Author, Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Description of Factors of Complex Care Needs
Schore 1999[95] Schore 1997[96] Schore 2011[97] (Good)	To examine the HCFA case management demonstration projects' success in attracting clients, features and costs of case management, impact on client self-care and symptoms, and use of services	Project I: Diagnosis of congestive heart failure Project P: Diagnosis of congestive heart failure or chronic obstructive pulmonary disease Project H: Diagnosis of congestive heart failure, chronic obstructive pulmonary disease, ischemic heart disease, stroke, pneumonia and sepsis, major joint replacement, nutritional and metabolic problems (including diabetes, dehydration, and decubitus ulcers), or cancer	Project I: out of state beneficiaries, comorbid conditions that would make education-focused intervention impractical Project P: "reviewed charts with specially developed clinical criteria" (unspecified) Project H: patients living more than 25 miles from hospital, no primary physician on staff, and a prognosis of less than 6 months survival	Randomized trial	Mean age: 77 years (all projects) Sex: Over 50% female (all projects) Race/Ethnicity: Projects I and P >90% White, Project H ~75% White	Project I: Diagnosis of congestive heart failure Project P: Diagnosis of congestive heart failure or chronic obstructive pulmonary disease Project H: Diagnosis of congestive heart failure, chronic obstructive pulmonary disease, ischemic heart disease, stroke, pneumonia and sepsis, major joint replacement, nutritional and metabolic problems (including diabetes, dehydration, and decubitus ulcers), or cancer	Number of secondary diagnoses at last hospitalization before enrollment, intervention vs. control Project I: 3.8 vs. 3.9 Project P: 4.9 vs. 5.1 Project H: 3.1 vs. 3.2

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Boult 2011[8] Boult 2008[10] Boyd 2010[11] Wolff 2010[9] (Good)	18% receiving Medicare, Kaiser, TRICARE/ US Family Health Plan	Yes, Kaiser of the Mid-Atlantic states, Johns Hopkins Community Physicians and MedStar Physician Partners	RNs who completed a course in guided care nursing.	Guided care nurse working in partnership with patients' primary care physicians provided the following: comprehensive assessment, evidence-based care planning, monthly monitoring of symptoms and adherence, transitional care, coordination of health care professionals, support for self management, support for family caregivers, and enhanced access to community services.	Yes, completed course in guided care nursing.	Primary care clinic	Visits and phone	50 to 60 patients	NR
Fitzgerald 1994[30] (Fair)	NR	NR	Nurse case managers	Protocol-driven, multifaceted intervention designed to 1) meet patients' medical, social support, and service needs; 2) improve access to care; 3) educate patients about their conditions and medications; 4) increase contacts with their care system; and 5) improve continuity and communication from the inpatient to the outpatient setting.	NR	General medicine clinic	Face-to-face at each scheduled general medicine clinic visit and over the telephone during regular monthly consultations.	NR	As needed, for consultation after ED visit, appointment followups, etc.

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Latour 2006[51] Latour 2007[156] (Fair)	National Health Care System, Netherlands	See previous cell	NR, refers to CM as trained nurse-specialist	Within 3–10 working days after hospital discharge CM, visited the patient at home to determine patient status, ADLs, and IADLs to determine a care plan. Tailored intervention to patient and may have included: referring patients to appropriate allied health and medical services, lifestyle recommendations, education in adherence and medication monitoring, telephone followup and CM made home visits at least every 2 months and more in necessary.	NR	Home, clinic and phone	See previous cell	NR	<u>Homes visits</u>: 72% of the initial visit lasted between 30-60 minutes. 52% of subsequent visits lasted 30–60 minutes (45.5% <30 minutes) <u>Clinic:</u> 79% 1-30 minutes in duration *Telephone:* 270 contacts (151 to patients, 119 to provider), Duration range: 5-10 minutes

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Martin 2004[61] (Good)	Medicare	Medicare Choice Plus, HMO	Nurse care coordinator, no other details	A nurse care coordinator was responsible for outbound contact to those in complex case management communicating with treating physicians and staff, following up on hospitalizations and ED visits, and arranging for home health care and equipment through the PCP. Overall, program included creation of a CM electronic record, comprehensive, periodic health status assessments, telephonic CM, patient education materials and coordination with community services.	NR	Clinic, phone	NR	50 to 70 patients per team	NR

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Newcomer 2004[78] (Fair)	PacifiCare	Yes, PacifiCare	6 NCMs, 2 per medical group monitored for quality through review and consultation with peers.	CM intervention included, health risk screening and a care plan, assessment, monitoring status of the patient and implementing care plan (including care plan goals), support for caregivers, treatment of adherence monitoring and careful attention of CM during times of transition (e.g., hospital to home). Initial assessment included a home visit if necessary. CM also determined if patients were of high, medium, or low risk. Depending on patient needs and risk, patients were given an active or monitoring status.	NR	Sharp Health Care Clinic	Telephone. Average contact hours with CM were 7.7 per year for each patient.	250 patients with 60 actively managed at any one time.	If active status, patients contacted via phone at least monthly and more likely weekly. For monitoring status, patients were contacted every 60-90 days.

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (a)[82] Site: Carle - Integrated Delivery System (Good)	Medicare	No (fee for service) (4/15) Yes, (not specified)	Care coordinator - Registered Nurse	Intervention goals collectively: (1) improving adherence to treatment recommendations through patient education (2) improving communication and coordination, including identifying worsening symptoms before they required hospital care (3) improving physician practice (4) increasing access to support. Services programs educating patients to improve adherence to medication, diet, exercise and self-care regimens standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator. Focus on increasing physician adherence to evidence-based or guide-line based care	Three-week orientation; directed observation by supervisor	Integrated home delivery system, (multiple primary care and specialty clinics)	Telephone	1:155	Weekly to quarterly by telephone; in person as necessary

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (b)[82] Site: CorSolutions - Provider of disease Care/ Coordinated Care/ QI services (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator Focus on increasing physician adherence to evidence-based or guide-line based care	Three-week orientation	Commercial disease management company, care coordination service centers	Telephone	1:145	Every 2 weeks for first few months; monthly thereafter
Peikes 2009 (c)[82] Site: Washington University - Academic Medical Center (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator Telemonitoring	Two-day orientation	Academic medical center	Telephone	1:50 for local 1:100 for telephone	At least every 6 weeks

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (d)[82] Site: Avera - Community Hospital (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator Telemonitoring	Orientation by supervisor	Community hospital	Telephone	1:88	Weekly for first 6 months; twice monthly thereafter
Peikes 2009 (e)[82] Site: CenVaNet - Provider of disease Care/ Coordinated Care/ QI services (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator Focus on increasing physician adherence to evidence-based or guide-line based care Limited telemonitoring	Two-week orientation; directed observation by supervisor	Commercial disease management company, care coordination service centers	Telephone	1:70	At least monthly by telephone; at least every 6 months in person

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (f)[82] Site: Charlestown - Retirement Community (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Orientation by supervisor; worked with experienced mentor	Retirement community	Telephone	1:60	Daily to monthly
Peikes 2009 (g)[82] Site: Health Quality Partners - Provider of disease Care/ Coordinated Care/ QI services (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Orientation; role playing; supervisor mentors	Commercial disease management company, care coordination service centers	Telephone	1:90	At least monthly

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (h)[82] Site: Medical Care Development - Community Hospital (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Orientation; worked with experienced mentor	Community hospital	Telephone	1:70	Three or four times during first month; monthly thereafter
Peikes 2009 (i)[82] Site: Mercy Medical Center - Community Hospital (Good)	Medicare	No	Care coordinator - Registered Nurse with BSN	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Four-week orientation	Community hospital	Primary: In Person + Telephone	1:50	At least monthly

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (j)[82] Site: Qmed - Provider of disease Care/ Coordinated Care/ QI services (Good)	Medicare	No	Care coordinator - Licensed Practical Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Orientation	Care coordination service centers	Telephone	1:200	Every other month
Peikes 2009 (k)[82] Site: Georgetown - Academic Medical Center (Good)	Medicare	No	Care coordinator - registered nurse with BSN	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Worked with experienced mentor for 6 to 8 months	Academic medical center	Telephone	1:36	At least monthly

Author, Year (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Pre-intervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Peikes 2009 (I)[82] Site: Quality Oncology - Provider of disease Care/ Coordinated Care/ QI services (Good)	Medicare	No	Care coordinator - Registered Nurse	Programs educating patients to improve adherence to medication, diet, exercise and self-care regimens Standardized curricula and evaluation of educational effectiveness via monitoring clinical indicators, assessing patient knowledge and self-reported behavior, and having patients repeat/explain information back to coordinator	Two-week orientation; close oversight by supervisor for 6 months	Commercial disease manage-ment company, care coordination service centers	Telephone	1:40	Weekly to monthly
Schore 1999[95] Schore 1997[96] Schore 2011[97] (Good)	Medicare	No	Project I: Nurses Project P: Nurses Project H: One social worker and two nurses	Case management included assessment, service coordination, self-care education, and emotional support	NR	Project I: NR Project P: NR Project H: Hospital	Project I: Telephone Project P: Telephone Project H: In-person contact	Project I: 556 Project P: 376 Project H: 209	NR

Author, Year (Quality)	**Location of Face-to-face Time**	**Planning and Assessment**	**Patient Education**	**Self-Management Support**	**Coordination of Services**	**Medical Monitoring and Adjustment**	**Integrated within Primary Care**	**Health Information Technology**	**Comparator**
Boult 2011[8] Boult 2008[10] Boyd 2010[11] Wolff 2010[9] (Good)	NR	Yes	NR	NR	Yes	Yes, monitored medications but did not adjust.	Yes	No	Usual care group continued to receive care from their established primary care physicians.
Fitzgerald 1994[30] (Fair)	General medicine clinic	NR	Nurse case manger assigned to each intervention patient at hospital discharge. The nurse case manager's role included instructing patients about medical problems, facilitating access to usual care, and identifying and fulfilling unmet social medical needs with standard or alternative sources of care. The case managers counseled their assigned patients about their medical problems. This included discussing, in a standardized format, early warning symptoms and signs commonly associated with the patient's medical conditions, symptoms of possible adverse drug reactions, and appropriate prescribed therapies, such as diet and medication.	NR	Yes, CM scheduled appointments and tended to need for social support.	Medical monitoring but nurse case manager did not make adjustments; physician was consulted when adjustments were necessary.	Yes	NR	Usual care

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Latour 2006[51] Latour 2007[156] (Fair)	See previous cell, both home and clinic visits	Care plan considered the following interventions: family support (e.g., structuring, supportive interventions); mediation between patient and medical specialists or allied health professionals and referral; and improvement of compliance with medication, physical exercises, diet, smoking, and alcohol recommendations.	NR	Unclear though states, "self-management was promoted."	Yes, referring to allied health and other medical professionals. *Note: wrote letters to GP at the conclusion of intervention (unclear that they reported during the study though report 69 letters written to GP).*	Unclear though reported intervention could include adherence and monitoring of medication. No medical adjustments	Yes, CM gave provider results at the end of study.	NR	Usual care provided according to the recommendation of the medical specialist and the GP (did not include CM).

Author, Year (Quality)	Location of Face-to-face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health Information Technology	Comparator
Martin 2004[61] (Good)	NR	Yes, included comprehensive, periodic health assessments.	Yes, provided patient education materials (no other details provided).	NR	Yes, coordinated with PCP and arranged home health care.	NR for monitoring. For adjustment no, but IT system did monitor use of certain medications known to be contraindicated for use in the elderly. When filling one of these prescriptions, generated an alert to prescribing physician asking to reconsider/ check order.	Yes	Intervention included "Master Console," an electronic health care management system that delivered info to case management staff. Alerted team to clinical status of patient and any changes that may require case management.	No specifics regarding usual care.
Newcomer 2004[78] (Fair)	During clinic visits, average=25 minutes per visit.	A care plan was developed to address needs and problems of the patients and set attainable goals.	Yes, CM provided education materials on chronic illnesses, advice and discussed high risk behaviors with patients.	Presumably yes, but NR.	Yes, as needed, patients and family members give appropriate referrals (e.g., physical therapy), training in navigating the health plan and help with benefits/coverage, as well as community based programs and support groups. Also, CM coordinated with PCP through letters and phone calls when needed (See Notes).	Unclear, but stated this: CM . . . "had no direct role in chronic disease treatment management (such as periodic monitoring of weight gain or laboratory values)." No adjustment.	Yes, at the same clinic and CM communicated with PCP.	No	Usual care provided by PacifiCare but depended on hospital, ED, etc.

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Peikes 2009 (a)[82] Site: Carle - Integrated Delivery System (Good)	No, primarily telephone	Comprehensive patient assessment: review of medical and health service use history, current health, medications, health habits, functional status, and finances	Nurses educated patients to improve medication, diet, exercise, and self-care regimen adherence; materials part of electronic databases	Patient education based on behavioral change model	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Did monitor medications. Program coordinators called physicians to suggest medication adjustments.	Yes, program adminis-trators worked with physicians	Yes, Carle Care Management Information System	Control groups received "usual care," that did not include care coordinators
Peikes 2009 (b)[82] Site: CorSolutions - Provider of disease Care/ Coordinated Care/ QI services (Good)	In person patient assessment	Same as above	Same as above	Same as above	No coordination of additional services	Same as above.	No	CorSolutions CorConnect	same as above

Author, Year (Quality)	Location of Face-to-face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health Information Technology	Comparator
Peikes 2009 (c)[82] Site: Washington University - Academic Medical Center (Good)	In person patient assessment	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, program adminis-trators worked with physicians	StatusOne CareLink case management software	same as above
Peikes 2009 (d)[82] Site: Avera - Community Hospital (Good)	In-person patient assessment	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, some physicians employed by host; worked with staff.	Microsoft Access database	same as above

Author, Year (Quality)	Location of Face-to-face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health Information Technology	Comparator
Peikes 2009 (e)[82] Site: CenVaNet - Provider of disease Care/Coordinated Care/QI services (Good)	In-person patient assessment	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, physicians part of host network	InformaCare commercial disease management software	same as above
Peikes 2009 (f)[82] Site: Charlestown - Retirement Community (Good)	No, primarily telephone	Same as above	Same as above	Same as above	Assessed patients' needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, program adminis-trators and care coordinators worked with physicians	Canopy commercial Web-based case management software	same as above

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Peikes 2009 (g)[82] Site: Health Quality Partners - Provider of disease Care/ Coordinated Care/ QI services (Good)	No, primarily telephone, in person at home assessment for high risk patients only	Same as above	Same as above	Same as above	Assessed patients' needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, program adminis-trators worked with physicians	Microsoft Access database	same as above
Peikes 2009 (h)[82] Site: Medical Care Development - Community Hospital (Good)	In-person patient assessment	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, physicians employed by hospitals participating in the program	Clinical Management Systems commercial disease management software	Same as above

Author, Year (Quality)	Location of Face-to-face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health Information Technology	Comparator
Peikes 2009 (i)[82] Site: Mercy Medical Center - Community Hospital (Good)	In-person patient assessment	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, program staff worked with physicians	Mercy Case Management Information System	same as above
Peikes 2009 (j)[82] Site: Qmed - Provider of disease Care/ Coordinated Care/ QI services (Good)	No, primarily telephone	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, "many" program staff worked with physicians	QMeds OHMS, PIMS, and PAT	same as above

Author, Year (Quality)	Location of Face-to-face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health Information Technology	Comparator
Peikes 2009 (k)[82] Site: Georgetown - Academic Medical Center (Good)	In-person patient assessment	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Some physicians employed by host	Canopy commercial Web-based case management software	same as above
Peikes 2009 (l)[82] Site: Quality Oncology - Provider of disease Care/ Coordinated Care/ QI services (Good)	No, primarily telephone	Same as above	Same as above	Same as above	Assessed patients needs for non-Medicare support services or additional Medicare-covered services (home care; transportation; certain equipment and supplies; and disease-specific, diet, or smoking-cessation support groups)	Same as above.	Yes, "many" program staff worked with physicians	Quality Oncology Integrated Care Management System	same as above

Author, Year (Quality)	Location of Face-to-face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health Information Technology	Comparator
Schore 1999[95] Schore 1997[96] Schore 2011[97] (Good)	NR	NR	Project I: Client goals regarding CHF education Project P: Support services, cardiac rehabilitation and therapy, Medicare-covered services Project H: Support services, medical services, and education	Project I: Focused CHF education at each contact, educational pamphlet mailed after random assignment, quarterly newsletters Project P: Education at each contact Project H: Education as noted in case management plans	Project I: Referral to social worker for support services Project P: Arranged for services not provided by physician Project H: Arranged and coordinated support services	NR	Project I: No Project P: No Project H: Yes	No	Project I: Caregiver support Project P: Caregiver support Project H: Client advocacy and caregiver support

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Boult 2011[8] Boult 2008[10] Boyd 2010[11] Wolff 2010[9] (Good)	NR	Adjusted GC:UC Ratio of Service Use (95% CI) in all study groups; patients at very high risk (hierarchical condition category ≥ 1.6); Kaiser patients Hospital Admissions: 1.01 (0.83-1.23); 1.00 (0.78-1.28); 0.85 (0.61-1.19) 30-day Readmission: 0.79 (0.53-1.16); 0.81 (0.53-1.26); 0.51 (0.23-1.15) Hospital days: 1.00 (0.77-1.30); 0.88 (0.64-1.22); 0.79 (0.53-1.19) SNF admissions: 0.92 (0.60-1.40); 0.90 (0.52-1.54); **0.53 (0.31-0.89)** SNF days: 0.84 (0.48-1.47); 0.83 (0.39-1.76); **0.48 (0.28-0.84)** ED visits: 1.04 (0.81-1.34); 1.18 (0.84-1.66); 0.83 (0.56-1.21) Primary care visits: 1.02 (0.91-1.14); 0.98 (0.84-1.14); 1.08 (0.90-1.29) Special visits: 1.07 (0.93-1.23); 1.09 (0.91-1.30); 0.93 (0.75-1.15) HHC episodes: **0.70 (0.53-0.93)**; 0.84 (0.60-1.23); 1.09 (0.69-1.74)	NR	NR	13534/2391/904	54/0/850	54/NR	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Fitzgerald 1994[30] (Fair)	Mortality intervention vs. comparator 10.5% vs. 10.4%, p=0.90 Intervention vs. comparator visits to primary care physicians in the GMC: 0.30 vs. 0.26 visits per patient per month, p=0.02. Service need being provided, number per patient: 2.42±1.74 vs. 2.30±1.70, p=56.	Intervention vs. comparator Hospital readmissions number of readmissions patient/month 0.099±.15 vs. 0.102±.13, p=0.79 number of hospital days, patient/month 0.767±1.27 vs. 0.869±1.42, p=0.33 Nursing homes number of admissions per patient per month 0.006±.032 vs. 0.005±.031, p=0.67 number of days, patient/month 0.64±3.42 vs. 0.22±1.27, p=0.04	NR	NR	4076/1068/668	66/13/656	10% withdrawals	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Latour 2006[51] Latour, 2007[156] (Fair)	After adjustment, QOL and HADS showed NS though unadjusted, the median difference sections of QOL of quality of life and HADS favored the control group.	ED readmissions (control vs. intervention): 11 (15.9%) vs.16 (20.6%); (Crude RR: 1.30; 95% CI 0.64 to 2.58) Care utilization: Mean difference of CM-control (95% CI): <u>Primary Care</u> Practice visits: 1.39 (0.94; 2.68), p=0.05 Telephone: -0.56 (-2.17; 1.05) Home visits: 1.13 (-0.42; 2.68) NS for supportive care (e.g. nursing visits) or admissions to rehab clinic, nursing home or residential home.	NA	NR	NR/1,291/208	61/6/147	61/NR (presumably 0)	Included INTERMED approach to intervention (see link below for details): http://www.intermedfoundation.org/homepage

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Martin 2004[61] (Good)	Intervention vs. Control 1) Number of deaths: 191 vs. 21; p=0.18 Change in Intervention vs. Control 2) SF-36 Health Domains a) General: -1.5 vs. -2.3; p=0.09 b) Mental: -.013 vs. 0.01; p=0.74 c) Physical fracture: -4.3 vs. 4.0; p=0.67 d) Social: -1.4 vs. -2.8; p=0.04 3) Change in satisfaction with health care plan: 0.32 vs. 0.12; p<0.01	Intervention vs. Control 1) Inpatient admissions (1000/patient/year): 430 vs. 421; p=0.89 2) Inpatient bed-days (1000/patient/year): 1929 vs. 1989; p=0.46 3) SNF admissions (1000/patient/year): 36 vs. 37; p=0.73 4) SNF bed-days: 616 vs. 748; p=0.02 5) Mean cost/member: 6828 vs. 7001; p=0.61		NR	13,304/NR/8504	1467/0/6158	1467/0	Case management component of intervention was part of a larger disease management program, Senior Life Management. Did not report results of case management subgroup.

Author, Year (Quality)	**Results by Patient Health Outcomes**	**Results by Resource Utilization Outcomes**	**Results by Process Measure Outcomes**	**Harms Reported**	**Number Screened/ Eligible/ Enrolled**	**Number Withdrawn/ Lost to Followup/ Analyzed (Overall)**	**Total Withdrawals; Withdrawals due to Adverse Events**	**Notes**
Newcomer 2004[78] (Fair)	Mean values at baseline; 12 months SF-12 Mental: CM: 52.4; 51.9 Control: 52.4; 52.3 SF-12 Functional: CM: 38.9; 38.7 Control: 38.3; 38.4	Mean values at baseline; 12 months Monthly days in hospital: CM: .9; 1.0 vs. Control: 1.2; 1.3 % 1 or more nursing home admission CM: 7.9; 6.8 vs. Control: 11.9: 12.6	NR	None	5859/NR/3079	NR/3079	NR/0	Also includes data of reasons for the likelihood of service use but this does but overall (not comparing CM vs. control). CM monitored physician use and clinic appointments and contacted those who repeatedly missed appointments (or if PCP requested contact). CM intervened by calling to remind members, facilitate transportation, or coordinated with caregivers to also attend patient visits.

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (a)[82] Site: Carle - Integrated Delivery System (Good)	Mortality Treatment-Control Difference (%) (non sign. p-values, except as noted) -0.6	Adjusted Annualized Hospital admissions: CM-control difference, (90%CI); % difference 0.022 (−0.026 to 0.070) 4.2, p=0.45 Adjusted Medicare expenditures: ($) Total CM-control difference, (90%CI); % difference 209 (153 to 265) 30.1 p<0.001	(Treatment % vs. Control %; difference) Being taught to follow a healthy diet: 71.5 vs. 45.6; 24.9 Colon cancer screening: 42.9 vs. 42.1; .08 Mammography: 74.8 vs. 71.2; 3.6 Eye examination: 86.5 vs. 83.3; 3.2 Hemoglobin A1C testing: 94.9 vs. 94.7; .02 Urine microalbuminuria testing: 81.0 vs. 60.2; 20.8	Pt. self report of adverse medical events collected, but specific harms related to Case management, NR	Entire Study Total: 18 309 patients (n=178 to 2657 per program) Individual sites: Enrolled After 12 and 24 Months: 2,283 2,642	Analyzed (Overall) Treatment (n = 9427) Control (n = 8975) Treatment only: 10%	NR	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (b)[82] Site: CorSolutions - Provider of disease Care/ Coordinated Care/ QI services (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference −0.057 (−0.174 to 0.059) −3.2; p=0.42 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference 213 (25 to 400) 8.2; p=0.06	Being taught to follow a healthy diet: 75.1 vs. 64.8; 10.3 Colon cancer screening: 36.4 vs. 41.3; -4.9 Mammography: 32.6 vs. 34.1; -1.5 Eye examination: 75.8 vs. 73.2; 2.6 Hemoglobin A1C testing: 82.7 vs. 77.9; 4.8 Urine microalbuminuria testing: 25.5 vs. 22.7; 3.1	same as above	Enrolled After 12 and 24 Months: 671 2,162	43%	-0.1	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (c)[82] Site: Washington University - Academic Medical Center (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference 245 (96 to 395) 12.9 p=0.007	Being taught to follow a healthy diet: 59.9 vs. 53.7; 6.2 Colon cancer screening: 49.3 vs. 47.0; 2.4 Mammography: 56.4 vs. 57.3; -0.9 Eye examination: 85.2 vs.87.3; -2.1 Hemoglobin A1C testing: 86.1 vs. 86.0; .01 Urine microalbuminuria testing: 27.9 vs. 31.4; -3.5	same as above	Enrolled After 12 and 24 Months: 1,425 2,038	15%	-0.7	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (d)[82] Site: Avera - Community Hospital (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference −0.025 (−0.199 to 0.150) −1.8 p=0.82 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference 236 (65 to 408) 17.0 p=0.02	Being taught to follow a healthy diet: 70.5 vs. 55.6; 14.9 Colon cancer screening: 36.9 vs. 37.2; -0.3 Mammography: 44.3 vs. 43.7; .06 Eye examination: 87.4 vs. 85.6; 1.2 Hemoglobin A1C testing: 82.0 vs. 80.8; 1.2 Urine micro-albuminuria testing: 19.8 vs. 27.8; -8.0	same as above	Enrolled After 12 and 24 Months: 318 624	28%	-0.5	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (e)[82] Site: CenVaNet - Provider of disease Care/ Coordinated Care/QI services (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference 0.039 (−0.038 to 0.116) 5.9 p=0.41 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference 111 (22 to 200) 13.0 p=0.04	Being taught to follow a healthy diet: 75.5 vs. 41.2; 33.4 Colon cancer screening: 41.8 vs. 41.5; 0.3 Mammography: 46.4 vs. 47.5; -1.1 Eye examination: 90.4 vs. 89.0; 1.4 Hemoglobin A1C testing: 88.1 vs. 88.3;-.02 Urine microalbuminuria testing: 833.4 vs. 27.1; 6.3	same as above	Enrolled After 12 and 24 Months: 1,074 1,305	16%	1.7	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (f)[82] Site: Charlestown - Retirement Community (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference 0.118 (0.025 to 0.210) 19.0 p=0.04 Adjusted Medicare expenditures: ($) Total Treatment-control difference, (90%CI); % difference 405 (267 to 542) 40.6 p<0.001	Being taught to follow a healthy diet: 46.3 vs. 24.4; 21.8 Colon cancer screening: 45.4 vs. 42.8; -.05 Mammography: 62.0 vs. 49.6; 12.4 Eye examination: 96.5 vs. 89.4; 7.1 Hemoglobin A1C testing: 81.9 vs. 78.7; 3.2 Urine microalbuminuria testing: 9.9 vs. 3.4; 6.5	same as above	Enrolled After 12 and 24 Months: 430 802	11%	-0.4	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (g)[82] Site: Health Quality Partners - Provider of disease Care/ Coordinated Care/ QI services (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference −0.049 (−0.111 to 0.012) −11.4 p=0.19 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference 19 (−68 to 107) 2.8 p=0.72	Being taught to follow a healthy diet: 84.5 vs. 32.8; 52.0 Colon cancer screening: 42.8 vs. 36.6; 6.2 Mammography: 77.1 vs. 72.22; 4.9 Eye examination: 87.8 vs. 92.0; -4.2 Hemoglobin A1C testing: 97.5vs. 92.8; 4.7 Urine microalbuminuria testing: 95.6 vs. 93.0; 2.6	same as above	Enrolled After 12 and 24 Months: 498 1,140	2.50%	-2.3*	*Difference between the treatment and control groups significantly different from 0 at the 0.10 level, 2-tailed test.

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (h)[82] Site: Medical Care Development - Community Hospital (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference −0.050 (−0.207 to 0.107) −3.4 p=0.60 Adjusted Medicare expenditures:($) Treatment-control difference, (90%CI); % difference 28 (−153 to 209) 1.7 p=0.80	Being taught to follow a healthy diet: 85.3 vs. 71.0; 12.5 Colon cancer screening: 48.8 vs. 49.6; .08 Mammography: 50.4 vs. 48.5; 1.9 Eye examination: 86.5 vs. 83.3; 3.2 Hemoglobin A1C testing: 86.6vs. 89.9; 1.4 Urine microalbuminuria testing: 38.2 vs. 37.8; 0.4	same as above	Enrolled After 12 and 24 Months: 393 876	38%	1	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (i)[82] Site: Mercy Medical Center - Community Hospital (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference −0.168 (−0.283 to −0.054) −17.1 p=0.02 Adjusted Medicare expenditures:($) Treatment-control difference, (90%CI); % difference 134 (15 to 252) 11.1 p=0.07	Being taught to follow a healthy diet: 66.4 vs. 45.5; 20.9 Colon cancer screening: 35.2 vs. 36.7; -1.5 Mammography: 47.9vs. 44.7; -1.9 Eye examination: 97.8 vs. 97.0; 0.8 Hemoglobin A1C testing: 87.7 vs. 86.1; 1.6 Urine microalbuminuria testing: 38.2 vs. 37.8; 0.4	same as above	Enrolled After 12 and 24 Months: 627 865	13%	-0.9	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (j)[82] Site: Qmed - Provider of disease Care/ Coordinated Care/ QI services (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference 0.006 (−0.047 to 0.059) 1.4 p=0.86 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference	Being taught to follow a healthy diet: 44.3 vs. 29.9; 13.5 Colon cancer screening: 43.8 vs. 43.8; -0.1 [sic] Mammography: 66.6 vs. 68.5; -1.9 Eye examination: 88.4 vs. 86.8;1.6 Hemoglobin A1C testing: 90.5 vs. 90.1; .04 Urine microalbuminuria testing: 47.5 vs. 49.5; -2.0	same as above	Enrolled After 12 and 24 Months: 1,404 1,454	12.50%	0.3	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (k)[82] Site: Georgetown - Academic Medical Center (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference −0.494 (−0.919 to −0.069) −24.0 p=0.07 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference	Being taught to follow a healthy diet: NA Colon cancer screening: NA Mammography: 37.2 vs. 20.8; 16.4 Eye examination: 81.7 vs. 79.2; 2.5 Hemoglobin A1C testing: 78.8 vs. 77.5; 1.3 Urine microalbuminuria testing: 31.1 vs. 19.8; 11.3	same as above	Enrolled After 12 and 24 Months: 108 199	26%	-1.4	

Author, Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peikes 2009 (I)[82] Site: Quality Oncology - Provider of disease Care/ Coordinated Care/ QI services (Good)	NR	Adjusted Annualized Hospital admissions: Treatment-control difference, (90%CI); % difference 0.049 (−0.366 to 0.463) 4.4 p=0.85 Adjusted Medicare expenditures:($) Total Treatment-control difference, (90%CI); % difference 67 (−26 to 160) 9.0 p=0.24	NR	same as above	Enrolled After 12 and 24 Months: 63 141	45%	-0.8	
Schore 1999[95] Schore 1997[96] Schore 2011[97] (Good)	Mortality* Project I: 19% at one year, 27% at two years Project P: 26% at one year Project H: 14% at one year *No comparison between interventions and controls	Estimated impact of project on any inpatient hospital admissions Project I: 2.2 (p=0.46) Project P: -1.5 (p=0.71) Project H: 10.0 (p=0.06) Estimated impact of project on number of inpatient hospital admissions Project I: 0.03 (p=0.71) Project P: 0.03 (p=0.83) Project H: 0.31 (p=0.06) Estimated impact of project on ED visits Project I: -0.01 (p=0.90) Project P: -0.02 (p=0.88) Project H: 0.85 (p=0.01)	NR	NR	Project I: NR/8,002/1,134 Project P: 3,628/2,537/806 Project H: 4,135/1,674/442	Voluntary disenrollment Project I: 17% Project P: 2% Project H: 8%	NR	

Abbreviations: CAD=coronary artery disease, CHF=congestive heart failure, CI=confidence interval, COPD=chronic obstructive pulmonary disorder, HD=health department, HMO=health maintenance organization, MCCD=Medicare Care Coordination Demonstration, MMSE=Mini-Mental State Examination, NCM=nurse care manager, NR=not reported, PAC=post-acute care, QOL=quality of life, RN=registered nurse.

Evidence Table 2. Observational Studies of Case Management for Older Adults with Multiple Chronic Diseases

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (Age, Gender, Race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Bird 2007[114] Bird 2010[115] (Fair)	Patients with COPD and/or CHF	Care coordinator using a project manager and six multi-skilled care facilitators with professional expertise in nursing. The aim of this model was to: improve health outcomes, promote a better quality of life, and reduce the use of acute hospital based services	Patents who in the previous 12 months who had made two or more presentations for COPD and/or CHF	COPD intervention group vs. comparator: Male 40 vs. 31, female: 38 vs. 15 age: 64+/-16 vs. 70 +/- 9 CHF intervention group vs. comparator: Male 35 vs. 14, female: 32 vs. 8 age: 77+/-9 vs. 76 +/- 11 Race: NR	Cohort	NA
Dorr 2008[123] (Good)	Patients $\geq$ 65 years and enrolled in Medicare Part B. 49% diabetes; 26% depression; 72% hypertension; 22% CHF 3/4 of population had >2 more comorbidities, 23% Hs previous hospitalization	Nurse care managers supported by specialized information technology in primary care employed to manage chronically ill patients.	Physicians referred patients at will to a care manger for any perceived care management need, and thus patients were assigned nonrandomly to care management (intervention) as soon as they made documented contact with a care manager.	Age Mean : 76 years 15% $\geq$ 85 years 65% Female 1,478 (64.6) Race: 95% White	Controlled clinical trial, 2 years	Categorical, exact matching of intervention and control patients was done based on age (in 5-year increments), previous use (hospitalizations), comorbid score, sex, specific chronic illnesses (diabetes mellitus, depression, and cardiovascular disease), and referral to hospice within 90 days of study start date

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (Age, Gender, Race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Duke 2005[124] (Poor)	Patients had an average of 12 chronic conditions and took 15 medications daily.	NR	>65 years of age or older, resided in a private home or in 1 of 3 local assisted living communities in Pitt County, and received their health care at the BSOM Geriatric Clinic.	>65 years of age, other NR	Pre/post enrollment in case management program	NR
Huws 2008[130] (Poor)	Patient population 50 years and older in all practices in Swansea, Wales.	5 practices in Swansea, Wales used CM program and remaining 30 practices served as controls. AT CM sites, advanced practice nurses (APNs) took introductory courses in history-taking, diagnostic skills, visits to patients, practices, voluntary agencies, social services, and intermediate care and rehabilitation units. APNs were led by a senior nurse-manger. CM packages were individually tailored to selected patients and could include: self-help advice, career support, coordination, and planned primary and secondary health care. Sub-population of 'high-risk' patients also identified.	APNs given names of patients in their practices who had at least 2 admissions in previous year and/or a new unplanned admission during the interventions year. Patients referred to APNs screened for eligibility based on clinical interview, medication review, consideration of social circumstances, and functioning and judging risk of readmission. Patients then placed into high, medium or low unplanned readmission risk categories.	≥50 years old. Other NR.	Nonrandomized cohort with pre/post case management program, 12 months before and after intervention.	NR

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (Age, Gender, Race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Keating 2008[132] (Poor)	Recent exacerbation or decompensation of chronic illness <90 days; recent falls (2 in 2 months); recently bereaved and at risk for medical decline (death of spouse or family member in past 6 months); cognitively impaired, living alone, medically unstable, or in receipt of a high intensity social service package; registration with one of the practices involved in the Evercare project.	Use the EARLI score to categorize patients into low, medium and risk of hospitalization. If high risk, received case management.	Patients at risk of hospitalization.	> 65 years of age, others NR	Pre/post demonstration project	NR
Kruse 2010[133] (Fair)	Patients $\geq$ 65 years and seen at least 3 times by a family medicine outpatient team during 1998.	NP (nurse partner) assessed patients' health maintenance needs, reviewed medications, saw patient at office, provided patient education, coordinated referrals to specialty physicians and home health services, and provided followup phone care to check on patients after doctor visits or hospitalizations.	Patients at least 65 years of age and seen at least 3 times.	Mean age: 76 years 67% Female	Quasi-experimental with control, 5 years followup	Adjusting for age and sex Selection of controls: matched 1:2 with patients who had $\geq$3 outpatient visits with another clinic team during 1998

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (Age, Gender, Race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Lu 2006[137] (Fair)	Community elders $\geq$ 65 years with HTN, diabetes mellitus and HC, known as the three highs.	Patients diagnosed at least twice with one of the three highs in Case Management Record.	NR	Mean age=72.6 years 60% Female 74% had HTN, 55% had diabetes, 15% with HC. 61% had 1 of 3 highs, 35% had 2 of 3 highs and 4% had all 3.	Before and after design extracting secondary data from a 3-month CM program. Data extracted from Case Management Record.	Used paired t-tests to evaluate before and after results.
Luzinski 2008[138] (Poor)	Geriatric individuals with $\geq$1 chronic illnesses.	CMs assess needs and develop individualized care plans to determine interventions as needed and include assistance with medication management, coordination of transportation and coping strategies to help patient manage chronic illnesses more effectively. CMs promoted self-advocacy by patient education and referring to community resources. CM maintained relationships with patients through home visits and telephone calls.	Referred to CCM program for many reasons and include confusion with medications or treatment plans, chronic conditions at risk of complications (e.g., CHF, COPD, and diabetes), frequent ED visits or hospitalizations, poor coping skills, inadequate family or support systems, insufficient financial resources, frequent missed appointments, frequent visits for unnecessary problems and ineligibility for home care.	NR	Before and after design, 6 months previous to enrollment compared to post-6 months.	NR

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (Age, Gender, Race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Moran 2008[141] (Poor)	Patients undergoing surgeries at Flintshire, North East Wales practices.	Nurse CMs trained in unified assessment using an assessment and care planning strategy between health and social care services. Close working arrangements between social services and nurse case managers. Utilization of an experienced nurse skilled in the management of chronic illnesses.	Phase 1: Cases sought through secondary care data; patients ≥65 with at least 1 of following: 2 or more hospital admissions in last 12 months, 2 or more A&E attendances in last 12 months, 4 or more medications, a recent bereavement or loss Phase 2 and onward: Referral accepted from any source and through secondary care data; assessments made of those recently discharged from hospital of patients aged ≥50 with 1 or more long-term illness	NR	Pre/Post Case management program, 12 months before and after intervention	NR
Onder 2007[143] Onder 2008[144] (Poor)	Random sample of elders admitted to the home care programs in 11 different European Home Health Agencies (2001-2003)	Home care program with case management and the standard (without CM).	Patients receiving home care services.	Mean age= 82 years 74% Female	Retrospective cohort	Demographic variables, number of chronic diseases, functional and congenitive impairments and hospitalization in the past 6 months.

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (Age, Gender, Race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Oliva 2010[83] (Good)	Patients in the intervention (RN case management) group from one site in a multi site trial.	Highly trained RN case managers used evidence-based case management practices and disease management protocols to deliver and coordinate care.	Randomly assigned after meeting inclusion criteria for larger randomized trial.	>65 years of age, Medicare enrolled, with at least one of 5 specified chronic conditions, and for this analyses one of the conditions had to be CHF	Secondary (sub group)analyses of data collected during a multisite randomized trial	Compare
Picariello 2008[145] (Fair)	Geriatric patients with 2 or more hospital admissions, SNF, or ER within a 30 day period	Geriatric case management team, geriatric case manager (registered nurse) and social worker, telephonically interact with the member, the primary care providers, and family members to achieve program goals.	Members referred through: monthly screening of administrative data, monthly review of PRA schores, or direct physician referral	Average age: 78 62% female intervention n=101 comparison n=1585	Quasi-experimental study	NR
Schifalacqua, 2000[147] Schifalacqua, 2004[148] (Poor)	NR	High-risk/ Level III Medium-risk/ Level II Low-risk/ Level I	High-risk clients directly referred to nurse and/or social work CM. Medium-risk clients referred to telemanagement nursing staff that conduct a second telephone interview and gather additional data related to client needs. Low-risk clients receive a telephone call from geriatric outreach program, which provides introduction to the health care system and ensur3es that clients know how to access care and services such as transportation and pharmacy discounts or home delivery.	NR		NR

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Bird 2007[114] Bird 2010[115] (Fair)	NR	Mortality, utilization of hospital services, quality of life scores	Mortality: a lower mortality rate (18% vs. 36%) was observed in the intervention group.	COPD - the intervention group experienced a reduction in ED presentations (10%), admission (25%) and hospital in-patient bed days (18%). The comparator group, by contrast, experienced an increase in ED presentations (45%), admission (41%), and in-patient bed days (51%). CHF: the intervention group reduced their presentations to ED (39%), admission (36%) and hospital in-patient bed days (33%). The comparator group showed lesser reductions in ED visits, admissions, and in-patient bed days.	COPD patients reported a significant reduction in their symptoms (p<0.005) and the CHF patients reported an improvement in their overall health and quality of life scores (p<0.001).	NR	

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Dorr 2008[123] (Good)	NR	CMP vs. Comparator: Deaths (%): 1) 1 year: 6.5 vs. 9.2; OR 0.68, p=0.01 2) 2 year: 13.1 vs. 16.6; OR 0.77;, p=0.07	NR	CMP vs. Comparator 1) Hospitalizations (%): a) 1 year: 22.2 vs. 23.3, OR: 0.94, p=0.55 b) 2 years: 31.8 vs. 34.7; OR: 0.88; p=0.23 2) PQI Hospitalizations (%): a) 1 year: 4.7 vs. 5.3, OR: 0.87, NS b) 2 years: 8.9 vs. 8.7; OR: 1.03, NS 3) ED visits (%): a) 1 year: 33.3 vs. 32.3; OR 1.04, NS b) 2 year: 49.9 vs. 43.8: OR 1.28, p<0.05	NR	CM completed a patient assessment (used stages-of-change model, focusing on self-efficacy, knowledge, readiness to change, and patient-directed goal setting). CM techniques included motivational interviewing, education and validated instruments. CM also addressed patient's social, financial, and cognitive barriers. Specialized IT system and database utilized protocols, alerts and included a tickler system and was accessible through the patient's EHR.	

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Duke 2005[124] (Poor)	NR	MMSE and MGDS scores	Reported that MMSE score declined over study period and MGDS showed an improved perception on QOL	54% reduction in ED visits; 69% reduction in hospital admissions; 64% reduction in hospital LOS	NA	NR	Case management for both medical and mental conditions, telehealth assessments for medically compromised patients, hospice use and acceptance for end-of-life care needs, education for the patient and family members or caregivers about specific care needs and concerns

Author Year (Quality)	**Incidence (if cohort study)**	**Patient Health Outcomes**	**Results by Patient Health Outcomes**	**Results by Resource Utilization Outcomes**	**Results by Process Measure Outcomes**	**Effects of Confounders, Intensity of Case Management, Duration**	**Notes**
Huws 2008[130] (Poor)	NR	NR	NA	Intervention sites experienced a slight reduction in medical and geriatric hospital admissions (absolute risk reduction .909 admissions per 100 patients) Adjusted relative risk reductions: 1) Admissions per registered patient: Point estimate: 0.909, 95% credible limit (0.841-0.984), p=0.018 2) Admissions for proportion of registered patients ever admitted in the year: Point estimate: 0.935, 95% credible limit (0.855-1.022), p=0.138	NA	Most of rate reduction was due to a reduction in new admissions rather than readmissions.	
Keating 2008[132] (Poor)	NR	NR	NR	50% decrease in hospital admissions 49% decrease in number of days in the hospital	NA	NR	Case management team included a lead GP with 1 hour/week to review progress; a social worker and a community matron supplemented regular GP practice care of patients.

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Kruse 2010[133] (Fair)	1) ED visits (intervention vs. comparator groups: 0.71/1000 patient-days vs.1.04/1000 patient-days; p=0.034 2) Urgent care visits: 0.17/1000 patient-days vs. 0.43/1000 patient-days; p<0.001	Mortality	Intervention vs. comparator: Deaths: 26.9% vs. 27.3%; p=0.94	Relative risk reduction of intervention vs. comparator: ED visits: 0.32 (95% CI, 0.03–0.52) Urgent care visits: 0.59 (95% CI, 0.40–0.72)	NA	NA	
Lu 2006[137] (Fair)	NA	SBP, DBP, AC sugar, PC sugar and cholesterol	Mean values Before vs. After CM; p-value CM 1) SBP: 159.4 vs. 150.8; p=0.000 2) DBP: 91.1 vs. 88.6; p=0.000 3) AC sugar: 208.8 vs. 191.8; p=0.000 4) PC sugar: 288.3 vs. 254.0; p=0.003 5) Cholesterol: 281.3 vs. 263.1 ; p=0.122	NR	Significant change in SBP related to gender and location; change in cholesterol related to patient ethnicity.	NA	

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Luzinski 2008[138] (Poor)	NR	NR	NR	1) Cost: Saved an average of $93,000/year for the CCM patient or an annual savings of $233/patient. 6 months enrollment vs. 6 months preceding enrollment: 2) ED visits: 38% decrease 3) Inpatient admission: 63% reduction	NA	NR	
Moran 2008[141] (Poor)	NR	NR	NA	Median values before vs. after intervention: 1) ED admissions: 1.48 vs. 0.5; Median difference: 1, p=0.03; 95% CI 0.0 to 1.0 2) Length of Stay: 6.0 days vs. 0.0 days; Median difference: 2.0 days, p=0.27; 95% CI -3.0 to 7.0)	NA	NR	

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Onder 2007[143] Onder 2008[144] (Poor)	Nursing home admission (number of events), no CM vs. CM 274 vs. 81	Caregiver dissatisfaction and distress	CG Dissatisfaction (no CM vs. CM): 0.47 (0.29–0.73) CG Distress (no CM vs. CM): 1.04 (0.78–1.38)	OR (95% CI) of no CM vs. CM Nursing home admission OR: 0.56 (0.45-0.63)	NA	No effect of measured confounders.	
Oliva 2010[83] (Good)		NR	NR	Rehospitalization: NR for all chronic conditions; 40% over 4 years for CHF patients	Analysis looked at time of CM activities and time spent on it for patients who had a re hospitalization categorized by how many days were between the last CM encounter and the subsequent hospital admission. Mean times were higher when CM encounter was farther from admission (857 minutes for 167 to 402 days; 812 for 650 166 days; 684 for 23-64 days; and 309 for 2 -22 days)	Patients (all not just CHF) with no readmission in 4 years received slightly more NCM time (p<0.05). Over 4 years: NCMs spent 1,975 to 2,475 minutes per CHF patient. Time on CM varied slight among NCM but time was not associated with readmission risk. Odds of readmission did vary by individual NCM.	Descriptive data on time spent on case management for patients, not just those with CHF. NCMs spent 26 minutes per patient per month on documentation and 34 in patient care activities in a setting where the NCM to patient ratios was 1 FTE to 135.
Picariello 2008[145] (Fair)	NA	NR	NR	After one year of intervention, decreases: hospital days 7; skilled nursing facility days 12; ER visits .75; outpatient hospital visits 0.3 increases: physician office visits 1; home health visits 4	After one year of intervention, cost decreases: total $13,256; inpatient hospital $14,152; ER $146; skilled nursing facility $3,138; ambulatory surgery $15 increases: outpatient hospital $100; physician office $1,941; home health $655; prescription drugs $1,536	1 year	

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Schifalacqua 2000[147] Schifalacqua 2004[148] (Poor)	NR	Preventive indicators Disease management	Preventive indicators: Annual influence rate 63% (baseline) and 100 (6 months after NCM implementation) Pneumonia vaccine (within past 8 years) 44% (baseline) and 100% (6 months after NCM) Annual mammogram 44% (baseline) and 57% (6 months after NCM) Cervical pap smear 25% (baseline) and 50% (6 months after NCM) Colonoscopy 50% (baseline) and 75% (6 months after NCM) Sigmoidoscopy 42% (baseline) and 75% (6 months after NCM) Annual lipid profile 38% (baseline) and 100% (6 months after NCM).	Inpatient length of stay: Plan A was 6% lower than Plan B and 53% lower than traditional Medicare. Hospital days per thousand: Plan A was 9% lower than plan B and 22% lower than traditional Medicare. 30 Day readmission rate: Plan A 6.1% lower than Plan B and3.4% lower than traditional Medicare.	NCM are able to report several case examples where client and family education, support, and advance directive completion had a direct impact on the inpatient length of stay and cost. These clients and their families were able to understand their care options and exercise choice, which eliminated the delays to discharge that, are associated with seeking guardianship of patients without expressed advance directives.	CHF initiative focused on weight monitoring, diet counseling, and medication management. 91% of CHF patients are performing regular weight monitoring, while all patients have received counseling on diet and medication management. All of the NCM patients with asthma have received education. They are able to articulate survival skills necessary for living with asthma, and they are using an inhaler spacer for metered-dose inhalers. All NCM patients with diabetes have annual podiatry and ophthalmology examinations, and they can articulate the survival skills of living with diabetes.	

Abbreviations: CAD=coronary artery disease, CHF=congestive heart failure, CM=case management, DBP=diastolic blood pressure, HC=hypercholesterolemia, HTN=hypertension, FFS=fee-for-service, NCM=nurse case manager, NR=not reported, OR=odds ratio, QOL=quality of life, SBP=systolic blood pressure, SD=standard deviation.

Evidence Table 3. Trials of Case Management for the Frail Elderly

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Applebaum 2002[5] (Fair)	As a result of the extensive attention from the clinical nurse care manager there would be a better match of services to needs. As a result intervention clients would be more satisfied with acute and long-term care services received, feel like they had more control over the health services that they receive, would report higher function status, and would have reduced hospital and nursing home use and lower overall health care costs.	Chronically disabled home-care clients age 60+.	NR	Randomized trial 6, 12 and 18 months depending on date of entry into program	Treatment group: Average age 78.2 72% female 60.3% Caucasian Comparator group: Average age 79.5 71.1% female 58.6% Caucasian	Frail elderly Alzheimer/Dementia: treatment 17.8% comparator 11.5%	Chronically disabled older people receiving in-home services, financed through a local tax levy, who were at risk of using a high amount of acute services. High risk; hospitalized during the past year, used the emergency room in the past 6 months, experienced functional limitations in select instrumental or activities of daily living, or have one of a selected number of medical conditions.

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Bernabei 1998[7] (Good)	To evaluate the impact of a program of integrated social and medical care among frail elderly people living in the community.	People ages 65 and over who were recipients of home health services or home assistance programs.	NR	"Random allocation to an intervention group receiving integrated social and medical care and case management or to a comparator group receiving conventional care." Duration: 1 year	Mean age: 80 years Female: 70% Race NR	Frail elderly 1) NR 2) Mean value of geriatric depression score=10.6	Mean number of medical conditions=4.8; Mean number of medications=4.4 per patient

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Gagnon 1999[31]; Schein 2005[32] (Fair)	To compare the effects of nurse case management with usual care provided to community-dwelling frail older in regard to QOL, satisfaction with care, functional status, hospital admissions, length of hospital stay, and readmission to ED department. *Research question: are there differences in QOL, satisfaction with care, functional status, admission to hospital, length of hospital stay, or readmission to ED, for community-dwelling older people identified as being at risk of health decline who receive either NCM or usual care?*	Age ≥ 70 years; discharged home from the hospital ED; living in vicinity of community health centers of Montreal; able to speak English or French; passed the abbreviated Mini-Mental Health State Exam; require assistance with at least one ADL or 2 IADL; had a probability of 40% or more of admission to hospital as defined by the Boult assessment tool.	Admission to the ED from a long-term care facility or nursing home; participation in other research studies; currently followed by the geriatric team of the hospital; unavailable for $\geq$2 months during the period of the study; having a partner already participating; and hospitalization at the time of contact.	Randomized trial, 10 months	Age: 81 years Gender: 59% femaleRace: NR	Frail elderly >70 years of age and at risk for repeated hospital admissions discharged home from the emergency department.1) Diabetes: 22% Cardiac disease: 54% Self-reported health: 25% poor; 44% fair2) NR	65% had a hospitalization within the previous 12 months; 65% >6 visits with physician61% living alone though 73% reported a caregiver is available (see previous cell).

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Kristensson 2010[48] (Good)	The aim was to test sampling and explore sample characteristics in a pilot study using a case management intervention for older people with functional dependency and repeated contact with the health care services as well as to investigate the effects of the intervention on perceived health and depressed mood after 3 months. The aim was also to explore internal consistency in the life satisfaction index Z, ADL-staircase and Geriatric Depression Scale-20	Persons who lived in the municipality chosen for the study, aged 65 or over, needed help with at least two ADL such as cleaning or shopping, been admitted to hospital on at least two occasions, or have had at least four contacts with outpatient or primary care during the previous 12 months, be able to communicate verbally and have no cognitive impairment.	Not meeting the inclusion criteria. Refuse to participate. Deceased. Not reachable.	Randomized trial, 3 months	Intervention: Age: 82 Gender: 60% female Race: NR Comparator: Age: 85 Gender: 65% female Race: NR	Frail elderly, needed help with at least two ADL. Life satisfaction index, median (q1-q3): 13 (10-18) Diseases of the eye and adnexa: n=25 Diseases of the circulatory system: n=34 Pain in extremities: n=37 Difficulty hearing, dizziness and fatigue: n=28	NR
Leung 2004 (a)[54] (Poor)	To evaluate the effectivenessof case management provided to a group of home dwelling, frail elderly patients.	Hospital-discharged; age ≥ 60 years; ≥2 or more chronic medical illnesses, and a recent history of repeat hospitalizations (2 or more episodes in past 6 months).	NR	Randomized trial, 6 months	Mean age= 76 years (+/- 6 years) Gender: 53% femaleRace: NR	Frail elderly, two or more chronic medical illnesses. 1) 51% Hypertension; 12% HF; 32% with diabetes; 28% with COPD 2) NR	All

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Leung 2004 (b)[53] (Fair)	Evaluate cost-benefit of a case management project for older individuals in Hong Kong.	Patients aged 60 years and older discharged from a rehabilitative hospital in Hong Kong	NR	Randomized trial, 6 months	Intervention vs. Comparator Mean Age: 74 vs. 75 years 45% vs. 48% Female Race: NR	Most of the patients suffered from more than one chronic illness: chronic obstructive pulmonary disease, stroke, diabetes, and/or heart disease.	Frail elderly
Marshall 1999[58]; Long 2000[59]; Long 2002[60] (Good)	This demonstration project of an ambulatory CM program in Ohio goal was to eliminate fragmented care, inappropriate utilization, unnecessary cost, and confusion among Kaiser members for older members with chronic diseases. *Hypothesized health and function status and satisfaction with care would improve in CM group. Expected more outpatient visits (less costly) and fewer hospitalizations, ED use.*	Age ≥ 75 years; severe functional disability; excessive hospital use or emergency department use	NR	Randomized trial, 24 months (Assessments taken at 0, 6, 12, 24 months).	Mean Age: 82 years Gender: 64% female Race: NR Education: 65% did not complete 12th grade	Poor functional status, high utilizations of ED and/or hospital. 1) Mean ADL: 6.5 Mean IADL: 5.7 2) NR (though measured poor function status)	NR

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Rubenstein 2007[93] (Good)	To test whether a system of screening, assessment, referral, and followup provided within primary care for high-risk older outpatients improves recognition of geriatric conditions and health care outcomes.	Patients ≥ 65 years old receiving care at 2 practice groups SACC of the VA Greater Los Angeles Health care System who had at least one clinic visit at SACC in the previous 18 months. Patients identified by Geriatric Postal Screening Survey and scored >4.	Living outside a 30-mile radius of SACC, already enrolled in outpatient geriatric services at SACC, or living in a long-term care facility.	Randomized trial, 12 months with followup interviews at 2 and 3 years	Mean Age: 74 years 3% Female Race: NR 76% ≥ high school degree	Target conditions: falls/balance problems, urinary incontinence, depression, memory loss, and functional impairment.1) Average comorbid conditions=2.32) 47% with a >5 on geriatric depression score (range 0-15)	Unmet needs for geriatric services

Author Year (Quality)	Payer/Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient
Applebaum 2002[5] (Fair)	Medicare	No	Clinical nurse care managers supplemented regular care managers	Enhanced clinical service plus traditional care management, a sub-sample of 150 participated in fact-to-face interviews at baseline and at 6 and 12 months to assess service quality, health care utilization and health satisfaction, and physical functioning.	Yes, not specified	NR	Home care
Bernabei 1998[7] (Good)	Health agency of Rovererto, Italy	NA	CM trained in comprehensive geriatric assessment and case management, Geriatric Evaluation Unit and GP.	Case management and care planning by the community geriatric evaluation unit and general practitioners. 2 case managers conducted assessment visits every 2 months, available to deal with problems and to monitor services.	CMs received training in comprehensive geriatric assessment and case management.	Clinic	Assessment visits at least every two months and as needed
Gagnon 1999[31] Schein 2005[32] (Fair)	Montreal, Canada Health System	See previous cell	4 nurses with a minimum of 2 years of geriatric nursing experience and worked full-time as NCMs for the study.	Patients in NCM group given a card with CM beeper number, CM available by beeper 8am-8pm Monday-Friday. CM provided integrated care including support patients and caregivers during times of transitions (e.g., hospital to home), and changes in resource needs. The CM coordinated the work of all health care providers and implemented a responsive plan of care. *CM met weekly with research team members to ensure uniformity in care.*	24 hours (3 days) of initial training which included an introduction to role of CMs, resources available, and study expectations. Each NCM developed a guide to community services available to clients. Skills validated by conducting full geriatric assessments of selected patients.	University hospital and two community health centers, patient's home, phone followup	Home visits and calls, averaged 3.6 home visits per patient and 2.8 calls per month for each patient.

Author Year (Quality)	Payer/Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient
Kristensson 2010[48] (Good)	NR	NA	CMs were 2 nurses specialized in geriatric nursing, employed part-time.	Four dimensions: Case management: Assessment, care plan care coordination, home visits, telephone calls and advocacy. General education: Education about the health care system, social activities, nutrition, exercise, etc. Safety and continuity: contactable by phone. Specific education: Related to the respondents' specific health status, individual needs and medication.	CMs underwent 1 week of training about case management in general, the intervention program, fall prevention, common diseases and medication-related problems in older people, nutrition for older people and the health care organization.	NR	Home visits, phone calls and when needed, accompanying participants to outpatient visits
Leung 2004 (a)[54] (Poor)	Hong Kong Health Care System	NA	4 CM trained in nursing elderly patients.	Scope of intervention included, regular monitoring health status to provide preventive proactively; available for via phone 8am-9pm; home visits, if needed; prescribing of community-based supportive services (including community nursing services). Included access a case geriatrician by the CM for medical support which included telephone consultation, assessment of subjects in the outpatient department, and admission of subjects to the hospital.	NR	Unclear but hospital and via phone	Phone

Author Year (Quality)	Payer/Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient
Leung 2004 (b)[53] (Fair)	Hong Kong Health Care System	NR	Case management was delivered by a social worker plus a registered nurse.	Regular (usually biweekly) home visits and telephone consultations; comprehensive geriatric assessment using Hong Kong version of Minimum Data Set-Home Care; formulation, implementation, and revision of care plans with reference to the results of MDS-HC and discussion with elderly care recipients and their informal caregivers; linking of elderly care recipients with formal health and social services in an integrated care approach, that is, through formal referral procedures plus routine case conferences; monthly monitoring of elderly care recipients' health and hospitalization patterns via a computing program - Integrated Patient Administration System - operated by the Hospital Authority of Hong Kong; on-site and/or over-the-phone health and psychosocial counseling; health educational programs; and supportive groups and educational classes for elderly care recipients and their informal caregivers.	NR	NR	NR

Author Year (Quality)	Payer/Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient
Marshall 1999[58]; Long and Marshall 2000[157]; Long 2002[60] (Good)	Kaiser	Yes, Kaiser of Northern Ohio	2 CMs from both nursing and social work with prior geriatric CM experience	CM protocols were developed (in consultation with geriatrician) by the study team and defined scope of work for CM and adapted as needed. Initial visit of CM was a home visit to explain the study (and obtain consent), and conduct an initial 2-4 hour assessment visit. After initial visit, CM developed a care plan and for complicated cases, CM care plan was reviewed by interdisciplinary team.	NR	Depended on location of patient, home, hospital nursing home visits, home visits, family conferences and telephone	Presumably home visits and phone

Author Year (Quality)	Payer/Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient
Rubenstein 2007[93] (Good)	VA Greater LA Healthcare System	Yes, VA	Physician assistant with geriatric expertise	1) Initial assessment over the phone to identify specific risks and unmet needs and CM made specific referrals and recommendations and referrals for services accordingly. If needed, CM conducted this at the geriatric assessment clinic. Based on information collected, patients were given referrals and recommendations. 2) Participants referred to the geriatric clinic received a physical examination geriatric assessment (evaluation of physical health, functional status, and mental health). Also, a geriatric psychiatrist was available to evaluate patients with dementia or depression. 3) CM participants were discussed with team and a care plan was developed. 4) CM followed up with patients who a 1-month after initial and afterwards, every 3 months via phone.	NR	The geriatric assessment clinic within the primary care practice group	Phone

Author Year (Quality)	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care
Applebaum 2002[5] (Fair)	75-100 home care patients	NR	Patients home	Yes	NR	NR	NCMs supervised by project geriatrician	NR	Yes
Bernabei 1998[7] (Good)	No more than 20 subjects per case manager	NR	NR	Initial assessment included the following: physical function, daily living, cognitive function and mood and the geriatric depression scale as well as providing a complete list of diagnoses and drug treatments. Subsequent visits were every 2 months and more if needed. Also recorded the number of home visits by GPs.	NR	NR	CM provided coordination and initiation of services (with initial assessment visit) for participants.	NR	Yes, CM was part of an interdisciplinary team which included a GP and geriatric evaluation unit.
Gagnon 1999[31] Schein 2005[32] (Fair)	40-55 patients per CM with an average of 46 patients/CM	3.6 home visits per month for each patient and 2.8 calls per month for each patient. (36 home visits and 28 telephone calls per patient)	NR	Yes, initiated a responsive plan of care.	NR	Not explicit.	Yes, CM developed a list of community resources to give to patients.	NR	Yes

Author Year (Quality)	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care
Kristensson 2010[48] (Good)	4 for 47 subjects (~10 per CM)	NR	NR	Yes, included in intervention	NR	NR	Provided community-based supportive services	Yes, as part of the intervention, monitored medication but did not adjust.	Not clear if CM and team geriatrician reported to GP
Leung 2004 (a)[54] (Poor)	2 part-time CMs, n=46	Home visits were once monthly or more frequent if participant had special needs	Initially when participants were in homes, if needed, when participants were on outpatient visits	Initial assessment followed by monthly followup, using Mini Data Set for Home Care, a comprehensive geriatric assessment questionnaire from which a care plan was developed, monitored and followed up. CM coordinated care and provided advocacy when needed, accompanying them to outpatient visits or encouraging participation in various social activities.	About health care system, social activities, nutrition, exercise etc	Participants encouraged to engage in various social activities. Education on What to eat, how to exercise, where to turn to in different matters. Participants encouraged to take a walk when having pain and joining social activities when feeling isolated.	CM provided advocacy when needed: establishing contacts with caregivers, guiding towards an adequate level of care or as support in health care contacts. Helping by contacting physician to sort out a medical problem, establishing contact with home-help officers.	CM made evaluation of participants prescribed medications. If problems were detected, one of the physicians involved in the project was contacted.	CMs were nurses in geriatrics, supported by primary care physicians and one hospital-based geriatric specialist. CMs participated in weekly meetings with staff at primary care centers and with home care nurses.

Author Year (Quality)	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care
Leung 2004 (b)[53] (Fair)	NR	361 home visits; 1171 telephone consultations; 145 face-to-face counseling sessions at the hospital	Home visits and in the hospital	Individual care plans were developed for all clients through accurate assessment of their clinical condition and regularly updated or revised according to their changing health status.	Patients were offered health educational programs and supportive groups and educational classes for elderly care recipients and their informal caregivers.	Patients were offered health educational programs and supportive groups and educational classes for elderly care recipients and their informal caregivers.	Yes, medical and social	NR	NR
Marshall 1999[58]; Long and Marshall 2000[157]; Long 2002[60] (Good)	2 CM acting as a team for 140 in CM group	NR	Initial assessment visit was 2-4 hours	Care plan was developed after initial visit and for complex cases reviewed by interdisciplinary team for approval.	NR	NR	Yes, scheduled medical appointments, accompanied participants to appointments and met with staff to coordinate care across sites (e.g., hospital, clinic). Arranged nonmedical services such as respite care, meals on wheels, nursing home placement, Medicaid eligibility and transportation to doctor's visits.	NR but presumably CM discussed this with PCP and did not adjust	Yes

Author Year (Quality)	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care
Rubenstein 2007[93] (Good)	NR	Followup calls 1-month after initial CM contact and subsequent calls every 3 months	NR	Developed a care plan after discussion with interdisciplinary team	Yes, CM provided health promotion recommendations and health education based on info collected during initial telephone contact.	NR	Yes, referred to specific services such as audiology and social work when needed by patient	NR	Yes, embedded within geriatric clinic within primary care group

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Applebaum 2002[5] (Fair)	NR	Normal care management services	Mortality: 6 months, 5% of the treatment group vs. 7.6% of the comparator group. Average number of survival days (175 vs. 174). 12 months, 16% treatment group vs. 11% for the comparator group. Average number of survival days (336 vs. 346). These patterns continued at 18 months showing no intervention effect on mortality	Health care use by Medicare Hospital admissions (% with 1 admission or more): first 6 months treatment 27.9% comparator 28.1% second 6 months treatment 26.1% comparator 33.3% third 6 months treatment 32.4% comparator 28.2% Nursing home admission (% with 1 admission): first 6 months treatment 9.9% comparator 10.4% second 6 months treatment 7.2% comparator 13.9% (p ≤ .05) third 6 months treatment 14.7% comparator 15.4%	Physical functioning and satisfaction with health Average number of ADLs, getting help (range 0-6): baseline treatment 1.28 comparator 1.56 6 months treatment 1.23 comparator 1.35 12 months treatment 1.15 comparator 1.26 Average number of IADLs, getting help (range 0-7): baseline treatment 3.78 comparator 3.95 6 months treatment 3.56 comparator 4.00 12 months treatment 3.58 comparator 3.42 Overall health status (range 0-16; high score better health): baseline treatment 10.40 comparator 10.60 6 months treatment 10.50 comparator 10.30 12 months treatment 10.30 comparator 9.20	NR	NR/NR/NR/308	11 dropped out	NR	

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Bernabei 1998[7] (Good)	NR	Care with GP including office visits, home visits, nursing and social services, home aides and meals on wheels.	Adjusted mean of functional outcomes* of CM vs. comparator: 1) ADL: 2.0 vs. 2.6; p<0.001 2) IADL: 4.1 vs. 4.4 p<0.05 3) Mental status questionnaire: 2.8 vs. 3.4; p<0.05 4) Geriatric depression scale 10.9 vs. 12.8 p<0.05 Mortality CM vs. comparator; HR, (95% CI) 12 vs. 13 died HR: 0.99 (0.89-1.09) *Higher number=greater impairment	Number of admissions of CM vs. comparator; HR (95% CI) 1) Nursing home: 10 vs. 15; HR: 0.81 (0.57 to 1.16) p=0.3 2) Acute hospital 36 vs. 51; HR: 0.74 (0.56 to 0.97), p<0.05 3) Nursing home or hospital: 38 vs. 58; HR: 0.69 (0.53 to 0.91) p<0.01 4) ED: 6 vs. 17; HR: 0.64 (0.48 to 0.85) p<0.025	Adjusted mean number of medications in intervention (baseline vs. 1 year followup): 5.4. vs. 4.7 (p<0.05)	NR	NR/224/199	0/0/NR	0/NR	Note: CMs from the national council (not involved in study) performed baseline and final assessments.
Gagnon 1999[31] Schein 2005[32] (Fair)	No	For usual care group, hospital and community services provided separately.	NCM vs. Comparator; Mean Difference (95% CI) Satisfaction: 25.0 vs. 23.9; 1.1 (-0.1, 2.3), NSADL: vs. 13.6 vs. 13.4; 0.2 (-0.2, 0.6), NSIADL: 10.5 vs. 10.3; 0.2 (-0.5, 0.9), NS	NCM vs. Comparator; Mean Difference (95% CI) Hospitalizations: 0.5 vs. 0.4 0.09 (-0.05, 0.23), NS Hospital LOS: 13.0 vs. 11.9; 1.1 (-4.7, 6.9), NS ED Admissions: 1.2 vs. 0.9; 0.32 (0.01, 0.63) p=0.041	NR	NR	1893/680/427 Of 680, 253 were not frail	NR/118/427	NR/NR	

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Leung 2004 (a)[54] (Poor)	NR	Usual care	NR	Self-reported health status was 50 vs. 57 for the intervention and the comparator group.	NR	No harms reported	Screened n=111 Excluded n=65 Enrolled n=46 (23 intervention, 23 comparator)	Excluded n=65: Not meeting inclusion criteria n=17 Refused to participate n=39 Deceased n=6 Not reachable n=3 Followup n=20 Discontinued intervention n=6 Deceased n=4 Declined participation n=2 Delayed followup n=8	NR	

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Leung 2004 (b)[53] (Fair)	NR	Comparator group received conventional and often fragmented health and social services, such as home visits by community nurses and home help service, provided by existing care providers.	Intervention group, mean number of health problems before vs. after: 2.0 vs. 1.8; mood symptoms: 1.7 vs. 0.8; mental functioning: 1.3 vs. 1.1; ADL: 0.8 vs. 1.1; continence: 0.12 vs. 0.11; behavioral symptoms: 0.05 vs. 0.07; informal support: 0.3 vs. 1.1 Comparator group, mean number of health problems before vs. after: 1.9 vs. 1.9; mood symptoms: 1.8 vs. 0.9; mental functioning: 1.5 vs. 1.4; ADL: 0.8 vs. 1.2; continence: 0.08 vs. 0.3; behavioral symptoms: 0.02 vs. 0.08; informal support: 0.4 vs. 1.2	Intervention group, hospitalization rate, mean before vs. after: bed-days in acute hospital in 6 months, 8.1 vs. 3.8; unplanned admissions to hospitals, 1.1 vs. 0.7; attending emergency rooms, 0.3 vs. 0.4 Attendance of community-based health services, mean before vs. after: community nursing service, 1.2 vs. 1.2; geriatric day hospital, 2.5 vs. 2.6 Comparator group, hospitalization rate, mean before vs. after: bed-days in acute hospitals in 6 months, 4.9 vs. 4.7; unplanned admissions to hospitals, 0.9 vs. 0.7; attending emergency rooms, 0.3 vs. 0.2 Attendance of community-based health services: community nursing service, 0.7 vs. 0.5; geriatric day hospital, 0.7 vs. 1.3	Intervention group, MDS-HC results, mean before vs. after: mood symptoms, 1.7 vs. 0.8; informal support, 0.3 vs. 1.1; number of health problems, 2.0 vs. 1.8; mental functioning, 1.3 vs. 1.1; ADL and instrumental ADL, 0.8 vs. 1.1; continence, 0.12 vs. 0.11; behavioral symptoms, 0.05 vs. 0.07 Comparator group, MDS-HC results, mean before vs. after: mood symptoms, 1.8 vs. 0.9; informal support, 0.4 vs. 1.2; number of health problems, 1.9 vs. 1.9, mental functioning; 1.5 vs. 1.4, ADL and instrumental ADL, 0.8 vs. 1.2; continence, 0.08 vs. 0.3; behavioral symptoms, 0.02 vs. 0.08	NR	260/260/260	NR	NR	NR

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Kristensson 2010[48] (Good)	NR	Usual care included of regular medical followup through the hospital service system of Hong Kong.	Baseline and post-intervention differences on the functional performance between groups (intervention vs. comparator): 1) Level of ADL: +0.3 vs. 0.2 (1.1), NS2) Level of transfer: 0.4 (1.2) +0.2 (1.0), NS**3) Level of continence +0.3 vs. 0.0, < 0.05 (intervention group worse)**4) Level of mental status −0.1 vs. 0.2, NS6) Level of mood symptoms −0.5 vs. −0.2, NS7) Level of impairment +0.1 vs. −0.1, NS	Mean difference in total number of outcome between the intervention vs. comparator groups: 1) Acute hospital bed-days: −3.3 vs. 3.9, p<0.01 2) Rehabilitation hospital bed-days: −4.6 vs. 13.4, p=0.05 3) Hospital bed-days: −7.9 vs. 17.2, p=0.001 4) Episodes of unplanned hospital admission −0.2 vs. 0.3; p<0.05 5) Episodes of hospital admission −0.7 vs. 1.3; p=0.001 6) Attendances at ED−0.2 vs. 0.4, NS 7) Attendances at outpatient dept−0.8 vs. 0.2; p=0.05 Attendances at geriatric day hospital −0.8 vs. −0.9; NS 8) Home visits by community nurse 6.7 vs. −1.2;p<0.05	NR	NR	NR/NR/92	6/0/92 6 died during study (2 in intervention, 4 in comparator)	0/0	

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Marshall 1999[58]; Long and Marshall 2000[157]; Long 2002[60] (Good)	No	Usual care was determined by contracts without CM coordinating care.	CM vs. Control at Year 2 : Functional Status 1) Mean ADL: 6.5 vs. 8.1, p<0.01 2) Mean IADL: 5.6 vs. 6.1, p<0.05 3) Mean Health Status: 2.4 vs. 2.7, NS 4) Mean satisfaction: 2.3 vs. 2.3, NS	CM vs. control at Year 2: 1) Hospitalization rates, 36% vs. 30%, NS 2) Mean # of outpatient visits: 14 vs. 10, NS 3) ER rate: 66 vs. 78%, NS 4) Mean number of patient ER visits: 1.6 vs. 1.4, NS	NR	NR	NR/NR/317	NR/109/208	NR/NR	CM kept provider records of study participants.

Author Year (Quality)	Health IT	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Rubenstein 2007[93] (Good)	NR	Usual care	Mean values: Y0, Y1, Y3 *Y0=Baseline* Depression CM: 4.9, 3.5, 3.9 Comparator: 5.2, 4.1, 3.4 Falls (>1 falls in previous 3 months): CM: 152, 79, 64 Comparator: 160, 71, 54 Incontinence CM: 188, 118, 91 Comparator: 199; 143; 105 Functional Status: a) ADLCM: 84.1; 85.3; 82.4 Comparator: 82.8; 82.3; 85.2 b) IADLCM: 53.9; 61.3; 56.5 Comparator: 53.4; 59.1; 58.2 Health Perception: CM: 33.5; 36.0; 35.6 Comparator: 33.7; 35.5; 36.2	Mean values: Y1, Y2, Y3 Hospital utilizations (Number participants admitted): CM: 210, 168, 159 Comparator: 217, 171, 131 Number hospital days: CM: 0.57; 0.56; 0.55 Comparator: 0.51; 0.56; 0.49	NR	NR	2646/1001/792	260/0/532	260/NR	

Abbreviations: ADL=activities of daily living, IADL=instrumental activities of daily living, CI=confidence interval, CM=case management, COPD=chronic obstructive pulmonary disease, HF=heart failure, HR, hazard ratio, GP, general practitioner, NA, not applicable, NCM=nurse case manager, NS, not significant, OR=odds ratio, QOL=quality of life, VA=Veterans Affairs, SACC= Sepulveda Ambulatory Care Center.

Evidence Table 4. Observational Studies of Case Management for the Frail Elderly

Author Year (Quality)	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Chi 2004[118] (Fair)	Disabled elderly people. Elderly people, over the age of 60, living in the Da'an district of Taipei who had functional disability in the ADL, IADL, or cognitive function. *Note: comparators were selected from a list of disabled elderly people in the community with similar health and physical functions as the experimental subjects.*	Hospital-based care management model in close coordination with the discharge planning program at hospital.	NR	Age: 47% 65-79 years; 47% >80 years 52% Female 36% < $30,000 Others: 1) 58% 3-5 chronic conditions 2) NR though 62% severely cognitively impaired	Quasi-experimental with control, 6 months	Adjusted for demographics, number of chronic conditions, functional status and cognitive impairment
Fletcher 2009[126] (Poor)	Heart of Birmingham Primary Care Trust (Midlands-based community service provider in England) patients at least 75 years old with maximum social care packages or two or more emergency admissions during preceding 3 months	Implementation of a case management program, in which nine case managers with backgrounds in nursing, housing, and social work each managed 60-70 vulnerable elderly people. Case managers implement a comprehensive needs assessment and provide an individual care plan.	75 years and older; either on a maximum social care package (in England) or had two or more emergency admissions within a specified 3 month period	Pre: N=207; Age: 83.2; Race: 57% White, 26% African Caribbean, 13% Asian, 4% Other; 52% Female Post: N=211; Age: 83.8; Race: 51% White, 22% African Caribbean, 23% Asian, 5% Other; 62% Female	Pre-Post, 12 months each	Stratified analysis by sex and ethnicity

Author Year (Quality)	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Gravelle 2006 (Fair) intervention n=64	Frail elderly aged 65 years and older with a history of emergency admissions living in England receiving case management	Advanced practice nurse carried out a comprehensive geriatric assessment, using structured assessment tools, and a physical examination, which resulted in an individualised care plan agreed with the patient, the general practioner , and other staff. Patients were then monitored at frequency determined by classification of risk. Benefits that the nurses reported included altering medication to avoid advrrse reaction, coordinating care to reduce fragmentation among services, arranging access to community based services, and a range of other interventions.	Patients were selected on the basis of age and history of hospital admission	Mean female in intervention: 0.57; in comparator: 0.56	Before and after analysis	NR
Hammer 2001[128] (Poor)	Patients at a North Carolina rural community hospital who are at high risk for institutionalization and/or use health care system frequently	Nurse CMs accompanied clients to physician appointments, assisted with social service programs, worked with vocational rehabilitation services, arranged transportation, and monitored clients	Screening criteria included: frequent use of health care system at secondary or higher levels, multiple providers, cognitive deficits, functional limitation in ADLs or IADLs, lack of able caregiver, living alone, low income, complicated	NR	Pre/Post case management program, 12 months before and after intervention, or baseline vs. 12 months of CM	NR

Author Year (Quality)	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
		while still in the program.	mental, social, medical or behavioral impairments.			
Hebert 2003[129] (Poor)	Complex, frail elderly patients.	NR	Older than 65 years; moderate-to-severe disabilities (SMAF score ≥ 15/87) and requiring >2 health care or social services	NR	Implementation of PRISMA program, aimed at improving continuity of care	NR
Morales-Asencio 2008[140] (Fair)	Patients initiating the Home Care (HC) program from Andalusian Healthcare Service targeting the following groups: 1) terminally ill with advanced stage, progressive, incurable, multi-symptomatic disease with no reasonable chance of responding to specific treatment and estimated survival not ≤ 6 months; 2) dependent, requiring assistance for daily activities and immobilized at home.	The NCM provided a home visit with a comprehensive assessment, established coordinating services for patients, provided support and services to caregivers (e.g., support workshops for caregivers) and provided followup through telephone.	Patients and caregivers initiating the Home Care (HC) programme from the Andalusian Healthcare Service targeted subjects.	Age: 76 Gender: 63% female Race: NR	Quasi-experimental, prospective, multi-centre study, with concurrent control	NR
Schraeder 2008[149] (Fair)	677 persons aged 65 and older were determined to be at high-risk for mortality, functional decline, or increased health service use.	The 36-month intervention emphases collaboration between physicians, nurses and patients, risk identification, comprehensive assessment, collaborative planning, health	All individuals who joined the health plan during the first year of operation were mailed a 50-item health questionnaire (n=4053). After telephone contact with non-responders, a total of 3562 (treatment = 2012;	Age, mean ± SD, years: treatment 75.4±7.1 comparator 76.4±7.9. p=0.067 Gender, female: treatment 53.4% comparator 60.3%. p-value= 0.084 Race, minority: treatment 7.3%	Nonrandomized, 36 month comparison of two geographically distinct primary care populations	Managed care plan contracted with one multi-specialty, physician group practice and nine smaller, independent physician groups for primary care, and two urban and five rural hospitals to provide care to enrolled patients. Usual care consisted of 13 counties in west central Illinois, with a more diverse population

Author Year (Quality)	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
		monitoring, patient education and transitional care among chronically ill older persons living in the community.	comparison = 1460) questionnaires were returned, for an overall response of 88%.	comparator 23.1% p<0.001		base.

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Chi 2004[118] (Fair)	NR	Self rated health (no units). Patient and caregiver satisfaction. *Note: results are adjusted multivariate logistic regression models.*	Self rated health CM vs. comparator: OR; 0.86 (95% CI 0.36 - 2.08). Patient and the caregiver satisfaction the CM group was less likely to experience a decrease in satisfaction level. Patient: 0.05 (95% CI 0.01 - 0.30) Caregiver: 0.25 (95% CI 0.11 - 0.57)	CM group was more likely (OR 1.98; 95% CI = 1.05-3.74) than the comparators to experience a decrease in expenditure. Mean values: Baseline: 45756; 37645 Followup: 48926; 43910	NA	NR	Subjects in the comparator group were selected from a list of disabled elderly people in the community with similar health and physical functions. Usual care is provided by the Department of Health, Taipei City Government. CM included the following elements: 1) case finding, referral to local services in the community; 2) consultation with subjects and caregivers; 3) screened for urgent needs (via questionnaire); 4) comprehensive assessment and subsequent care plan; 5) implementation of care plan; 6) monitoring and reassessment
Fletcher 2009[126] (Poor)	NR	NA	NA	Total hospital admissions Before CM=188; After CM= 141 (chi-square = 5.1; p=0.28) GP contact increased in CM cohort: 3.8 vs. 2.2 times during study period (p=0.003) Reduction of costs: Mean GP cost per patient fell from £116.76 in pre-CM cohort to £90.54 in CM cohort. Nursing cost fell from £18.34 to £8.11 per patient. Nurse contact decreased in CM cohort: 1.0 vs. 1.9 times during study period (p<0.001)	NA	NR	CM program called Specialist Workers for Older People. CM program included a comprehensive needs assessment and development of individual care plans. Case managers also maintained contact with relevant agencies to arrange for required services. Also referred patients to a variety of services, such as other professionals (e.g. social workers, psychiatric nurses), charities (e.g. Age Concern, Red Cross) and befriending services.

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Gravelle 2006 (Fair) Intervention n=64	NR	Hospital episode mortality	Effect with intervention 35.4% Without intervention: NR	Effect with intervention: emergency admissions: 15% emergency bed days: 20% Without intervention: NR	NR	20 months	
Hammer 2001[128] (Poor)	NR	Cognitive function, ADL, IADL, Nutrition	1) Average number of ADL deficits at baseline vs. 1 year of CM: 0.92 vs. 1.56 2) Average number of IADL deficits at baseline vs. 1 year of CM: 5.44 vs. 6.4 3) Nutritional risk increased 1.25% compared to baseline 4) Of 16 clients with cognitive deficits at admission, 5 improved, 4 experienced no change and 7 declined after a year of CM. Of remaining 9 clients, 3 declined in cognitive ability.	Compared with 12 month period before CM: 1) ED visits increased 9.6% and length of stay decreased 14.3% in patients in CM program for 12+ months. 2) ED visits increased 31% and length of stay decreased 170% in patients in CM program for 10-12 months.	Cost savings to hospitals based on ED visits and length of stay: For CM clients in program for 12+ months = $29,081 savings. For CM clients in program for 10-12 months = $69,439 savings.	NR	No p-values or confidence intervals were reported.

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Hebert 2003[129] (Poor)	NR	Caregiver burden, functional decline	Reduced caregiver burden Function decline (comparator vs. study patients): 12 months: 49% vs. 31%; p=0.002 24 months: 36% vs. 26%; p=0.066	NA	NA	NR	
Morales-Asencio 2008[140] (Fair)	NA	Patient survival, satisfaction and caregiver burden	Patient survival, satisfaction, and caregiver burden Comparator vs. intervention, RR (95% CI); p-value 1) Patient survival: 0.87 (0.51–1.5); p=0.68 2) Satisfaction Intervention: 16.9 (16.3–17.4) Comparator: 14.7 (13.6–15.7) p=0.001 3) Caregiver: high-rate of non-responders prevented analysis	Home visits, social worker (SW) interventions, patient interventions, hospital readmissions, caregiver visits to health center Mean values, intervention vs. comparator 1) Home visits: 7.6 (6.1–9.1) vs. 11.8 (9.1–14.5); p=0.02 2) SW interventions: 1.0 (0.8–1.3) vs. 0.4 (0.2–0.6); p<0.0001 3) PT interventions: 7.9 (5.2–10.6) vs. 3.2 (1.4–5.1); p<0.0001 4) Hospital readmissions: 0.75 (0.47–1.03) vs. 0.7 (0.4–0.9); p=0.60 5) Caregivers visits: 7.8 (5.7–9.9) vs. 26.3 (19.2–33.4).	NR	12 months	

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Schraeder 2008[149] (Fair)	NR	NR	NR	Treatment vs. comparator Any hospital admission: 51.0% vs. 53.8% p=0.352 2 or more hospital admission: 19.2% vs. 28.8% p=0.006 Mean hospitalizations for service users only ± SD: 1.76±1.27 vs. 2.30±1.83 p=0.001 Mean hospital bed days for service users only ± SD: 8.19±10.15 vs. 13.89±16.54 p=0.002 Any ED visit without hospitalization: 16.8% vs. 12.1% p=0.086 Mean ED visit for service users only ± SD: 1.48±0.87 vs. 1.79±1.20 p=0.135 Mean cost of care per patient per month ± SD: $1193 ± $1953 vs. $708 ± $1028 p<0.001	NR	36-month intervention included addition of RN to the primary care practice of intervention group physicians. Also included routine telephone monitoring to identify changes in condition and adherence to treatment regimes, proactive post illness followup, and disease education	

Abbreviations: ADL=activities of daily living, CI=confidence interval, CM=case management, IADL=instrumental activities of daily living, NR=not reported, OR=odds ratio.

Evidence Table 5. Trials of Case Management for Dementia

Author Year (n) (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Callahan 2006[17] (n=153) (Good)	The authors tested the effectiveness of a collaborative care model to improve the quality of care for Alzheimer patients. Primary hypothesis: patients in the intervention group would have lower total NPI scores compared with usual care patients at 12 months.	Possible or probable Alzheimer disease based on Diagnostic and Statistical Manual of Mental Disorders criteria	Nursing home patients, non-English speakers, no access to a telephone, or no caregiver consent to participate in the study	Randomized trial (randomized by physician) Duration: 1 year intervention	Age mean: 77 Female: 43% Race: Black: 50% Medicaid recipient: 73% Married: 48% Mean MMSE score: 18	Alzheimer's disease and/or Dementia Most had multiple comorbid chronic conditions (mean chronic disease score:8)	Multiple comorbidities; socioeconomically disadvantaged
Chien 2008[18] (n=88 dyads) (Fair)	To test the effectiveness of a dementia care management program on caregiver and patient health outcomes.	Inclusion criteria for caregivers: 18 years old or >; living with and caring for a relative diagnosed with Alzheimer's type dementia(based on DSM-IV criteria)	Caregivers with mental illness of their own, or who cared for the patient < 3 months.	Randomized trial, 6 months; 12 month followup period	Caregiver Mean age: 43.6 ± 9.2 (range: 34-65) Female caregivers: 64% Patient mean age: 67± 6.8 (range 64-79) Female: 43% MMSE mean: 17.5 (SD 4.7)	Alzheimer's disease related dementia 1) NR 2) NR	NR

Author Year (n) (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type; Duration of Intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Chu 2000[20] (n=78 dyads) (Poor)	To determine whether a comprehensive home care program for early stage AD patients would delay caregiver burden and delay institutionalization.	Patients: possible diagnosis early stage AD; no concomitant illness; not at risk of placement to long term care; lived in the city; not in or eligible for regular home care program Criteria for caregivers included: principle informal caregiver for the client; no serious illness; lived with the client or in the city.	Not diagnosed with AD	Randomized trial Duration: 18 months	Age : 68% 75 years or > Gender :50% Female Race and/or ethnicity: NR SES: NR Education level: 45% 10 years or less; mean MMSE score 23;	Mild AD 1) No comorbidities per protocol 2) NR	NR

Author Year (n) (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Clark 2004[22] (n=210) (Poor)	To evaluate effects of care consultation delivered within a partnership between a managed health care system and an Alzheimer's Association chapter. A priori hypothesis: "patients offered care consultation will have decreased utilization of managed health care services and improved psychosocial abilities."	Kaiser member, dementia or diagnosis code for memory loss, 55 years or >, live outside nursing home, live in service area.	NR	Randomized trial, 12 months	NR	Dementia or memory loss 1) NR 2) Depression; N=85	NR

Author Year (n) (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type; Duration of Intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Eggert 1991[24] Zimmer 1990[25] (n=520; subgroup analysis, n= 94) (Poor)	To compare two models of case management (team care and centralized individual care) for SNF patients living at home. A priori hypotheses: Team care would result in 1) same or lower overall health care utilization and expenditures; 2) more satisfaction with health care provided; 3) better functional and health status, or no difference than comparators in degrees of change; 4) greater informal supports.	Age 18 or older, at risk or in need of long-term care at the skilled nursing level, living at home, eligible for Medicaid and Medicare waivers, residing within the catchment area	NR	Randomized trial	Median age: 77; Females: 73%; Race: Non white 24%; Medicaid eligible: 47%;	Chronically ill, disabled, elderly. CVD - 29%, Arthritis 29%, Diabetes 20%, Dementia 18% Stroke effects 17%, Cancer 17%;	Elderly, chronically ill, disabled, eligible for skilled nursing care

Author Year (n) (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type; Duration of Intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Eloniemi-Sulkava 2001[26] (n=100 dyads) (Good)	To determine whether community care of demented patients can be prolonged by means of a 2-year support program based on nurse case management	age 65 and older and entitled to payments from the Social Insurance Institution for community care because of a dementing disease; had no other severe diseases; living at home with an informal caregiver; residing in one of five Finnish municipalities	if patients and their caregivers were not able to participate in annual training courses	Randomized trial - 2 years; enrollment between Oct 1993and Jan 1995; 2 year followup.	Mean Age 79 years; Range (65-97); Female 53%; Race/ethnicity NR; SES, NR; Moderate dementia 31%, Severe dementia 30%	Dementia Comorbidities: NR	High need for support services
Eloniemi-Sulkava 2009[27] (n=125 dyads) (Good)	To determine whether a 2-year multicomponent intervention program can prolong community care of people with dementia	Couples: eligible if one spouse was caring for a partner with dementia at home and living in Helsinki, Finland; participants with dementia: diagnosis of dementia based on specialists' exams.	Couples in which one spouse had another severe disease with a prognosis of an estimated life span of <6 months.	Randomized trial - 2 years; enrollment Feb 1 to May 31, 2004; end of followup Jan 31, 2006; (length of intervention varied between 20 to 24 months)	Caregiver mean age: 75; Female caregivers: 63%; Race/ethnicity NR; SES, NR; Patient mean age: 78; Female: 38% Stage of dementia according to MMSE: Mild, 26% Moderate 55% Severe, 19%	Dementia (85% Alzheimer's), Comorbidity: NR	NR

Author Year (n) (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Jansen 2011[44] Jansen 2005[45] (n=99 dyads) (Good)	To assess outcomes of transmural care model for MS compared to patients receiving traditional usual care	Score on the MMSE <24 or a risk of dementia of 50% or more according to the 7 MS; has a primary caregiver.	For patients: assistance by an outpatient geriatric or psychiatric team for cognitive problems, terminal illness,insufficient command of the Dutch language, participation in other research projects, institutionalization; For caregivers: terminal illness, providing <1 hour of care/week, insufficient command ofthe Dutch language.	Randomized trial, 1 year intervention	Patient mean age: 82;Female: 64%; Race NR; SES NR; Mean MMSE score: 22; Caregiver Mean age: 63 Female caregivers: 70% Living with patient: 44%	Dementia>1 chronic disease: 76%	Burden of AD disease

Author Year (n) (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type; Duration of Intervention**	**Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Lam 2010[49] (n=102, case management group n=59, comparator group n=43) (Fair)	To evaluate a case management model for people with mild dementia, whereby resources within the family and in the community were mobilized and optimally used. Case management approach is effective in reducing the burden of family caregivers of older people with mild dementia.	65 years and older Community dwelling diagnosed with mild dementia, with CMMSE score of 15 or above, and/or Clinical Dementia Rating of 1	No family caregiver. Refused home visits by case manager. Subjects with significant concomitant disease with more than one hospital admission in the previous 12 months.	Randomized trial; 4 months intervention and 12 months followup	CM group: Age: 78; Gender: 59% female; Comparator group: Age: 78 Gender: 56% female	Dementia Psychogeriatric	Elderly; general lack of good networking in the primary health care system in Hong Kong.

Author Year (n) (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Mittelman 2006[65] Mittelman 2004 (a)[66] Mittelman 2004 (b)[67]; Roth, 2005[68] (n=406) (Good)	To determine the effectiveness of a counseling and support intervention for spouse caregivers of Alzheimer disease patients: delaying time to nursing home placement; caregiver symptoms of depression; negative caregiver appraisals of behavior problems; changes in social support and psychosocial outcomes.	Caregiver living with AD patient; relative of caregiver or patient living in the NY metro area; agree to participate in a support group	NR	Randomized trial; enrollment 1987-1997; 17-year longitudinal followup	Caregiver mean age: 71; Female caregivers: 60%; Race: NR; SES: NR Patient mean age: 74 Gender: NR Stage of dementia: Mild 34% Moderate 41% Severe 25%	Alzheimer's patients (the caregivers of) Comorbidities: NR	Caregiver burden; patient with AD at high risk for nursing home placement

Author Year (n) (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Mittelman 2008[69]; Brodaty 2009[70] (n=158 dyads) (Good)	To determine the effectiveness of a counseling and support intervention for spouse caregivers of Alzheimer disease patients taking donepezil: 1) caregiver symptoms of depression; (A priori hypothesis: the psychosocial interventionwould reduce caregiver depressive symptoms) 2) rates of nursing home placement and mortality.	Patient: Meet specified criteria for probable AD, Global Deterioration Scale score of 4 to 5, no contra-indication to donepezil; stable on other medications; in good physical health; able to give informedconsent or not object to participating, reside in the community with their spouse; Spouse: primary caregiver;	Spouse caregiver: previous formal caregiver counseling; no family member other than the caregiver available to participate in family counseling.	Randomized trial; 2 year intervention; up to 8.5 years followup	Caregiver age: Mean = 71.3 years (SD: 8.2, 47-88 years); Female caregivers: 56%; Race: NR; SES: NR Patient age: Mean = 73.8 years (SD:7.48, 51-91) Gender: NR Stage of dementia: (GDS 3) 2% Mild (GDS 4) 57% Moderate (GDS 5) 39% Severe (GDS 6) 2%	Alzheimer disease1) NR2) Caregiver depression: Moderate (12%), Severe (1%)	Burden of AD disease

Author Year (n) (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Newcomer 1999 (a)[73]; Newcomer 1999 (b)[74]; Newcomer 1999 (c)[75]; Miller,1999[76]; Shelton 2001[77] MADDE (n= 8,138) (Poor)	Effects of the Medicare Alzheimer's Disease Demonstration on: 1- Caregiver Burden and Depression; 2- Use of Community-based Services; 3- Medicare Expenditures; 4- Nursing Home Entry	(1, 2): received a baseline assessment and at least one semi-annual reassessment within the study period of 36 months; (3): participants who received their health care through Medicare FFS; (4): those who remained in the program >30 days after enrollment	No informal caregiver at baseline; already receiving case management services	Demonstration Project, randomized design Duration up to 3 years (project ended Nov 31, 1994)	Mean age: 78.9 years; Female: 61.3%; Race/ethnicity: White/non-Hispanic 87.3%	Alzheimer's Comorbidities: NR	Caregiver burden; patient with AD at high risk for nursing home placement
Vickrey 2006[107]; Duru 2009[108] (n=408 dyads) (Good)	To test the effectiveness of a dementia guideline–based disease management program on quality of care and outcomes for patients with dementia.	Age 65 years or older, enrolled in Medicare (either fee-for-service or managed care plans), had a dementia diagnosis, and had an informal caregiver at least 18 years of age; Clinic inclusion criterion: primary care clinics	NR	Cluster randomized trial Duration: 12 months	Patient mean age: 80; Female: 55%; Caregiver Mean age: 66; Female caregivers: 69%; Lives with patient: 70%	Dementia Comorbidities: NR	Burden of AD disease

Author Year (n) (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Callahan 2006[17] (n=153) (Good)	Medicaid recipient: 73%	NR	Two AP (geriatric NPs)	CMs monitored client/caregiver symptoms and stressors and instituted behavioral interventions based on protocols; collaborated with PCP on pharmacological therapy; worked in collaboration with PCP and other multidisciplinary team members.	NR	Embedded with primary care practices	Clinic visits, telephone calls, and group sessions	75 patients per year	Caregivers and patients seen by CM in primary care clinic bimonthly; lengthened to monthly for a period of 1 year; telephone interviews at 6, 12, and 18 months. Face-to-face number of CM contacts: mean [SD], 7.7 [5.8]; median, 7 [range, 0-28] over 12 months; telephone contacts: (mean [SD], 6.7 [5.8]; median, 5 [range, 0-35]).
Chien 2008[18] (n=88 dyads) (Fair)	NR (Hong Kong study)	NR (Hong Kong study)	Nurse	An education and support group for family members in addition to routine dementia care through the dementia resource center (pharmacotherapy, social and recreational activities for patients)	Case managers received 32 hours of formal training by the study researchers	Dementia resources center	During 12 sessions, plus home visits with education about dementia care	NR (unclear, each family received 1 CM--total number of CMs NR)	Home visits every other week; Twelve 2-hour sessions every other week

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Chu 2000[20] (n=78 dyads) (Poor)	NA (Canada)	No	SW	CM responsible for providing/ coordinating need-based services for patients enrolled in a comprehensive home care program; part of a multidisciplinary team	NR	NR	Telephone, home visits	NR	Monthly contact by phone or home visit; frequency increased as needed.
Clark 2004[22] (n=210) (Poor)	Kaiser	Kaiser	Social workers	Alzheimer's Association care consultation-Care consultants initiate contact and follow a standardized protocol for service delivery includes helping patients organize an efficient andcoordinated helping network help patientscope with emotional issues.	NR	NR	mainly phone contact;	NR	Varies according to need; average of 10 communication contacts with each patient and/o rcaregiver per year
Eggert 1991[24] Zimmer 1990[25] (n=520; subgroup analysis, n= 94) (Poor)	Medicare (86%), Medicaid (47%)	NR	2 CMs per team: community health nurse and social worker	Neighborhood Team Model: CM responsible for assessment, care plan development, arrangement/ provision of some direct services, patient monitoring, approval of Medicare and Medicaid services.	NR	Community-based	Home visits	40-45	Individualized

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Eloniemi-Sulkava 2001[26] (n=100 dyads) (Good)	NR (Finnish health care system)	NR (Finnish health care system)	Registered nurse with a public health background	Patients and their caregivers were enrolled in a 2-year support program based on nurse CM (involved systematic and comprehensive support by the FCC, who had access to the program physician.	Extensive training, support, and advice in dementia care from dementia specialists at the beginning of the study and throughout	Worked at the Department of Public and General Practice in the University of Kuopio	In-home visits and phone calls; 24 hour availability by mobile phone	50 patients maximum over the course of the study	Frequency of contacts varied from once a month to five times a day (problematic situations at home accounted for the great variability) (author's note: caregivers contacted FCC after hours only 10 times in 2 years)
Eloniemi-Sulkava 2009[27] (n=125 dyads) (Good)	Finnish health care system	Finnish health care system	Position Title: FCC; trained public health registered nurse with advanced practice education (3.5 years) and special education in dementia care (1 year)	FCC responsible for providing/ coordinating individual, need-based services; A home visit from the FCC initiated the intervention; The core elements of the intervention (FCC's actions, a geriatrician's medical investigations and treatments, goal-oriented support group meetings for spouse caregivers, and individualized services)	A dementia expert trained the FCC and geriatrician for their work and tutored them throughout the intervention	The FCC and the geriatrician worked in the Central Union for the Welfare of the Aged in Helsinki	FCC Services (Range per Family), n: Phone calls to and from families, 2,192 (1–91); FCC Services (Range per Family), n: Home visits, 337 (1–43), Office visits, 23 (1–4),	50 to 60 couples per FCC in partnership with a geriatrician	FCC Services (Range per Family), n: Phone calls to and from families, 2,192 (1–91);

Author Year (n) (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Jansen 2011[44] Jansen 2005[45] (n=99 dyads) (Good)	NR (Netherlands)	NA	Three district nurses who are specializedin geriatric care.	Assessment, planning, coordination, collaboration, and monitoring of care	Nurses were trained in working with the computerized assessment/ management program used in the study, and in organizing family-meetings. They also attended seminars on how to deal with dementia patients and their caregivers.	NR	In person	3 nurse case managers, study n=99 dyads	At least 2 home visits at the start of the intervention; telephone contact at least every 3 months; nurses available for telephone consultation; mean time of 10.8 hours/year per dyad (range 0.75–28 h).
Lam 2010[49] (n=102) (Fair)	NR	No	Community-based occupational therapist	CM group: 1. Assessment and advice 2. Home-based program on cognitive stimulation 3. Case management Comparator group: 1 home visit, no access to case management	NR	Community-based	CM group: initial home visit, telephone calls and followup at hospital clinic visits	59	(Median): Home visits (3); Phone (8); clinic (2)

Author Year (n) (Quality)	Payer/ Insurance Carrier (e.g., Medicare, Medicaid, private)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Mittelman 2006[65] Mittelman 2004 (a)[66] Mittelman 2004 (b)[67]; Roth 2005[68] (n=406) (Good)	NR	NR	Family counselor	Six sessions of individual and family counseling, support group participation, and continuous ad hoc telephone counseling	NR	NR,(likely NYU Alzheimer's Disease Center)	Face to face counseling sessions, ad hoc telephone counseling and support group; intervention support provided for an unlimited time	NR	Six counseling sessions occurred within 4 months of enrollment; ad hoc telephone counseling.
Mittelman 2008[69]; Brodaty 2009[70] (n=158 dyads) (Good)	NR; (3-country study: USA, UK, and Australia)	NR; (3-country study: USA, UK, and Australia)	Counselor	Five sessions ofindividual and family counseling for the caregiver within 3 months of enrollment and continuous availability of ad hoc telephone counseling; (patient received donepezil)	NR	NR	Face to face counseling sessions, ad hoc telephone counseling;	NR	Continuous availability of ad hoc telephone counseling

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Newcomer 1999 (a)[73]; Newcomer 1999 (b)[74]; Newcomer 1999 (c)[75]; Miller1999[76]; Shelton 2001[77] MADDE (n= 8,138) (Poor)	Medicare (Medicaid clients excluded)	NR	Model A sites (with one exception) and all Model B sites employed social workers as case managers; Illinois CMs were nurses.	Two case management models; differed by case manager-to-client ratios and service expenditure ceilings per month; Model A: target case manager-to-client ratio of 1:100; Model B: target case manager-to-client ratio1:30; support services: caregiver education, training, caregiver support groups, mental health and counseling services, transportation to education and support groups. Community services: chore, personal care, companion, and adult day care.	NR	NR	NR	Model A: CM-to-client ratio1:100; Model B: CM-to-client ratio 1:30	NR

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Vickrey 2006[107]; Duru 2009[108] (n=408 dyads) (Good)	Approximately 77% were in Medicare managed care settings, with the remainder in Medicare fee-for-service arrangements.	Approximately 77% were in Medicare managed care settings, with the remainder in Medicare fee-for-service arrangements.	NR for health care organization CM (main CM); Community agency– based dementia care managers were primarily social workers.	Care managers performed a structured home assessment, initiated a care plan, and provided ongoing followup as needed, with in-home reassessments every 6 months.	Formal training in the use of the Internet-based care management software used in the study (community-based CMs received joint training)	unclear (within the health care organization)	Home visits and phone.	each full-time care manager = approximately 50 patient/ caregiver dyads	Initial in-home assessment (77% received an initial visit); ongoing followup by phone as needed (calls every 30 days on average; average of 15/year, median 12); in-home reassessments every 6 months (55% had a formal reassessment - median, 7 months; range, 4-16 months). Median number of assessment and reassessment visits was 2.

Author Year (n) (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated Within Primary Care	Health IT
Callahan, 2006[17] (n=153) (Good)	Scheduled visits at primary care clinic.	Yes	Education on communication skills; caregiver coping skills; legal and financial advice; patient exercise guidelines; caregiver guide; optional support group counseling (56% of patients/ caregivers attended at least 1 session).	Yes (main focus of CM intervention).	Yes	Yes Adjustment: unclear (collaborated with PCP)	Yes; PCP and CM had weekly meetings with a multidisciplinary support team.	CM supported by a web-based longitudinal tracking system: managed patient contact schedule, tracked patient's progress and current treatments, communicated patient's and caregiver's clinical status to care team.
Chien 2008[18]; (n=88 dyads) (Fair)	Home visits every other week; Twelve 2-hour sessions every other week (assumedly held at the dementia resource center);	Provided a structured needs assessment and worked with caregivers to prioritize problem areas and formulate a multidisciplinary education program on effective care.	Caregiver education: educational workshop about dementia care (three sessions)	Educational workshop about the family role and strength rebuilding (six sessions) community support resources (one session)	Coordination of all levels of family care based on results of the needs assessment;	Routine dementia care at the center included pharmacotherapy and symptom severity assessment. Adjustment NR	NR	NR

Author Year (n) (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated Within Primary Care	Health IT
Chu 2000[20] (n=78 dyads) (Poor)	In-home visits (frequency varied according to need)	CM assisted patients, with long term planning, assessed clients and caregivers with: MMSE, GDS - Short Form, and Alberta Assessment and Placement Instrument	Education regarding disease process and caregiver skill training	Yes, provided to caregivers	Coordinated (as needed) a wide variety of support services;	NR Adjustment: No	Yes, physicians assessed medical factors and project coordinator/case manager applied other eligibility criteria	NR
Clark 2004[22] (n=210) (Poor)	During initial intake assessment	Structured initial assessment, identified problems and developed strategies for using personal, family, and community resources	Education on simplifying daily activities,establishing manageable routines, and keepinga journal	Based on "empowerment conceptual framework"; and families ability to make their owndecisions if given sufficient information and coaching	Enlist support and involvement from family members and friends; connect families to additional community resource; connect to mental health resources.	NR	NR	Yes, Kaiser electronic medical records
Eggert 1991[24] Zimmer 1990[25] (n=520; subgroup analysis, n= 94) (Poor)	Home visits; emphasis on in-person contact	Yes	Individualized	Yes	Yes	Yes, included some hands-on nursing care.	No	NR

Author Year (n) (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated Within Primary Care	Health IT
Eloniemi-Sulkava 2001[26] (n=100 dyads) (Good)	In-home visits (frequency varied according to need)	Yes	Annual training courses (10-day course at study entry, 5-day course at 1 and 2 years) for patients and their caregivers; included a patient medical check-up and psychological assessment	Yes	Yes (assistance with arrangements for social and health care services)	Yes, Adjustment unclear	FCC had access to the program physician for consultation and medical care as needed	NR
Eloniemi-Sulkava 2009[27] (n=125 dyads) (Good)	FCC Services (Range per Family), n: Home visits, 337 (1–43), Office visits, 23 (1–4)	During the first home visit by the FCC, the initial support plan was created in cooperation with the couples	Three 2-hour dementia information sessions for caregivers and family members; large proportion of patients received home based exercise training; (part of the intervention, FCC role not defined)	Caregivers participated in 5 goal-oriented peer support group meetings during the first followup year (part of the intervention, FCC role not defined)	FCC Services (Range per Family), n: Phone calls for arranging services 1,928 (1–97); services were primarily arranged through the municipal social and health care system; if required services were not available in the municipal service system, the FCC was able, through an intervention budget, to tailor services for the couples using private sector or nonprofit organizations	The FCC operated in partnership with the geriatrician, whose medical expertise the intervention couples had at their disposal Adjustment: NR	The intervention couples continued their own physician's visits; FCC and geriatrician cooperated closely with them.	NR

Author Year (n) (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated Within Primary Care	Health IT
Jansen 2011[44] Jansen 2005[45] (n=99 dyads) (Good)	Two initial home visits.	Care plan formulated during first and second home visits; Met monthly to discuss innovations and geriatric cases; supervised by a staff member	unclear (although seems implicit)	Organized family-meetings toeducate relatives, improve social support and relieve caregivers	Assessment, planning, coordination, collaboration, and monitoring of care.	Yes; the nurses referred patients and caregivers to other health care professionals, including diagnostic services, and they monitored results.	The nurses visited the PCPs to report on their patients.	CM utilized a computerized multidimensional instrument which assessed the general functioning of the patient, and provided management protocols.
Lam 2010[49] (n=102) (Fair)	Home visits; one for comparator group and regularly for CM group.	CMMSE CSDD NPI PWI-ID	Training on home-based cognitive stimulation strategies which included reading newspapers together, reminiscence by old-time photos and continued engagement in usual house-hold tasks and leisure activities.	CM advised on safe performance in basic self-care activities with environmental modification to promote safe home living, behavioral management, and communication techniques.	CM encouraged subjects to be registered with local social centers so that the family could tap into the locally available social services. CM liaised with staff in the social centers involved to ensure smooth integration of the subjects into the activity schedule	NR	Liaised closely with clinic geriatricians	NR

Author Year (n) (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated Within Primary Care	Health IT
Mittelman 2006[65] Mittelman 2004 (a)[66] Mittelman 2004 (b)[67]; Roth 2005[68] (n=406) (Good)	Two individual and four family counseling (location NR, likely NYU Alzheimer's Disease Center) sessions tailored to each caregiver's specific situation, encouragement of weekly support group participation, and availability of ad hoc telephone counseling.	Yes	Aside from scheduled counseling sessions in first 4 months, agreement to participate in a support group was an eligibility criterion (58% joined a group within 12 months)	Yes (main focus of intervention)	Provided resource information and referrals for auxiliary help, financial planning, and management of patient behavior problems. Each caregiver in the intervention group had access to all the interventions, and was provided with support for an unlimited time.	No	No	NR
Mittelman 2008[69]; Brodaty 2009[70]; (n=158 dyads) (Good)	Five sessions ofindividual and family counseling within 3 months; (some face-to-face ad hoc counseling in Australia)	Yes	Scheduled counseling sessions	Yes (main focus of intervention)	Resource information,help in an emergency, and other routine services	Patients were examined and tested by a health care professional at each followup visit in the first year.Adjustment: No; a clinician assessed patient response to donepezil at 3-month followup and could increase dose to 10 mg if necessary.	No	NR

Author Year (n) (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated Within Primary Care	Health IT
Newcomer 1999 (a)[73]; Newcomer 1999 (b)[74]; Newcomer 1999 (c)[75]; Miller 1999[76]; Shelton 2001[77] MADDE (n= 8,138) (Poor)	NR	Formal assessments	Caregiver education and training	Education and support groups	Purpose of demonstration project	Health status monitoring while in adult day care. NR for adjustment.	No	NR
Vickrey 2006[107]; Duru 2009[108] (n=408 dyads) (Good)	Home	Structured home assessment, reassessments every 6 months	Caregiver education: interactive educational seminars on relevant care issues such as the evaluation of acute behavior changes	CM collaborated with the caregiver to prioritize problem areas and teach problem-solving skills	Yes, initiated care plan actions, and sent a summary to the primary care physician and other designated providers; 3 community agencies collaborated to provide specific care services (e.g., access to respite care).	NR	Yes, a physician champion was established within each health care organization; The care manager sent an assessment summary, a problem list, and selected recommendations to the patient's PCP.	An Internet-based care management software system was used for care planning and coordination (included structured assessment, algorithms linking specific care management actions to assessment results, and inter organization care coordination and referral protocols).

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Callahan 2006[17] (n=153) (Good)	"Augmented usual care": counseling for patient and care giver by geriatric NP regarding diagnosis of Alzheimer disease, written educational materials, and a referral to community resources; PCP treated as deemed appropriate.	Intervention patients: experienced significant improvements in total NPI scores (reflecting fewer behavioral symptoms) at 12 and 18 months compared with patients who received usual care; NDD for measures of cognition or function; No significant differences in rates of nursing home placement.	Usual care: fewer cumulative physician or nurse visits (mean [SD], 5.6 [5.1]; median, 4 [range, 0-27]) than intervention patients (mean [SD], 9.3 [13.4]; median, 5 [range, 0-67]) (p=0.03) and differences persisted at 18 months (7.5 [median, 5.5; range, 0-36] vs. 12.9 [median, 9.0; range, 0-127]; p=0.02).	NR	NR	464 patients screened; 258 patients ineligible 253 no diagnosis of Alzheimer Disease; 5 no caregiver; 53 patient refused/ 74 Physicians randomized (153 Patients)	37 Physicians /(69 Patients) Assessment: 49 Patients Assessed --69 Patients Included in Primary Analyses; 37 Physicians Assigned to Intervention (84 Patients)18-months Assessment: 65 Patients Assessed; 84 Patients Included in Primary Analyses (ITT)	NR (deceased but cause of death NR)

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Chien 2008[18]; (n=88 dyads) (Fair)	Routine dementia care through the dementia resource center (pharmaco-therapy, social and recreational activities for patients, and written caregiver educational materials), and 6 monthly education sessions	Statistically significant difference (p<0.01) between groups favoring the intervention group: Mean NPI score at 6/12 months-Dementia care: 68.1/64.2, standard care: 84.5/85.1	Statistically significant between group differences in frequency (p<0.01) and duration (p<0.001) favoring the intervention group: Mean number of times at 6/12 months-Dementia care: 3.2/2.9); standard care: 5.4/6.4 ; Mean duration (days per month) at 6/12 months-Dementia care: 11.1/9.4 days; standard care: 16.9/17.1 days	Statistically significant between group differences favoring the intervention group p<0.001: Family Caregiving Burden Inventory Mean at 6/12 months-Dementia care: 56.7/48.3 ; standard care: 63.0/65.9; World Health Organization QOL Scale Mean at 6/12 months-Dementia care: 75.1/81.4; standard care: 69.8/65.2.	NR	Total of 88 of 200 pairs of eligible patients and primary caregivers	1 patient in the standard care group died at 6 month posttest; 2 intervention group dyads failed to complete the program but remained in the study group/88 dyads analyzed.	None
Chu 2000[20] (n=78 dyads) (Poor)	Comparator group given an information package on community resources.	No significant differences between groups for any of these outcomes level of cognitive impairment; frequency of behavior problems; depressive symptoms; delayed institutionalization.	NR	Measurement of caregiver burden; Significant difference in favor of the intervention at 6 months, but not at 3, 10, 14, and 18 months.	NR	Enrolled 78 pairs of clients/ caregivers	Analyzed: 37 pairs in treatment and 38 comparators; analyzed 75 pairs (3 pairs clients / caregivers excluded for wrong diagnosis)	NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Clark 2004[22] (n=210) (Poor)	patients and caregivers able to independently contact Association and use services (education and training programs, support groups, respite care); no interaction with Care Consultants/ no care planning process;	depression significantfor intervention variable and memory difficulties -- depression in the intervention group decreases forpatients whose memory difficulties worsen from T1 to T2.(beta=0.33; p 0.07), significantly decreased feelings of embarrassment and isolationdue to memory problems (beta= 0.17; p 0.07),and decreased difficulty coping with memory problems (beta=0.22, p 0.05)	Hospital admission and ED visits significant forthe intervention variable and self-reported memory difficulties (beta= 3.49; p<0.10, beta=2.56; p<0.10, respectively); sub-sample of patients with average or greater than average memory difficulties, coefficients for theintervention variable negative and significant forboth hospital admission and ED visit (beta= 2.97; p=0.07 and beta=2.30; p=0.03)	Among the patients with more self-reported memory difficulties,the intervention group was more satisfied with thequality of Kaiser services: (beta=0.23; p 0.07)	NR	Screened: 525; Eligible 233; Enrolled 210	121 of the 210enrolled cases completed	89 completed 1 year followup

Author Year (n) (Quality)	**Describe Comparator**	**Results by Patient Health Outcomes**	**Results by Resource Utilization Outcomes**	**Results by Process Measure Outcomes**	**Harms Reported**	**Number Screened/ Eligible/ Enrolled**	**Number Withdrawn/ Lost to Followup/ Analyzed (Overall)**	**Total Withdraw-als; Withdraw-als due to Adverse Events**
Eggert 1991[24] Zimmer 1990[25] (n=520; subgroup analysis, n= 94) (Poor)	Centralized Individual Model: Core CM functions (assessment/ planning) delegated to hospitals and certified home health agencies	Subgroup analysis: No significant difference between groups for satisfaction, functional status, informal supports.	Overall costs for team-managed patients were 14% less than for individually-managed patients (p=0.065, CI -34.2% to +1.3%); subgroup analysis of patients with dementia: Overall costs for team-managed patients were 41% less than for individually-managed patients.	NR	NR	Screened NR/ eligible 563; enrolled (n=520)	Unclear	NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Eloniemi-Sulkava 2001[26] (n=100 dyads) (Good)	Usual services provided for geriatric patients in community care by the municipal social and health care system or the private sector	During the first months, the rate of institutionalization was significantly lower in the intervention group than in the comparator group (p=0.042) but the benefit of the intervention decreased with time (p=0.028); Estimated probability of staying in community care up to 6, 12, and 24 months was 0.98, 0.92, and 0.63 in the intervention group and 0.91, 0.81, and 0.68 in the comparator group, respectively. (survival curves suggest that severely demented subjects benefited the most from the intervention (median time of staying in community care: intervention group 647 days, comparator group 396 days)	NR	NR	NR	Screened 141; eligible 126; enrolled 100; intervention (n=53), comparator (n=47)	100% analyzed	None

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Eloniemi-Sulkava 2009[27] (n=125 dyads) (Good)	Usual community care: receiving care and services from the municipal social and health care system, the private sector, or both, depending on their own initiative (the Finnish municipal service system includes a large variety of services, and families with members with dementia have the right to access these services); families were provided with information and referrals to community resources and written educational materials	At 1.6 years, comparator group vs. intervention group in long-term institutional care (25.8% vs. 11.1%, p=0.03). At 2 years, NSD. The 2-year adjusted hazard ratio for the intervention group was 0.53 (95% CI = 0.23–1.19, p=0.12).	Intervention led to reduction in use of community services and expenditures. The difference for the benefit of intervention group was -7,985 Euro (95% CI -16,081 to - 1,499, p=0.03). When intervention costs were included, the differences between the groups were not significant. The largest differences between the intervention and comparator groups appeared in the use of long-term institutional care (intervention 2,340 days vs. comparator 5,351 days) and in the district nurses' home visits (388 vs. 1,931).	NR	NR	Screened n=197 couples; Eligible/ enrolled n=125 couples; intervention (n=63 couples), comparator (n =62 couples)	100% of those enrolled were included in the analysis	NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Jansen 2011[44] Jansen 2005[45] (n=99 dyads) (Good)	Participating pairsreceived care (health care and welfare services available in the Netherlands) depending on their own initiative. They had no access to family meetings, or the computerized assessment;	No statistically significant and clinically relevant differences over time between the two groups for QOL.	NR	No statistically significant and clinically relevant differences over time between the two groups.	NR	Screened: NR, Eligible NR; Enrolled 99 dyads; Intervention (n=54), Comparator (n=45)	Withdrawn/died: Intervention 26%; Comparator 34%	NR
Lam 2010[49] (n=102) (Fair)	Usual care	CM group: 4 months, 12 months MMSE: 1.0, -1.0 CSDD: -1.0, -1.0 NPI: -4.5, -2.0 PWI-ID: 0.0, 10.7 Comparator group: 4 months, 12 months MMSE: 0.0, -1.5 CSDD: -0.5, -0.5 NPI: -5.0, -7.0 PWI-ID: -0.7, 1.4	Baseline (n): CM, Comparator Paid helpers: 19, 7 Day Care: 28, 18 Home help: 5, 5 Respite care: 0, 1 4th month (n): CM, Comparator Paid helpers: 27, 6 Day care: 44, 19 Home help: 3, 3 Respite care: 1, 0 12th month (n): CM, Comparator Paid helpers: 21, 7 Day care: 37, 14 Home help: 3, 3 Respite: 0, 0	None of the changes of primary and secondary outcomes at fourth and twelfth months showed significant group difference.	NR	102 recruited. Randomized to CM n=59, comparator n=43.	At 4 months: CM group: n=2, 1 deceased 1 drop out Comparator group: n=1, deceased At 12 months: CM group: n=4, 2 deceased, 2 CVA Comparator group: n=3, 3 deceased.	NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Mittelman 2006[65] Mittelman 2004 (a)[66] Mittelman 2004 (b)[67]; Roth 2005[68] (n=406) (Good)	Resource information and help upon request; did not receive formal counseling sessions, and generally did not have contact with the intervention counselors.	Caregivers in the intervention group were able to keep their spouses at home longer than caregivers in the usual care comparator group (hazard ratio 0.714, p=0.015), (median time difference: 585 days). Patients whose spouses received the intervention experienced a 28.3% reduction in the rate of nursing home placement compared with usual care comparators (hazard ratio = 0.717 p=0.025); Frequency of behavior problems significantly increased over time, but no difference between groups in the pattern of change over a 4-year period.	NR	Improvements in caregivers' satisfaction with social support, response to patient behavior problems, and symptoms of depression collectively accounted for 61.2% of the intervention's beneficial impact on placement (p=0.406); significantly fewer symptoms of depression (p<0.05) in CM, 161 weeks (3.1 years); significantly lower appraisals (p=0.037); Significant positive effects on number of support persons (p=0.01), amount of caregiving assistance received (p=0.0002), and caregivers' ratings of satisfaction with their social support networks (p<0.0001); effects of change in satisfaction with social support were significant predictors of both change in stress appraisals (p<0.0001) and change in depression (p<0.0001).	NR	Screen: NR; Eligible: NR, Enrolled 406; Intervention (n=203), Comparator (n=203)	Unclear	NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events
Mittelman 2008[69]; Brodaty 2009[70] (n=158 dyads) (Good)	Resource information, help in an emergency, and routine services, but not formal structured counseling sessions.	Over a mean of 5.4years (SD 2.4), there were no differences in NH placement or mortality by intervention group.	NR	Symptoms of depression decreased for treatment caregivers and increased for comparator caregivers at 6 months, with the trend continuing over 2 years of followup (0.031).	NR	Screened: 169 dyads; Eligible/enrolled: 158 dyads; Intervention: 79; Comparator: 79.	At 2 years - withdrawn: (intervention 13, comparator 19); lost to followup (intervention 26, comparator 18); analyzed overall: 158	Total withdrawals 22; withdrawals due to adverse events: NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdraw-als; Withdraw-als due to Adverse Events
Newcomer 1999 (a)[73]; Newcomer 1999 (b)[74]; Newcomer 1999 (c)[75]; Miller 1999[76]; Shelton 2001[77] MADDE (n= 8,138) (Poor)	Usual care, which generally at the time of enrollment, did not include CM services.	At 6 months, less than a one-point difference between treatment and comparators for burden on a 32-point scale (mean scores of 14.4 vs. 14.9, p<0.05), no statistically significant difference in other periods; less than half a point difference between treatment and comparators for depression on a 15-point scale at 18 and 24 months (mean scores of 4.17 vs. 4.53, and 4.06 vs. 4.36, p<0.05), no statistically significant difference in other periods;	(2): Intervention group was at least twice as likely as comparator group to be using any of the four community-based services; No consistent differences between demonstration models; (3): For demonstration sites separately and combined, there was a tendency toward reduced expenditures observed for the treatment group; in two sites, differences were or approached statistical significance for expenditures averaged over 3 years; expenditure reductions approached budget neutrality with program costs in two sites. (4):No difference on permanent nursing home entry rates for intervention	NR	NR	(1, 2): 8,138 received a baseline assessment at enrollment; Eligible for analyses (n=5,307), (excluded:189 did have an informal caregiver at baseline, 2,642 died, were placed in nursing home, withdrew, or changed caregiver prior to second assessment period); (3): eligible for analysis: (n=5,649); (4): eligible for analysis: (n=8,095);	(1,2): 36 % of the initial sample were residing in the community and received a 36-month reassessment; (4): attrition within 30 days (3.5%): 97 died, 160 entered a nursing home, 35 dropped out; loss-to-followup 811	NR

Author Year (n) (Quality)	Describe Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events
Vickrey 2006[107]; Duru 2009[108] (n=408 dyads) (Good)	Patients, caregivers, and providers were not offered study interventions; patients received care as usual;	Participants who received the intervention had higher care quality on 21 of 23 guidelines (p<0.013); Higher proportions of intervention participants received community agency assistance (p<0.03); Patient health-related QOL, overall quality of patient care, caregiving quality, social support, and level of unmet caregiving assistance needs were better for participants in the intervention group than for those in the usual care group (p<0.05); A higher proportion in the intervention group were taking a cholinesterase inhibitor at followup (p=0.032); No significant difference in caregiver health-related QOL between the 2 groups.	No significant differences in the mean monthly cost of health care and caregiving services for intervention vs. usual care patients using the societal perspective or the payer perspective (and total costs did not differ for patients enrolled in managed Medicare vs. fee-for-service Medicare); No significant differences in inpatient or outpatient utilization between the 2 study groups at followup.	Significantly higher mean percentage in the intervention group than in the usual care group (63.9% vs. 32.9%), adjusted difference, 30.1% [95% CI, 25.2% to 34.9%] p<0.001;	NR	1043 patients initially identified; 91 were ineligible, 308 declined to participate, and 236 did not respond; total enrolled (patient/ caregiver dyads) 238 in the intervention group and 170 in the usual care group	407 had complete utilization data at baseline; survey response rates = 88% at 12 months and 82% at 18 months, excluding 32 deaths in the intervention group and 26 deaths in the usual care group. Analyzed - main analysis; 296 of 408 enrolled; sensitivity analysis;354 patients who completed at least 1 followup survey and for 260 patients who survived for the entire study period and completed surveys at both 12 months and 18 months.	NR

Abbreviations: AD=Alzheimer's disease, CI=confidence interval, CM=case management, CMMSE=Chinese version of Mini Mental State Examinations, CSDD=Cornell Scale for Depression in Dementia, DSM=Diagnostic and Statistical Manual of Mental Disorders, CVD=cardiovascular disease, FCC= Family Care Coordinator, GDS=Geriatric Depression Scale, MADDE= Medicare Alzheimer's Disease Demonstration and Evaluation Study, MMSE=Mini-Mental State Examination, NA=not applicable, NP=nurse practitioner, NPI= Neuropsychiatric Inventory, NR=not reported, PWI-ID=Personal Well-Being Index-Intellectual Disability, SES=socioeconomic status, SD=standard deviation, QOL=quality of life.

Evidence Table 6. Observational Studies of Case Management for Dementia

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (age, gender, race)	Study Design/ Type	Adjusted Variables, Selection of Controls (for case-control studies)
Challis 2002[117] (Fair)	Diagnosis of dementia, significant needs unmet by the existing services, and perceived risk of institutionalization	Case managers maintained structured care plans which were completed at regular intervals using a tool specifically designed for the study.	Staff from the community mental health team for the elderly made referrals	Mean age: 81 years; 30% male Race/ethnicity: NR	Quasi-experimental design	Aspects of needs, quality of care, and quality of life, encompassing the perspectives of the older person, carers, and the assessing researcher.

Author Year (Quality)	Population	Categorization of Exposure	How Subjects Were Referred to Case Management	Demographics (age, gender, race)	Study Design/ Type	Adjusted Variables, Selection of Controls (for case-control studies)
Specht 2009[151] (Poor)	Counties were selected based on rural demographics. Selected in pairs of those served by same Area Agency on Aging and Alzheimer's Association Chapter. Participants included if had memory impairment, even "suspected" and based on county of residence. Not excluded based on age or economic criteria but traditional case management system serves only those over 60 years of age and most services from other funding sources reserved for those who qualify under stringent income guidelines.	Registered nurses who received training in dementia management and assessment acted as nurse case managers in intervention group; They completed assessment with caregiver and care recipient to identify issues and instituted interventions that met needs; performed home visits as needed with at least monthly contact, and always available by phone. Periodic re-assessment to modify care plan as required. Other interventions were reminiscence, role supplementation, environmental restructuring for health and safety, and resource mobilization. Information about the disease provided, as well as assistance to care recipient with activities of daily living, respite for caregiver and encouragement of use of services and support groups.	Enrollment through a local project facilitator; collected comparator data and made referrals. Referrals also made by participant, or family, or by physicians, public health or social service workers calling local area agencies or case management offices.	<u>Care recipients:</u> Intervention group, n=107 vs. Comparator group, n=40: Mean age (SD): 82.4 (8.2) years, range: 43.0-95.4 years vs. 78.5 (8.6) years, range: 53.6-91.5 years; p=0.012 Gender: 68.2% female (n=73) vs. 57.5% female (n=23); p=0.247 Race: NR Total annual income (US dollars): <8,000: 27.2% (n=25) vs. 15.4% (n=6) 8,000-11,999 : 22.8% (n=21) vs. 23.1% (n=9) 12,000-14,999: 17.4% (n=16) vs. 15.4% (n=6) 15,000-19,999: 17.4% (n=16) vs. 10.3% (n=4) 20,000-29,999: 8.7% (n=8) vs. 20.5% (n=8) >,=30,000: 6.5% (n=6) vs.15.4% (n=6) p=0.043 Live with caregiver: 70.1% (n=75) vs. 85.0% (n=34); p=0.089 Groups significantly different on age, diagnosis of Alzheimer's, annual income, health changed in last 12 months, ADL index (p<0.05) <u>Caregivers:</u> Intervention group, n=75 vs. Comparator group, n=34: Mean age (SD): 63.9 (14.7) y, range: 31.1-92.3 vs. 69.2 (11.5) y, range: 46.6-85.7; p=0.071 Gender: 75.7% female (n=56/74) vs. 63.6% female (n=21/33); p=0.246 Race: NR Total annual income (US dollars): <8,000: 28.3% (n=15) vs. 19.2% (n=5) 8,000-11,999 : 11.3% (n=6) vs. 19.2% (n=5) 12,000-14,999: 9.4% (n=5) vs. 7.7% (n=2) 15,000-19,999: 15.1% (n=8) vs. 11.5% (n=3) 20,000-29,999: 15.1% (n=8) vs. 26.9% (n=7) 30,000-39,999: 11.3% (n=6) vs.3.9% (n=1) >,=40,000: 9.4% (n=5) vs. 11.5% (n=3) p=0.687 Groups significantly different on relation to care recipient, caregiver endurance (p<0.05)	Prospective matched cohort	p.197: Care recipient analyses: mixed model analysis adjusted for presence/absence of caregiver Caregiver analyses: Not adjusted but co-variate analysis performed to test care recipient variables (GDS, MMSE, ADL index, behavior rating index, functional abilities rating, age, and caregiver characteristics (age, education, health) with caregiver stress, well-being, and endurance potential by extending logistic regression model to include 1 covariate at a time.

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration
Challis 2002[117] (Fair)	NR	QOL and quality of care for older people and their carers.	QOL measures : (statistically significant ($p<0.05$) results at 6 months) CM more satisfied with their home environment, improvements in social contact; reduction in distressing behavior Quality of care measures: (statistically significant results at 6 months and maintained at 12 months) reduction in needs overall as rated by carers $p<0.001$; reduction in ADL needs $p<0.01$; reduction in levels of risk $p<0.05$; Carer's needs and QOL: (statistically significant [$p<0.05$] results for CM group at 12 months) reduction in total hours of input by carers; reduction of felt burden for carers. Destinational outcomes: Differences between the two groups in the rate of placement are not evident until after the first year. By 18 months 56% receiving CM and 51% receiving usual care remained in their own homes. At 2 years, 51% of CM group remained at home compared with 33% of the usual care group.	The differences in service receipt constitute the main differences in costs, with the majority of the increased cost for CM accounted for by total professional visits (24%) [CM 63 days/year, usual care 33.5 days/year, $p<0.01$)], total home care (44%) [CM 13.3 days/year, usual care 4.7 days/year], and acute hospital care (27%) [CM psych 12.4 days/year and medical 18.3 days/year vs. usual care psych 7.0 days/year and medical 13.7 days/year)	NR	Case management: Provided appropriate services; had access to all relevant health and social service resources. Duration: 2 years

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration
Specht 2009[151] (Poor)	NA	Care recipient: 1) ADL index: 1-5, 1=more care 2) Behavior rating index: 1-13, 1=less negative behaviors 3) MMSE:1-30, 1=more impairment 4) GDS:1-7, 1=less impairment Caregiver: 1) Stress 2) Well-being 3) Endurance potential	Care recipient: ***Comparing outcomes at followup for intervention vs. comparator groups:*** Followup data at 3-9 months for n=93 vs. n=32 Followup data at 9-15 months for n=64 vs. n=23 1) ADL index (1-5, 1=more care): Baseline: 2.14+/0.07 vs. 2.48 +/-0.15 3-9 months followup: 2.31+/-0.07 vs. 2.50+/-0.15, p≤0.003 9-15 months followup: 2.45+/-0.07 vs. 2.55+/-0.14, p≤0.0001 2) Behavior rating index (1-13, 1=less negative behaviors) Baseline: 1.71+/-0.06 vs. 1.60+/-0.11 3-9 months followup:1.67+/-0.06 vs. 1.80+/-0.13 9-15 months followup: 1.58+/-0.06 vs. 1.72+/-0.13 3) MMSE (1-30, 1=more impairment) Baseline: 20.76+/-0.64 vs. 20.41+/-1.45 3-9 months followup: 21.66+/-0.66 vs. 20.70+/-1.80 9-15 months followup: 21.15+/-0.76 vs. 20.60+/-1.67 4) GDS (1-7, 1=less impairment) Baseline: 4.0+/-0.1 vs. 3.4+/-0.3 3-9 months followup: 4.2+/-0.1 vs. 3.6+/-0.3 9-15 months followup: 4.3+/-0.1 vs. 3.7+/-0.3 Significant group differences noted above. Other variables not significant between groups. Caregiver: ***Comparing outcomes at followup for intervention vs. comparator group (p.200):*** Followup data at 3-6 months for n=40 vs. n=23 Followup data at 9-15 months for n=29 vs. n=16 During 15 months followup, intervention and comparator groups showed significantly different patterns of change over time for all 3 outcomes; (p=0.014 for stress, p=0.002 for WB, p=0.006 for EP)	NR	NR	Study cites limitations as follows: followup evaluations not done in timely manner, lack of followup decreased number of participants in analysis, care recipient groups and caregiver groups significantly different at baseline Case management: Initial assessment, home visits as required (often weekly in the beginning), "periodic" reassessment. Always available by phone. Duration: 3 years of grant

Author Year (Quality)	Incidence (if cohort study)	Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration
Specht 2009[151] (Poor) Continued			1) Proportion with extensive stress did not significantly change in intervention group over time (p>0.38), although there was an increase amongst comparator group at 3-9 month followup (p=0.077) that decreased at 9-15 month followup. At 3-9 months, comparator group more likely to have extensive stress compared to intervention (OR=5.56; 95% CI 1.27-24.37; p=0.19) 2) Proportion with substantially compromised WB increased significantly in comparator group at 3-9 month followup (p=0.018), remained high at 9-15 month followup. Compromised WB decreased during followup in intervention group, not significant. At 9-15 months followup, comparator group more likely to have compromised WB than intervention group (OR=8.07; 95% CI 1.10-59.32; p=0.038) 3) Proportion with inadequate EP decreased significantly at 3-9 months in intervention group (p=0.013). Proportion with inadequate EP in comparator group increased at followup, not significant. ***Covariates associated with caregiver outcomes:*** Caregiver extensive stress associated with higher care recipient behavior rating index, per unit increase (OR=3.52; 95% CI 1.81-6.83; p=0.005) Substantially compromised WB associated with higher behavior rating index, per unit increase (OR=2.28; 95% CI 1.20-4.35; p=0.035) and associated with caregiver health change, per unit increase (OR=2.10; 95% CI 1.23-3.59) Inadequate endurance associated with care recipient age, per 5 year decrease (OR=1.61; 95% CI 1.30-5.18; p=0.027)and associated with caregiver age, per 10-year decrease (OR=1.61, 95% CI 1.13-2.29; p=0.020)			

Abbreviations: ADL=Activities of Daily Living Index, CM=case management, EP=endurance potential; GDS=Geriatric Depression Scale, MMSE=Mini-Mental State Examination, SD=standard deviation, QOL=quality of life, WB=well-being.

Evidence Table 7. Trials of Case Management for Congestive Heart Failure

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
DeBusk 2004[23] (Good)	To determine whether a telephone-mediated nurse care management program for heart failure reduced the rate of rehospitalization for heart failure and for all causes over a 1-year period.	Hospitalized between 5/1998-10/2000 in one of five medical centers with provisional diagnosis of HF; new-onset or worsening HF on the basis of 1) shortness of breath 2) ≥1 corroborating clinical sign or radiologic abnormality consistent with HF.	Scheduled for coronary artery bypass or valvular surgery; cardiac surgery in the preceding 8 weeks; serum creatinine >5 mg/dL; dialysis or awaiting renal transplant; pulmonary disease requiring home oxygen; other disease(s) expected to result in death within 1 year; cognitive mental deficits, substance abuse or severe psychiatric disorders; expected to move from the area within 1 year.	Randomized trial, intervention for 1 year	Age: Mean (SD) 72 (11) years; Median NR; Ranges < 60 (15%), 60-70 (23%), 70-80 (39%), >80 (24%); Female 48%; Race: White (83.5%), Black (5.8%), Asian (17.3%) Hispanic (3%) American Indian (5.8%) SES: NR	Heart Failure (severity at baseline: NYHA class I or II (49%), class III or IV (51%)) 1) Hypertension (63%); Coronary artery disease (51%) 2) NR	Disease severity; number of comorbidities

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Jaarsma 2008[43] (Good)	To examine the effects of a nurse-led disease management program at two levels of intensity on the combined endpoints of death and readmission to the hospital.	Admitted to one of 17 study hospitals with symptoms of HF, NYHA class II to IV, age 18 years or older, evidence of structural underlying heart disease on imaging, either preserved or impaired left ventricular ejection fraction, stable on standard medications for HF prior to hospital discharge	Concurrent inclusion in another study or HF clinic, inability to complete the questionnaires, invasive procedure or cardiac surgery intervention performed within the last 6 months or planned to be performed within the next 3 months, ongoing evaluation for heart transplantation, and inability or unwillingness to give informed consent.	Multicenter randomized trial with blinded endpoint evaluation	Mean age: 71+/-11 Female: 38% Living alone: 39% NYHA functional class: II 50% III 46% IV 4%	Heart failure 1) HTN 43%; AFib 36% ; DM 28% Stroke 10% ; COPD 43% 2) NR	Multiple comorbidities, severity of disease (all patients NYHA Class II-IV)

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Kasper 2002[46] (Good)	To determine whether a multidisciplinary outpatient management program decreases CHF hospital readmissions and mortality over a 6-month period.	English-speaking, admitted at one of two study hospitals with a primary diagnosis of NYHA class III/IV CHF, one or more risk factors for CHF readmission (age >70 years, left ventricular ejection fraction <35%, CHF hospital admission in the previous year, ischemic cardiomyopathy, peripheral edema at discharge, <3 kg of weight loss in hospital, PVD, or hemodynamic findings (during the index admission) of pulmonary capillary wedge pressure>25 mm, cardiac index <2.0, systolic BP>180, diastolic BP>100).	Valvular heart disease requiring surgical correction, substance abuse, peripartum cardiomyopathy with left ventricular outflow tract obstruction, restrictive cardiomyopathy, constrictive pericarditis, psychiatric disease or dementia, concurrent noncardiac illness likely to cause repeat hospital admissions, heart transplantation likely to occur within 6 months, uncorrected thyroid disease, serum creatinine >265 picomoles/L, long-term IV therapy at home, cardiac surgery or MI during index admission, active participation in another research trial, unwilling to provide informed consent, residence in a nursing home, rehab facility, or outside the service area.	Randomized trial, intervention duration 6 months	Age (years): Mean (62), Median (63.5), Range (25-88);Male: 60%Race: White 64%, Black 35%; NYHA class (at time of randomization): II: 36%, III: 59%	Chronic heart failure1) HTN: 67%; DM: 40%2) NR	Severity of disease (eligible patients all NYHA class III or IV at hospital admission), majority with 1-2 comorbidities, patients with moderate impairment in functional capacity and quality of life.

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Laramee 2003[50] (Fair)	To test the effect of hospital-based nurse case managementon readmission rate in a heterogeneous CHF population. The case-managed group would exhibit a 50% lower 90-day readmission rate than the usual care group and maintain equivalent or better adherence to plan of care.	Clinical signs and symptoms for CHF and either moderate-to-severe left ventricular dysfunction or radiographic evidence of pulmonary congestion and symptomatic improvement following diuresis; at risk for early readmission (one or more of the following: history of CHF, knowledge deficits of treatment plan or disease process, potential or ongoing lack of adherence to treatment plan, previous CHF hospital admission, living alone and four or more hospitalizations in the past 5 years).	Discharge to a long-term care facility; planned cardiac surgery; cognitive impairment; anticipated survival of fewer than 3 months; long-term hemodialysis.	Randomized trial; 12 week intervention; enrollment period July 5, 1999, through April 30, 2001.	Mean age (SD): 71 (12); Median and Average age: NR; Female 46%; Race NR; Income <$10,000: 24%	CHF 1) Hypertension (74%); Diabetes (43%); COPD (23%); PVD (15%); Hyperlipidemia (58%); Obesity (48%) 2) NR	Multiple comorbidities and risk for early hospital re-admission

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Peters-Klimm 2010[84] (Good)	To explore whether a primary-care based CM intervention for HF patients would improve health-related QOL, HF self care, and patient-reported QOC.	Age> = 40 years; objective leftventricular CHF; EF = or < 45%; NYHA I with hospital admission because of CHF within the last 24 months or NYHA II-IV; stable disease at enrollment; capable to give informed consent.	Participation in another clinical trial within the last 30 days; residency in a nursing home; primary valvular heart disease with relevant hemodynamic effects, hypertrophic obstructive/restrictive cardiomyopathy, status post/pre organ transplant, acute left ventricle failure, life expectancy of < 2 years due to other illness, impaired mental state; drug abuse.	Prospective, two-arm randomized trial, patient enrollment Dec 2006 and Jan 2007; 1-year intervention.	Age: Median and Range NR, Mean (SD) 70 (10); Male: 73%; Race: NR; SES: lower social class (according to modified German Winkler-index) 31%	Chronic congestive heart failure 1) AFib 27%; ; PAD 17%; Cerebrovascular disease 19%; COPD 26%; Diabetes 34%; HTN 79%;; Dyslipidemia 70%; 2) Depression 20%	CHF; Likely to have additional comorbidities and polypharmacy
Pugh 2001[85] (Poor)	Patients who receive enhanced discharge planning, post-discharge instruction, and intensive post-hospital collaboration with their providers will demonstrate more favorable outcomes (increased functional status and higher quality of life) than their counterparts who receive usual care, and that the costs will be neutral.	65 years or older, diagnosis of CHF at levels 2, 3, or 4 as indicated by the NYHA rating and candidates or discharge to home or a retirement community as determined by the attending physician. Those receiving services from home health care agencies were also eligible for participation.	Admitted to a skilled care facility, had a concomitant disease which could have altered the prognosis of the patient's 1-year survival, had heart failure due to a corruptible cause, were unable to return for followup evaluation, or if they were unable to ambulate because of loss of function of lower extremities.	Randomized trial; 6 months	Age: Average 77 years; Gender: 56% female; Ethnicity: all white	Coronary Heart Failure	Elderly. Treatment group 48% and usual care group at 44.1% for NYHA level 3

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Rich 1993[88] (Poor)	To test the effectiveness of a multidisciplinary approach to prevent hospital readmission of elderly patients with CHF *A priori:* up to 50% of readmissions are potentially preventable	>70 years of age, diagnosis of congestive heart failure while hospitalized, with one [moderate] or more [high] risk factors for rehospitalization (> 3 hospitalizations in last 5 years, prior history of CHF, cholesterol < l50 mg/dL, right bundle-branch block on admission).	Death prior to discharge, residence outside catchment area, planned discharge to nursing home or chronic care facility, terminal malignancy, severe mental incapacity or psychiatric illness.	Randomized trial; 90 day followup *(duration of intervention unclear)*	Age: treatment group 80 (+/-6.3) years, comparator 77.3 (+/-6.1) years p=0.04 Male: 41%; Race: White 52%; SES: NR	Congestive Heart Failure 1) Diabetes: 31% HTN 66% 2) Coexisting mental illness not reported	Elderly; Moderate (n=61) to high (n=37) risk of rehospitalization
Rich 1995[89] (Fair)	To assess the effect of a nurse-directed, multidisciplinaryintervention on rates of readmission, quality of life, and costs of care for elderly patients with CHF.	>70 years of age admitted with CHF and at risk for readmission (prior history of HF, or >3 hospitalizations for any reason in last 5 years, or CHF precipitated by acute MI, or uncontrolled HTN (systolic >200 mm Hg or diastolic >105 mm Hg).	Residence outside catchment area, planned discharge to a long-term-care facility, severe dementia or other serious psychiatric illness, anticipated survival of less than 3 months, refusal to participate by either the patient or the physician, and logistic or discretionary reasons (including participation in pilot study - Rich 1993)	Randomized trial, 90 day followup *(duration of intervention unclear)*	Age: Comparator (78.4+/-6.1), treatment (80.1+/-5.9), p=0.02; Female: 64%; Nonwhite race:56%; Education greater than 8th grade: Comparator 48%; treatment 35%, p=0.03; Married: 35%; Living alone: 43%	Congestive Heart Failure1) HTN:76%; DM: 28%2) NR	Elderly; at risk for early hospital readmission

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Riegel 2002[90] (Fair)	To assess the effectiveness of a standardized telephonic nurse case managementintervention in decreasing resource use in patients with chronic HF. Primary hypothesis: HF hospitalization rates would be lower in the CM than in the comparator groups. Secondary hypotheses: CM intervention would decrease all-cause hospitalization, readmission rates, (for HF and all causes), average number of hospital days (for HF and all causes), and inpatient HF costs at 3 and 6 months.	Hospitalization at one of two hospitals with a confirmed clinical diagnosis of HF as the primary reason for the hospital visit and spoke either English or Spanish.	Cognitive impairment or psychiatric illness; severe renal failure requiring dialysis; terminal disease; discharge to a long-term care facility; or previous enrollment in an HF disease management program.	Randomized trial, 6 month duration	Mean age: 74 years Female: 50% Race: NR Primary language: English 72% Spanish 26% Functionally compromised (97%were NYHA class III or IV)	Chronic heart failure1) HTN: 69%; COPD: 36%; CAD: 65%; CVA: 10%; DM:42%; PVD: 17%; Renal disease without dialysis: 28%; Thyroid disease:15%2) NR	Multiple comorbidities, Spanish-speaking

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Riegel 2006[91] (Fair)	*A priori hypothesis:* Telephone case management would decrease hospitalizations (acute care use) and improve HRQL and depression in Hispanics of Mexican origin with HF.	Hospitalized with a primary or secondary* diagnosis of HF at one of two participating hospitals, self-identified Hispanics, community dwelling and planning to returnto the community after hospital discharge (*only if at high risk for a HF hospitalization because of age > 80 years, a highlevel of comorbid illness, or not being on an ACEI at admission)	History of cognitive impairment, on dialysis, acute MI within the preceding 30 days without established history of chronic HF, serious or terminal condition, major/ uncorrected hearing loss, lack of access to a telephone, or failure to give informed consent.	Randomized trial, duration 6 months, enrollment 2 years	Mean Age: 72.1 (+/- 11) years; Female 54%; Married: 60%;Education: Grade school or less 78%, Insurance: Medicaid 10%, Medicare 60%, No insurance 6%; Annual income <$15,000: 76%; Speak/read only Spanish: 63%;	Heart failure1) HTN 79%; COPD 28%; History of MI 28%; Diabetes 59%; Diabetes with end-organ damage 18%; Renal disease (with creatinine >3 mg%) 7%2) Depression treatment part of intervention.	Language barrier, low annual income, most with Medicare/Medicaid or indigent care insurance, most with less than high school education.

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex Care Needs
Sisk 2006[105] (Good)	To compare the effects of a nurse-led interventionfocused on specific management problems vs. usual care amongethnically diverse patients with systolic dysfunction in ambulatory care practices.*A priori hypothesis* patients in the focused nurse management program would have fewer hospitalizations and report better functioning than patients in usual care.	Adults 18 years of age or older; EF <0.40 or systolic dysfunction documented on a cardiac test; English-language or Spanish language speakers; community dwelling at enrollment; and current patient in a general medicine, geriatrics, or cardiology clinic at a participating site.	Medical conditions that prevented interaction with the nurse, including blindness, deafness, or cognitiveimpairment; pregnancy; renal dialysis; terminal illness; orprocedures that corrected systolic dysfunction;	Randomized trial; 12 month intervention.	Age: Median and Average NR, Mean (SD) 59 (14); Female: 46%; Ethnicity: Non-Hispanic black 46%, Hispanic 33%, Non-Hispanic white 15%, Other 6%; Spanish-language speaker 23%; High school education 46%; Inadequate health literacy 30%; Insured 96%; Living alone 32%;	Heart failure with systolic dysfunction.1) Alcoholism 9.4%; Angina 13.1%; Cerebrovascular disease 12.8%; Chronic pulmonary disease 31%; Diabetes 38.2%; Hypertension 70.7%; Ischemic heart disease 44.8%; Moderate or severe renal disease 13.5% 2) Psychiatric disorder 9.9% Depression 14.0%	Multiple comorbidities, ethnic minority population, age.

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Did case manager have the ability to adjust medications?	Primary Location of Case Manager
DeBusk 2004[23] (Good)	Kaiser Permanente	Yes; Kaiser Permanente California	Nurses	In addition to usual care, intervention group received a standardized, telephone-mediated intervention which included the following elements: initial educational session, including a videotape; baseline telephone counseling session; nurse-initiated followup telephone contacts; pharmacologic management; and nurse-initiated communication with physicians.	NR	Yes; could initiate and regulate HF meds according to study protocol (based on published treatment guidelines).	Unclear (possibly at Stanford University)
Jaarsma 2008[43] (Good)	NR	NR	Nurse specializing in management of patients with heart failure	Two levels of intervention (basic and intensive support); all intervention patients received: 1) inpatient visit by HF nurse for education and support 2) OP cardiology visit <2 months after discharge and then every 6 months. 1) Basic support: additional visits to the HF nurse at the outpatient clinic, and instructions to contact the nurse if there was any change in condition. 2) Intensive support: similar intervention but monthly contact with the nurse; weekly telephone contacts and home visit by the HF nurse in the first month; telephone calls, 2 home visits, and multidisciplinary advice given by a physiotherapist, dietician, and social worker.	All nurses were trained to increase the self-efficacy of patients.	No	Nurses in cardiology outpatient clinic
Kasper 2002[46] (Good)	NR	NR	Intervention team included: telephone nurse coordinator, CHF nurse, CHF cardiologist and the patient's primary physician.	Telephone nurse coordinator: followup phone calls with set script within 72 hours of discharge, weekly for 1 month, twice in 2nd month, then monthly; followed up problems as clinically indicated, but did not adjust meds; CHF nurses: monthly followup, usually in CHF clinic; followed a prespecified algorithm for medicine adjustment, diet, and exercise.	NR	CHF nurses adjusted medications under the directions of the CHF cardiologists following a prespecified algorithm.	Telephone nurse located in local call center; CHF nurses located at CHF clinics.

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Did case manager have the ability to adjust medications?	Primary Location of Case Manager
Laramee 2003[50] (Fair)	Heterogeneous insurance types	No	CHF case manager (CM) with a master's degree and 18 years of experience in critical care and cardiology.	Four major components: early discharge planning, patient and family CHF education, 12 weeks of telephone followup, and promotion of optimal CHF medications.	All case management completed by one CHF case manager.	No; (however the CM monitored CHF meds and dosages and made recommendations to health care providers based on consensus guidelines).	Hospital-based
Peters-Klimm 2010[84] (Good)	Study included GP practices (in Germany) that took all insurance types.	No	Doctor's assistants, equivalent to a nursing role; mean years of work experience (SD): 10.8 (9.1)	Regular monitoring of symptoms and medication adherence via telephone monitoring along with 3 home visits; direct feedback from CM given to employing GP.	Doctor's assistants participated in the study's case management workshops; duration of training was 1.5 days.	No. Able to inform GP upon urgency.	Embedded in primary care clinic

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Did case manager have the ability to adjust medications?	Primary Location of Case Manager
Pugh 2001[85] (Poor)	NR	NR	Nurse CM	Usual care group were followed by their primary care physician and a professional nurse was assigned to them each shift of each day. Care was coordinated using a primary nursing approach to patient care. Treatment group received enhanced discharge planning, were taught to manage their heart failure within parameters set by their physician using a workbook, received patient-specific printed material as well as ongoing nursing assessment, and followup by a nurse case manager for a 6-month period through telephone contacts and followup visits. CM provided a review of the subject's medication plan, diet, activity program, self-management parameters such as daily weights, and modifications to the medication regimen secondary to fluid retention. Subjects were scheduled to return to the clinic at 6 months after discharge to complete a QOL Questionnaire and take the Six-Minute Walk test.	NR	CM would provide modifications to the medication regimen secondary to fluid retention	Hospital
Rich 1993[88] (Poor)	NR	NR	Experienced cardiovascular research nurse.	Patient education, medication monitoring, post-hospital coordination with home health nurse, telephone follow up. Note: Study intervention was multidisciplinary and also included pre-discharge medication review by geriatric cardiologist, and in-hospital social worker, dietician, and home care team involvement.	NR	No	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Did case manager have the ability to adjust medications?	Primary Location of Case Manager
Rich 1995[89] (Fair)	NR	NR	Experienced cardiovascular research nurse.	Patient education, medication monitoring, post-hospital coordination with home health nurse, telephone follow up.Note: *Study intervention was multidisciplinary and also included pre-discharge medication review by geriatric cardiologist, and in-hospital social worker, dietician, and home care team involvement;*	NR	No	NR
Riegel 2002[90] (Fair)	NR	NR	RN	Telephonic case management by an RN using a decision support software program designed to emphasize factors shown to predict hospitalization in persons with HF (i.e., poor adherence to medication regimens and diet recommendations and lack of knowledge of the signs and symptoms of worsening illness).	The nurses received 10 days of intense training and continuing mentoring in case management thereafter (i.e., 15 one-hour sessions); a total of 95 hours of training was provided each case manager.	NR	Hospital
Riegel 2006[91] (Fair)	Insurance: Medicaid 10%; Medicare 60%; HMO 24% No insurance 6%	23.9% *unspecified HMO*	Two bilingual/bicultural Mexican-American registered nurses/special training in HF	Telephonic case management by a bilingual/bicultural RN using a decision support software program designed to emphasize factorsshown to predict hospitalization in persons with HF (i.e., poor adherence to medication regimensand diet recommendations and lack of knowledge of the signs and symptoms of worsening illness). *The intervention was refined to be culturally appropriate, including an emphasis on personalized caring, trust, inclusion of the family, and concrete solutions and problem solving in response to problems with self-care.*	NR	No	The nurse case managers were affiliated with the hospital.

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Did case manager have the ability to adjust medications?	Primary Location of Case Manager
Sisk 2006[105] (Good)	Insurance provider not specified, but overall, 95.6% of patients were insured.	No	Three registered nurses (2 of the nurses were bilingual English/Spanish)	Counseling on diet, medication adherence, and self-management of symptoms; served as a bridge between patient and clinician-coordinated medication changes and exams.	NR	No	One nurse at the 2 municipalhospitals, second nurse at the small community hospital, and second and third nurse delivered intervention at academic center.

Author Year (Quality)	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education (e.g., seminar)	Self-Management Support
DeBusk 2004[23] (Good)	Telephone, after initial face-to-face visit.	NR	Initial 1-hour educational session in person; a 45-minute baseline telephone counseling session within 1 week of randomization; followup telephone contacts scheduled at weekly intervals for 6 weeks; biweekly for 8 weeks; monthly for 3 months; bimonthly for 6 months; and as needed.	Initial 1-hour educational session with a nurse occurred in the patient's medical center.	Yes	Initial 1-hour educational session with a nurse occurred in the patient's medical center.	In the initial educational session, patients received educational materials, including methods for self-monitoring of symptoms, body weight, and medications.
Jaarsma 2008[43] (Good)	Home visits and telephone calls, as well as HF nurse clinic visits in both basic and intensive support groups.	NR	All patients were seen at an outpatient cardiology clinic within 2 months of discharge and every 6 months. 1) Basic support: scheduled for additional visits in HF clinic (estimated time investment of nurses was 20 hours per patient) 2) Intensive support: more contacts with the HF nurse than basic support plus weekly telephone calls and a home visit in 1st month post-discharge, plus 2 additional home visits (estimated time of nurses was 40 hours per patient).	Initial in-patient visit, HF clinic visits, and home visits.	Yes	Patients given a diary, brochures on HF and its management, and intensive education inpatient prior to discharge.	HF nurses for both support groups trained to increase patient self-efficacy in their interactions with patients.

Author Year (Quality)	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education (e.g., seminar)	Self-Management Support
Kasper 2002[46] (Good)	Telephone calls and CHF clinic visits	NR	Phone calls by nurse coordinator: one within 72 hours of discharge, weekly for one month, twice in second month and monthly thereafter (average: 9.5 calls per patient); CHF nurse visits at least monthly (8.5 visits per patient).	CHF nurse visits monthly, usually at clinic, sometimes at patient's home.	CHF nurse followed a treatment plan designed by the cardiologists.	Patient received list of correct medications, list of dietary and physical activity recommendations, and "patient education material" (not otherwise described).	NR
Laramee 2003[50] (Fair)	12 week telephone followup.	65-89 at any given time (included study and nonstudy patients)	Phone calls to patient and/or family members at 1-3 days after discharge, and at weeks 1, 2, 3, 4, 6, 8, 10, and12 (calls ranged from 5 to 45 minutes).	All face-to-face time occurred while the patient was hospitalized.	Developed the plan of care with patient and family.	Described as a major focus whenever in contact with patient or family.	Yes (described as a major focus when in contact with patient or family)

Author Year (Quality)	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education (e.g., seminar)	Self-Management Support
Peters-Klimm 2010[84] (Good)	Phone calls every 3-6 weeks and 3 home visits/year.	NR (there were 31 CMs from 21 practices, with an average of 3.2 intervention patients per practice)	Telephone and home visits: low to medium risk (NYHA I/II): phone call every 6 weeks and three home visits during the year; high risk (NYHA III/IV), phone calls every 3 weeks and three home visits during the year; Mean durations (SD; range) telephone calls: 10 (5; 2-38)minutes; Mean durations (SD; range) of 3 home visits: 55 (14; 30-120), 53 (16, 18-90) and 51 (17; 21-90) minutes, respectively. Total time per patient (telephone monitoring, travel time, home visits, and reporting) during the 12-month followup: low to medium risk (NYHA I/II); mean (SD) 5.2 (2.0) hours; high risk (NYHA III/IV); mean (SD) 6.7 (2.4) hours.	Initial clinic visit for CM introduction and patient education; 3 home visits/year.	Yes	Yes	Self-monitoring education and tools provided to patient at first clinic visit.

Author Year (Quality)	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education (e.g., seminar)	Self-Management Support
Pugh 2001[85] (Poor)	Initial visit in person, afterwards: telephone contact and followup visits.	NR	Mean # of CM/nurse visits per patient per month: usual care 3.08 intervention 4.92	Initial face-to-face in hospital and then follow up 6 months after discharge.	Teaching programs were individualized to meet each patient's learning needs, CM conducted interviews of the patients, family and/or significant others. CMs identified support systems, learning deficits, or emotional barriers that might inhibit the patient's ability to adjust to lifestyle changes or to cope with chronic illness.	Treatment group received enhanced discharge planning, were taught to manage their heart failure within parameters set by their physician using a workbook, received patient-specific printed material.	Study handouts and other written materials were handed out to take home; this was supplemented by videotapes related to heart failure and diet. Also, a written medication schedule was given to and reviewed with patient, family and/or significant other.
Rich 1993[88] (Poor)	In-hospital, followup by telephone	NR	Daily visits during hospitalization by research nurse, frequency of followup phone calls NR.	In-hospital	Early discharge planning by multi-disciplinary team	Daily visits during hospitalization by research nurse for disease management education.	Daily visits during hospitalization by research nurse for disease management education. Home-care nurse's role included reinforcing patient teaching.

Author Year (Quality)	**Primary Mode of Case Manager Contact with Patient**	**Caseload**	**Frequency of Visits and Phone Calls**	**Location of Face: Face Time**	**Planning and Assessment**	**Patient Education (e.g., seminar)**	**Self-Management Support**
Rich 1995[89] (Fair)	In-hospital and followup by telephone.	NR	Daily visits during hospitalization by research nurse, frequency of followup phone calls NR;	In-hospital	Early discharge planning by multi-disciplinary team.	Daily visits during hospitalization by research nurse for disease management education	Daily visits during hospitalization by research nurse for disease management education. *Home-care nurse's role included reinforcing patient teaching.*
Riegel 2002[90] (Fair)	Telephone	NR	Phone contact within 5 days after hospital discharge and thereafter at a frequency guided by the software and case manager judgment; an average of 17 phone calls at decreasing levels of intensity, length, and frequency over the 6-month followup period (median, 14 phone calls; IQR, 11-22 phone calls). Each patient was estimated to have received 16 hours of a case manager's time, most of which was spent counseling the patient over the telephone.	Not included in study. All contact by telephone.	Yes	Calls emphasized patient education; printed educational material mailed to patients monthly.	Yes; calls emphasized monitoring and patient education.

Author Year (Quality)	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education (e.g., seminar)	Self-Management Support
Riegel 2006[91] (Fair)	Telephone.	N=69 between 2 case managers but not specifically reported.	Telephone contact within 5 days after hospital dischargeand thereafter at a frequency guided by the softwareand nurse case manager judgment. Patients received an average of 13.5 (SD 5.9; median 13; interquartile range 11–16) telephone contacts and families received an additional 8.4 (SD 6.3; median 7; interquartile range 3–13) telephone contacts over the 6-month intervention period, with most calls early after hospital discharge.	None. Intervention was intended to be by telephone only.	Yes	Calls emphasized patient education; Printed educational material in the desired language was mailed to patients monthly and as needed when specific information was requested.	Yes; calls emphasized self-monitoring and patient education; printed educational material sent monthly and upon request (in appropriate language).
Sisk 2006[105] (Good)	Initial interview face-to-face, follow up by telephone calls, mailed questionnaire at 2, 4, 8, 12, and 24 weeks.	NR	One initial visit. Phone call every 3 months.	One initial face-to-face meeting.	Yes	HF disease and self-management education at initial visit and reinforced with each phone contact; Provided educational booklet in English or Spanish at initial visit.	Self-management education at initial visit and reinforced with each phone contact.

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
DeBusk 2004[23] (Good)	Intervention did not include discharge planning or social work involvement.	Telephone contacts with patients to monitor medications, laboratory assessments, symptoms, and other medical problems; yes; could initiate and regulate HF meds according to study protocol (based on published treatment guidelines)	Nurse-initiated communication with physicians about patients' current medical status was maintained and specific management problems were addressed.	NR	Nurse care managers spent an average of 9 hours per patient coordinating the treatment plan with patients and physicians during the first year.	Usual care provided by their primary health care providers included instruction on diet, drug adherence, physical activity, and response to changing symptoms.	1) Proportional Hazard (95% CI) for composite outcome: Cardiac cause: 0.85 (0.64-1.14), P >0.2; Any cause: 0.87 (0.69-1.08), p>0.2 2) Proportion of patients receiving angiotensin- converting enzyme inhibitors or angiotensin- receptor blockers (% treatment group vs. % usual care group): 90% vs. 75%; at 12 months: 90% vs. 88%. 3) Proportion of patients receiving β- blockers: (% treatment group vs. % usual care group): baseline: 38% vs. 32%; 12 months: 50% vs. 46%.
Jaarsma 2008[43] (Good)	Multidisciplinary advice was given to patients by a physiotherapist, dietician, and social worker in the intensive support group.	Patients examined at hospital discharge and for 18 months thereafter (this is not otherwise specifically described); no adjustment.	No. Patient coordinated visits were all to specialized HF clinics.	NR	None	Patients in the comparator group did not receive any treatment other than standard management by their cardiologist.	Death outcomes, comparator vs. basic support vs. intensive support; n (%): All causes: 99 (29) vs. 90 (27) vs. 83 (24) Reduction in mortality of 12% for basic (HR: 0.88 [95% CI 0.66 to 1.18; p=0.39]) and 19% for intensive support compared to comparator groups (HR: 0.81 [95% CI 0.60 to 1.08; p=0.15]); for both groups vs. comparator, HR 0.85 (95% CI 0.66 to 1.08, p=0.18)

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Kasper 2002[46] (Good)	Patients with limited financial resources were provided, if needed, a scale, a 3-g sodium "Meals on Wheels" diet, medications, a pill sorter, transportation to the clinic, and a telephone;	CHF nurse notified primary physician of abnormal lab values; CHF nurses adjusted medications under the directions of the CHF cardiologists following a prespecified algorithm.	Yes. Primary physicians approved of patient participation, as well treatment plan; they managed all problems not related to CHF and received regular updates from the CHF nurses; and were notified of abnormal laboratory values.	NR	None	Care by primary physicians; baseline therapeutic plan designed by CHF cardiologist documented in patient's chart without further intervention	Death: non-intervention:13, CM: 7, p=0.14. 1) Admissions for CHF: non-CM: 59 admissions among 35 patients; CM: 43 admissions among 26 patients; p=0.09; 2) QOL scores MLHF change from baseline: CM total mean: 35.7, intervention total median: 33, 25th to 75th %: 14-52; comparator total mean: 45.3, total median: 51, 25th to 75th %: 22-64, p=0.013) Duke activity status change from baseline: CM score mean: 1.1, score median: 1.0; comparator score mean 0.8, median: 1.0, p=0.44

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Laramee 2003[50] (Fair)	Responsible for in-hospital consultations and discharge planning; made arrangements for additional services or support after discharge as needed.	Yes (monitoring of CHF meds and dosages while hospitalized and after discharge); No to adjustment.	CM submitted progress reports to the PCP while the patient was in the hospital; After discharge the physician was informed of the patient's study participation and outlined the case management program. At study completion, the PCP received a letter that summarized the patient's condition and progress in the program. At week 6, if the patient was not taking an ACEI or ARB and a BB was appropriate or if he or she was not at target doses, a recommendation letter was sent to the responsible physician as a courtesy reminder.	NR	The CM wasavailable to the patient and family as a resource Monday- Friday during daytime hours.	Usual care group received standardcare, typical of a tertiary care hospital, and all conventional treatments requested by the attending physician. Inpatient treatments included social service evaluation (25% for usual care group), dietary consultation (15% usual care), PT/OT (17% usual care), medication and CHF education by staff nurses, and any other hospital services. Post-discharge car conducted by the patient's own local physician.	Patients in the intervention group were significantly more satisfied with their care in 13 of 16 items than the usual care group (p<0.01). All items that measured care instructionsand recovering at home were significantly better in the intervention group (p<0.01); Mean (intervention vs. comparator), 1-5 scale: Hospital care: 4.2 vs. 4.0, p=0.003; Hospital discharge: 4.3 vs. 4.0, p<0.001; Care instructions: 4.0 vs. 3.4, p<0.001; recovering at home: 4.4 vs. 3.9, p<0.001; Total score: 4.2 vs. 3.8, p<0.001. Medication Use and Target Dose Advancement, Number (%) of patients in Intervention vs. Comparator groups:1) at discharge: Taking ACEIs or ARBs: 121 (86%) vs. 115 (79%), p=0.16; Taking BBs: 91 (65%) vs. 89 (61%), p=0.63; Target dose of ACEI or ARB: 74 (64%) vs. 56 (51%), p=0.08); Target dose of BBs: 28 (33%) vs. 18 (23%), p=0.17at 12 weeks: Taking ACEIs or ARBs: 108 (84%) vs. 90 (80%), p=0.40; Taking BBs: 89 (70%) vs. 70 (62%), p=0.22; Target dose of ACEI or ARB: 64 (63%) vs. 42 (49%), p=0.08; Target dose of BBs: 27 (32%) vs. 18 (29%), p=0.72

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Peters-Klimm 2010[84] (Good)	NR	Monitoring of symptoms and medication adherence; no adjustment though CM gave GP feedback.	CM embedded in primary care and employed by the GP. CMs gave feedback (results of patient monitoring) directly to the GPs.	NR	None	Usual care (no CM) from primary physician.	Mean (SD) scores for CM vs. comparator Baseline: SF-36: physical composite score, 36.4 (11.0) vs. 36.9 (10.1); mental composite score, 45.8 (11.9) vs. 47.6 (12.8); KCCQ overall summary score: 65.4 (22.6) vs. 64.7 (22.7).Followup, Mean (SD), Mean difference [95% CI]: SF-36: physical composite score, 38.0 (8.6) vs. 38.3 (8.6), mean difference, -0.3 [-3.0, 2.5], cohens d=0.04, p=0.857; mental composite score, 46.5 (9.9) vs. 46.6 (9.9), mean difference, -0.1 [-3.4, 3.1], cohens d=0.01, p=0.929; KCCQ, 68.0 (16.9) vs. 66.3 (17.2), mean difference 1.7 [-3.0, 6.4], cohens d=0.10, p=0.477
Pugh 2001[85] (Poor)	CM collaborated with primary nurse, resident, and other appropriate members of the multidisciplinary team, including dieticians, social workers, and physical therapists.	Medication was monitored; adjustments NR	Primary care physicians and cardiologists were informed of changes in patient symptoms, and lab work was coordinated with the physicians.	NR	None	Usual care group: followed by primary care physician and professional nurse was assigned to them each shift of each day. Care coordinated using primary nursing approach to patient care.	Treatment group NYHA score of 4 at baseline was 8% and 0 at 6 months. Usual care group increased from 6.9% to 10%. Median score for Treatment was 3 at baseline and 2 at 6 months. Usual care group median score was 3 at baseline and 3 at 6 months. Treatment group average 6-Minute was 133.6 ± 115.5 at baseline and 166.5 ± 132.8 at 6 months. Usual care group average 6-Minute walk was 138.0 ± 107.1 at baseline and 133.2 ± 86.9 at 6 months.

Author Year (Quality)	**Coordination of Services**	**Medical Monitoring; Adjustment**	**Integrated Within Primary Care**	**Health IT**	**Others**	**Describe Comparator**	**Results by Patient Health Outcomes**
Rich 1993[88] (Poor)	Discharge summary completed by study nurse and transmitted to home health nurse.	No; No	No	NR	None	All conventional treatments requested by attending physician; (Social-service consultations and home-care referrals were over 30% less frequent among usual care group)	NR
Rich 1995[89] (Fair)	Discharge summary completed by study nurse and transmitted to home health nurse; *Note: Study intervention was multidisciplinary and also included pre-discharge medication review by geriatric cardiologist, and in-hospital social worker, dietician, and home care team involvement.*	No; No	No	NR	None	All conventional treatments requested by attending physician; included social-service consultations (46%), dietary consultation (49%) and home care after discharge (39%)	Mean ± SD Changes in quality of life scores, comparator vs. intervention:Total QOL change: 11.3±16.4 vs. 22.1±20.8, +96%, p=0.001; Dyspnea: 3.8±5.4 vs. 6.8±7.9, 79%, p=0.01; Fatigue: 2.7±6.1 vs. 5.4±5.5, +100%, p=0.01; Emotional function: 1.9±5.2 vs. 5.6±7.1, +195%, p=0.001; Environmental mastery: 2.9±5.0 vs. 4.4±5.3, +52%, p=0.10

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Riegel 2002[90] (Fair)	Consultation with physicians, other health care professionals, and community agenciesas needed; facilitated access to medications and patient/physician communication.	Monitored patient for HF symptoms.	Automated reports produced by the CM software updated physicians on patient progress, and physicians were telephoned by the case managers as needed; guidelines for the treatment of systolic HF distributed to physicians.	Decision support software used by CMs to guide and standardize care; automated reports produced by the software updated physicians on patient progress	NR	Care for patients in the usual care group was not standardized, and no formal telephonic case-management program was existed. These patients presumably receivedsome education regarding HF management prior tohospital discharge.	Patient satisfaction at 6 months (Mean ± SD), intervention vs. comparator:22.88 ± 2.85 vs. 21.66 ± 3.44; % change=+5.6; p=0.01 (with covariates BB use and chronic lung disease) and p=0.01 without covariates
Riegel 2006[91] (Fair)	4.6 (SD 4.4; median 3; interquartile range 1.5–7) CM contacts involved consultation with other professionals (egg, physicians, dieticians, social workers) and community agencies.	No; No	Reports mailed to physicians noted when patients were not receiving medications advocated in clinical guidelines.	Decision support software used by CMs to guide and standardize care.	None	Not standardized; involved no formal disease management program; HF management education before hospital discharge (lack of bilingual staff meant much of the discharge instruction was providedin writing).	HRQL and depression, intervention vs. comparator, mean ±SD (95% CI):1) 3 month results: MLHF emotional subscale: 1.5±2.8 (0.60-2.4) vs. 1.9±3.8 (0.92-2.9); MLHF physical subscale: 7.5±6.6 (5.5-9.4) vs. 8.4±7.4 (6.3-10.4); MLHF total: 12.3±11.8 (8.7-15.8) vs. 13.9±13.9 (10.1-17.6); EQ-5D VAS: 70.1±18.7 (63.8-76.5) vs. 64.0±27.0 (57.3-70.7); EQ-5D Index: 0.84±0.14 (0.79-0.89) vs. 2.3±2.3 (1.6-3.0); Depression by PHQ-9: 1.9±2.1 (1.3-2.5) vs. 2.3±2.3 (1.6-3.0)2) 6 month results: MLHF emotional subscale: 1.4±3.0 (0.53-2.3) vs. 1.9±3.3 (1.0-2.8); MLHF physical subscale: 7.5±7.1 (5.6-9.4) vs. 8.1±6.7 (6.0-10.1); MLHF total: 12.1±12.3 (8.9-15.3) vs. 12.9±10.9 (9.5-16.3); EQ-5D VAS: 73.4±17.4 (68.6-78.1) vs. 73.7±17.4 (68.6-78.8); EQ5D Index: 0.82±0.20 (0.77-0.88) vs. 0.78±0.20 (0.72-0.84); PHQ-9: 1.5±2.0 (0.92-2.1) vs. 2.0±2.1 (1.3-2.6)

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Sisk 2006[105] (Good)	At initial appointment, referred as needed to social services, prescription drug or other insurance coverage, home health services, management of depression.	Case managers suggested subsequent examinations indicated by the protocol: 1) ACE inhibitor or ARB: Check creatinine, potassium, and bloodpressure levels in 1–2 weeks. 2) Beta Blocker: Check blood pressure and heart rate in 1–2 weeks. Adjustment: advised provider on medication changes, but CM could not change medications.	Written note sent to patient doctor after each contact with patient, but case managers located at hospitals.	NR	NR	Patients received Federal consumer guidelines for managing systolic dysfunction but no other intervention.	Mean change in functioning score, intervention vs. comparator, difference (95% CI), adjusted difference (95% CI)12 months: SF-12 physical: 0.5 vs. -2.7, 3.2 (1.0 to 5.3), 3.1 (0.7 to 5.5); MLHF: -1.9 vs. 5.4, -7.3 (-12.1 to -2.6), -7.0 (-12.4 to -1.7)12 to 18 months: SF-12 physical: -2.1 vs. -0.5, -1.6 (-4.7 to 1.4), -1.7 (-4.2 to 0.9); MLHF: 0.0 vs. -4.6, 4.6 (-1.3 to 10.6), 4.7 (-0.1 to 9.5)

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
DeBusk 2004[23] (Good)	Proportional Hazard (95% CI) for time to first rehospitalization: Heart failure: 0.84 (0.56-1.25), p>0.2; Any cause: 0.98 (0.76-1.27), p>0.2 Mean number of emergency department visits in the treatment and usual care groups during the first year of followup: 3.2 (median, 2.0) vs. 3.5 (median, 2.0)	NR	No harms of intervention reported.	Screened:2786; Eligible: 835 Enrolled:462 intervention (n=228); usual care (n=234)	First year followup: Withdrawal 3% (intervention 8, usual care 15); Died 11% (intervention 21, usual care 29)	No withdrawals listed due to adverse outcomes.	
Jaarsma 2008[43] (Good)	1) Hospitalization Incidence rate: Intensive support group= 0.31, comparator group = 0.29 per follow up year; incidence rate ratio: 1.07 (95% CI 0.83 to 1.37; p=0.62) 2) Median duration of admission (days), intensive support vs. basic support vs. comparator: 9.5 (p=0.29) vs. 8.0 (p=0.01) vs. 12.0 3) Median number of days lost, number (25th and 75th percentiles): comparator: 12 (0.00, 173) basic support: 9 (0.00, 88.0; p=0.81) intensive support: 7.5 (0.00, 86.5; p=0.49)	NR	None reported due to the intervention.	2957 screened/1049 eligible/1049 enrolled; comparator (n=348), basic support (n=348), intensive support (n=353)	Comparator: 9 died before discharge, 1 crossed over to basic support Basic support: 8 died before hospital discharge, 1 crossed over to intensive support Intensive comparator: 9 died before discharge/ 0 lost to followup/1023 analyzed	27 total withdrawals/none due to adverse outcome of intervention	Substantial difference in contacts with the study cardiologists and the specially trained nurses in all 3 groups compared with the planned protocol: 33% more visits to the cardiologist for the comparator group; 40% more visits or telephone calls for basic support; and 10% more visits or telephone calls for intensive support.

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Kasper 2002[46] (Good)	Admissions for CHF: non-intervention: 59 admissions among 35 patients; intervention: 43 admissions among 26 patients; (p=0.09)	1) CM group more likely to be prescribed targetdoses of vasodilators (74 of 80 patients vs. 43 of 71 patients, p<0.001) 2) Percentage of patientscompliant with diet recommendations were significantly better in the CM group (65 of 94 patients vs. 38 of 85 patients, p=0.002)3) Patients more likely to be at their goal weight compared with non-CM group (47 of 94 vs. 17 of 85, p=0.001).	No harms reported due to the intervention.	1452 patients screened/200 eligible/200 enrolled, intervention (n=102), nonintervention (n=98)	0 withdrawn/0 lost to followup/200 analyzed	0 withdrawals, 0 due to adverse events	NR

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Laramee 2003[50] (Fair)	1) Length of stay, CM vs. comparator: Mean (SD) days: 5.5 (3.5) vs. 6.4 (5.2), p=0.10; Median (IQR) days: 5 (3-7) vs. 5 (3-7), p=0.35.2) Readmissions, CM vs. comparator, Number (%): 90- day: 49 (37%) vs. 46 (37%), p>0.99); CHF: 18 (14%) vs. 21 (17%), p=0.49; Cardiac: 15 (11%) vs. 10 (8%), p=0.40; Other: 24 (18%) vs. 23 (18%), p>0.99.3) Readmission days in hospital, CM vs. comparator: mean (SD): 6.9 (6.5) vs. 9.5 (9.8), p=0.15; median (interquartile range): 5 (2-8) vs. 7 (2-10), p=0.37.4) Predictors of readmission were increasing age (p<0.01), NYHA class at discharge (p<0.01), chronic renal failure (p=0.01), diabetes (p=0.04), and COPD (p=0.04). 5) CM had significantly fewer CHF readmissions than the usual care for patients admitted initially with weight gain (n=19, p=0.03) or chronic renal failure (n=9, p=0.05)6) Cost ($), CM vs. comparator: Initial admission, mean: 16,119 vs. 19,081, p=0.18; Total readmission, mean: 5,253 vs. 5,163, p=0.96; Total inpatient, mean: 21,373 vs. 24,245, p=0.31; Total outpatient, mean: 1,552 vs. 1,307, p=0.28; Total, mean: 23,054 vs. 25,536, p=0.39; Patients readmitted at least once; Total readmission, mean: 15,417 vs. 16,379, p=0.82.	Adherence scores (1- never to 5- always):1) 4-weeks (CM vs. comparator):Weigh self daily: 4.7 vs. 3.2, p<0.001; Check ankles and feet for swelling: 4.9 vs. 4.5, p=0.002; Follow fluid recommendation: 5.0 vs. 4.6, p=0.006; Follow low salt diet: 4.9 vs. 4.6, p<0.001; Take medications: 5.0 vs. 4.9, p=0.042) 12 weeks CM vs. comparator):Weigh self daily: 4.6 vs. 3.1, p<0.001; Check ankles and feet for swelling: 4.8 vs. 4.6, p=0.02; Follow fluid recommendation: 5.0 vs. 4.6, p=0.003; Follow low salt diet: 4.8 vs. 4.4, p<0.001; Take medications: 5.0 vs. 4.9, p=0.04	NR	Screened: 589; Eligible: 454; Enrolled : 287; intervention (n=141), comparator (n=146);	Attrition due to withdrawal/death/lost to followup: intervention 19, usual care 34.	Total withdrawals: 9 (usual care); withdrawals due to adverse events: NR	NR

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Peters-Klimm 2010[84] (Good)	NR	Mean (SD) scores for CM vs. comparatorBaseline: EHFScBS: 25.4 (8.4) vs. 25.0 (7.1); PACIC overall: 3.2 (0.9) vs. 3.2 (0.8); PACIC-5a: 3.2 (0.9) vs. 3.2 (0.9)Followup, Mean (SD), Mean difference [95% CI]: EHFScBS: 21.2 (6.4) vs. 24.8 (6.7), mean difference -3.6 [-5.7,-1.6], cohens d=0.55, p=0.001; PACIC overall: 3.8 (0.7) vs. 3.3 (0.7), mean difference 0.5 [0.3,0.7], cohens d=0.72, p=0.000; PACIC-5a: 3.8 (0.7) vs. 3.3 (0.7), mean difference 0.5 [0.3,0.8], cohens d=0.72, p<0.001	NR	Screened: 10653; Eligible: 256; Enrolled: 199; intervention (n=99), usual care (n=100)	Withdrawal/lost to followup: intervention 12%; usual care 7%; Analyzed overall: 90%	Total withdrawals: 9, 0 due to adverse events	NR
Pugh 2001[85] (Poor)	Number of readmissions for heart failure within 6 months of initial discharge for usual care was 22 and treatment was 18. Number of patients readmitted at least once within 6 months of initial discharge for usual care was 11 and treatment was 9. Readmission rate within 6 months of initial discharge for usual care was 47% and treatment was 50%.	NR	No harms reported	Enrolled n=58 usual care group n=31 treatment group n=27	Total withdrawn: n=17; Deceased before followup: n=11; usual care group n=5 treatment group n=6 Withdrew: n=6; from each group n=3	No withdrawals listed due to adverse outcomes.	

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Rich 1993[88] (Poor)	1) 90-day readmission rate: no significant differences between intervention and comparator groups or among moderate and high risk groups. 2) Readmission rate (special care vs. usual care): 33.3% vs. 45.7%, NS 3) Hospital days: no significant differences between intervention and comparator or among moderate and high risk groups.	NR	None reported due to the intervention	261 screened/98 eligible/98 enrolled; intervention (n=63), comparator (n=35)	Number withdrawn and lost to followup not specifically reported. 98 analyzed.	NR	21 patients died during initial hospitalization and were excluded from the analysis.
Rich 1995[89] (Fair)	1) 90-day survival rates without readmission: No significant difference between CM (64.1%) and comparator (5.6%), absolute difference, 10.5%, 95% CI -0.9 to +21.9%, percent difference 19.6%, p=0.09)2) 90- day analysis restricted to survivors of the initial hospitalization: significant difference between CM (66.9%) and comparator (54.3%) comparator group (95% CI 1.1-24.1, p=0.04)3) Readmissions (comparator vs. CM) for any cause:44.4% less for CM group (94 vs. 53) p=0.02; for CHF: 56.2% less for CM group (54 vs. 24) p=0.044) Hospital days (comparator vs. CM): 35.7% fewer for CM group (865 vs. 556) p=0.04 5) Costs of readmission in comparator group greater than CM group by average of $1058 per patient ($3236 comparator group vs. $2178 treatment group, p=0.03).	NR	No harms reported	1306 screened/282 eligible/282 enrolled, intervention (n=142), comparator (n=140)	17 patients in comparator group and 13 patients in the treatment group died.	NR	NR

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Riegel 2002[90] (Fair)	Resource use at 3 and 6 months (Mean ± SD), CM vs. comparator; % change; P value with and without covariates of BB use and chronic lung disease:**3 months**: 0HF hospitalization rate: 0.17 ± 0.43 vs. 0.31 ± 0.64; -45.7% change; p=0.03 without covariates, p=0.03 with covariates; All cause hospitalization rate: 0.45 ± 0.73 vs. 0.61 ± 0.88; -25.6% change; p=0.09 without covariates, p=0.25 with covariates; HF readmission rate: 14.6 vs. 22.8; -36% change; p=0.06 without covariates, p=0.06 with covariates; All-cause readmission rate: 33.8 vs. 41.2; -18% change; p=0.17 without covariates, p=0.40 with covariates; HF hospital days: 0.85±2.3 vs. 1.6±3.9; -45.9% change; p=0.054 without covariates, p=0.56 with covariates; All-cause hospital days: 2.6±4.95 vs. 3.5±7.2; -27% change; p=0.19 without covariates, p=0.35 with covariates; Inpatient HF costs ($): 981±3514 vs. 1509±4502; -35% change; p=0.07 without covariates, p=0.07 with covariates **6 months**: Hospitalization rate: 0.21±0.5 vs. 0.41±0.77; -47.8% change; p=0.01 without covariates, p=0.02 with covariates; All cause hospitalization rate: 0.62±0.88 vs. 0.87±1.1; -28.2% change; p=0.03 without covariates, p=0.11 with covariates; HF readmission rate: 17.7 vs. 27.6; -35.9% change; p=0.04 without covariates, p=0.06 with covariates; All cause readmission rate: 43.1 vs. 50.0; -13.8% change; p=0.21 without covariates, p=0.49 with covariates; HF hospital days: 1.1±3.1 vs. 2.1±4.6; -46.4% change; p=0.03 without covariates, p=0.05 with covariates; All-cause hospital days: 3.5±6.6 vs. 4.8±8.3; -28% change; p=0.11 without covariates, p=0.23 with covariates; Inpatient HF costs ($): 1192±3674 vs. 2186±6729; -45.5% change; p=0.04 without covariates, p=0.07 with covariates	NR	NR	1145 patients screened/ 573 (50%) met eligibility criteria Of these, 358(62%) were included in this study (N= 130 intervention group, N= 228 usual care group)	Withdrew during the course of the study (n=28); Lost to followup NR; 100% analyzed	Withdrew during the courseof the study (n=28), 0 withdrew due to adverse outcomes.	NR

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Riegel 2006[91] (Fair)	HF resource use, CM vs. comparator, mean ±SD (95% CI):1) 3 month: HF results: hospitalization: 0.10±0.35 (0.01-0.19) vs. 0.15±0.40 (0.06-0.25); readmission proportion: 21.7% vs. 26.2%, p=0.69; hospital days: 2.19±5.4 (0.8-3.6) vs. 2.40±6.2 (0.98-3.8); inpatient costs ($): 3045±7784 (302-5788); 4130±14468 (1304-6956)2) 6 month: HF results: hospitalization: 0.55±1.1 (0.32-0.78) vs. 0.49±0.81 (0.25-0.73); readmission proportion: 31.9% vs. 33.8%; hospital days: 3.65±7.8 (1.9-5.4) vs. 3.40±7.1 (1.6-5.2); inpatient costs ($): 5567±13137 (2009-9126) vs. 6151±16650 (2485-9818)3) 3 month all-cause results: hospitalization: 0.48±0.74 (0.27-0.69) vs. 0.65±1.0 (0.43-0.86); readmission proportion: 37.7% vs. 40.0%; hospital days: 3.11±5.7 (1.4-4.8) vs. 4.54±8.1 (2.8-6.3); inpatient costs ($): 4694±8356 (1342-8045) vs. 8019±18284 (4566-11472)4) 6 month all-cause results: hospitalization: 1.06±1.3 (0.74-1.4) vs. 1.08±1.4 (0.75-1.4); readmission proportion: 58.0% vs. 56.9%; hospital days: 6.33±9.4 (4.0-8.6) vs. 7.41±9.8 (5.1-9.8); inpatient costs ($): 10015±16104 (5322-14708) vs. 13967±22923 (9132-18802)	NR	NR	Screened: 425; Eligible: 225 (53%); Enrolled:135 (60%); Intervention (n=70), Comparator (n=65)	Lost to followup (n=0); Analyzed: intervention (n=69), comparator (n=65)	Withdrawals: 1; Withdrawal due to adverse events: NR	NR

Author Year (Quality)	**Results by Resource Utilization Outcomes**	**Results by Process Measure Outcomes**	**Harms Reported**	**Number Screened/ Eligible/ Enrolled**	**Number Withdrawn/ Lost to Followup/ Analyzed (Overall)**	**Total Withdrawals; Withdrawals due to Adverse Events**	**Notes**
Sisk 2006[105] (Good)	All cause hospitalizations (intervention vs. comparator):1) 12 months: Total hospitalizations, n: 143 vs. 180; hospitalizations/person year: 0.74 vs. 0.93, difference: -0.19 (-0.38 to -0.01), adjusted difference: -0.13 (-0.25 to -0.0001)2) 12 to 18 months: Total hospitalizations, n: 56 vs. 74; hospitalizations/ person year: 0.63 vs. 0.83, difference: -0.20 (-0.46 to 0.05), adjusted difference: -0.10 (-0.19 to -0.02)3) HF outcomes to 12 months: Total hospitalizations, n: 18 vs. 29; hospitalizations/person year: 0.14 vs. 0.28, difference: -0.14 (-0.23 to -0.04), adjusted difference: -0.10 (-0.17 to -0.03)4) ED visits to 12 months, n: 66 vs. 75; ED visits/ person year: 0.76 vs. 0.81, difference: -0.05 (-0.23 to -0.04), adjusted difference: -0.06 (-0.19 to 0.07)	NR	No death or hospitalization was deemed to be caused by the intervention.	Screened 1555, excluded 1149 (228 declined to participate, 36 did not keep intake appointments, 202 deceased, 370 unreachable, 349 ineligible) 406 randomized	All 406 patients included in 18 month analysis.*CM Group*: 86 completed followup survey (analyzed), 4 withdrew, 18 died before followup, 1 declined survey, 18 could not be reached for 18 month survey*Usual Care Group*: 86 completed followup survey (analyzed), 5 withdrew, 20 died before followup survey, 4 declined and 12 could not be reached for 18 month survey	No withdrawals due to adverse outcomes reported. 4 withdrawals intervention group and 5 withdrawals in usual care group before final survey.	NR

Abbreviations: ACEI= angiotensin converting enzyme inhibitor, ARB= angiotensin receptor blocker, BB=beta blocker, BP=blood pressure, CAD=coronary artery disease, CHF=congestive heart failure, CM=case management, COPD=chronic obstructive pulmonary disorder, CVD=cardiovascular disease, HF=heart failure, HRQL=health-related quality of life, HTN=hypertension, MI=myocardial infarction, NR=not reported, NYHA=New York Heart Association, PVD=peripheral vascular disease, SD=standard deviation, SES=socioeconomic status, QOL=quality of life.

Evidence Table 8. Observational Studies of Case Management for Congestive Heart Failure

Author Year (Quality)	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Creason 2001[119] (Poor)	Elderly CHF patients.	Team of volunteers including cardiac case manager, cardiologists, staff nurses, cardiac rehabilitation personnel, dietitian, and social worker focused on the development of teaching tools for staff to utilize on all patients who were admitted with diagnosis of CHF.	Direct referral from physician, primary nurse in the hospital, or cardiac care manager screening patients who have been admitted to the hospital with the diagnosis of CHF.	NR	Observational	NR

Author, Year	Incidence (if cohort study)	List Patient Health Outcomes	Results by patient health outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration
Creason 2001[119] (Poor)	NR	Functional outcomes Cost analysis	Patients who have successfully completed the program feel that their learning needs have decreased significantly. Prior to enter the clinic, the majority of the patients felt they had moderate learning needs, even though they had been educated in the hospital.	Readmission rate for comparison group was 12% vs. 2% for the CM group. Overall length of stay for comparison group was 5.33 days vs. 3.44 days for the CM group.	NR	RN contacts patient via phone for first time. RN will call patient twice weekly for 2 weeks, then once each week for 4 weeks, after which Prime Life (division of St. Mary's Health System that generally cares for the elderly) will call the patients once each month for 1 year. If the patient has any questions or problems, the cardiac case manager is immediately notified, so that she can call the patient and, if indicated, the physician.

Abbreviations: CHF=congestive heart failure, CM=case management, NR=not reported.

Evidence Table 9. Trials of Case Management for Diabetes Mellitus

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type; Duration of Intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population**	**Other Medical Comorbidities and/or Coexisting Mental Illness**
Babamoto 2009[6] (Fair)	To evaluate the relative effectiveness of an intervention delivered by community health workers as compared to NCM or standard provider care on health measures and clinical indicators among Hispanic persons newly diagnosed with DM-II.	(Recruited from 3 inner-city family health centers in LA between 7/02-7/03) 1. Hispanic/ Latino by self-report 2. Age 18+ 3. Diagnosis of DM-II within 6 months of enrollment	1. Previous diagnosis of gestational diabetes 2. Previous diabetes care management	Prospective, randomized trial. Duration: 12 months of recruitment, ~6 months of followup.	Mean age: CHW 51 +/- 12.5 NCM 50 +/- 12.1 Standard 50 +/- 11 % female: CHW 64; NCM 52; Standard 78 % Parent with DM: CHW 45; NCM 55; Standard 35	DM-II	Only reported comorbidity was hyperlipidemia: CHW 45% NCM 43% Standard 54%

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
Brown 2011[14] (Poor)	Purpose: To explore the feasibility of adding a nurse case manager to DSME to improve DSME attendance and to increase utilization of other available health care services. Hypothesis: Individuals receiving NCM would have higher intervention attendance and better health outcomes.	Age 35-70 Type-II DM	1. Prior participation in intervention studies by this group 2. Pregnancy 3. Medical conditions for which changes in diet and physical activity would be contraindicated.	Two cohort, pre-test, post-test comparator group design; CLUSTER RANDOMIZATION Duration not entirely clear, but authors discuss patient followup with DSME at 3 and 6 months - so presumably at least 6 months.	Mean age: 49.3 +/- 8.4 Intervention 49+/- 7.8; Comparator 49.7 +/- 9.2 % female: 69 Intervention 65%, Comparator 74% Preferred language Spanish: 61% Intervention 69%; Comparator 51% Duration DM: 7.1 +/- 6.1 (years) Intervention 7.4 +/- 6.3; Comparator 6.6 +/-5.9 Mean HgA1c Intervention 9.2 +/- 2.7; Comparator 10.6+/- 3 BMI Intervention 34.6+/-7.6; Comparator 32.2+/-5.4	DM-II	Cholesterol Intervention 171+/-53.4; Comparator 179.6+/-50.2 Triglycerides Intervention 254.4+/-270.5; Comparator 209.4+/-187.8 History of high cholesterol Intervention 60.4%; Comparator 60% History of MI Intervention 6.3%; Comparator 8.6% History HTN Intervention 47.9%; Comparator 54.3%

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]: (subset analysis to determine risk of retinopathy in type 2 diabetics) (Fair)	To determine if intensive DM case management using population-directed strategies could improve glycemic control in a Medicaid population of patients with DM-II in which minorities are over-represented. Additionally, to determine if intensive case management could prevent or delay diabetic retinopathy.	1. Age 18+ 2. DM-II for at least 1 year prior to recruitment 3. HgA1c >7.5%	NR	Randomized controlled trial Duration: 36 months	Mean age: Intervention 57 +/- 0.9 Comparator 56.9 +/- 1 % female: Intervention 72.6; Comparator 70.9 %African American: Intervention 16.1; Comparator 15.7 % Hispanic: Intervention 39.2; Comparator 38.4 Duration DM: Intervention 10.3 +/- 0.8 years Comparator 12 +/- 0.8 years HgA1c: Intervention 9.6 +/- 0.1 Comparator 9.7 +/- 0.1 BMI: Intervention 33.1 +/- 0.8 Comparator 31.5 +/- 0.8 SBP: Intervention 136 +/- 2 Comparator 134 +/- 1 LDL: Intervention 129.8 +/- 3.2 Comparator 130.1 +/- 3.6	DM-II	Intervention 171+/-53.4; Comparator 179.6+/-50.2

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type; Duration of Intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population**	**Other Medical Comorbidities and/or Coexisting Mental Illness**
Ishani 2011[42] (Good)	To determine whether nurse case management could effectively improve simultaneous rates of control for hypertension, hyperglycemia, and hyperlipidemia compared with usual care among veterans with diabetes.	Diabetic patients with1 or more: blood pressure (BP) > 140/90 mmHg; hemoglobin A1c (HbA1c)> 9.0%; Low density lipoprotein (LDL) > 100 mg/dL; consented to randomization	Life expectancy of less than 1 year; severe mental health condition or active substance abuse; pregnant or planning on becoming pregnant; living in an assisted living facility; unable to give consent.	Randomized trial. 12 months	N=556 Intervention group: N=278 Age: 65 Gender: 0.4% female Race: 93% white, 5% black, 1% other Usual care group: N=278 Age: 66 Gender: 2.5% female Race: 93% white, 4% black, 2% other	Diabetes: with hypertension, hyperglycemia and hyperlipidemia	1) CHF, neuropathy, stroke, retinopathy, current smokers. 2) NR

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
Gary 2003[33] (Fair)	To determine whether multi-faceted, culturally sensitive primary care-based behavioral interventions could improve measures of DM control.	1. Age 35-75 2. African-American ancestry 3. DM-II 4. Live in East Baltimore (by zip code) 5. Received primary care in the year prior at either Johns Hopkins Outpatient Center or the East Baltimore Center for primary care.	1. Have a comorbid illness which was felt to likely limit lifespan to <4 years (ex: cancer, AIDS) 2. Have end-stage diabetes complications (dialysis, renal transplant, blindness, or LE amputation)	Randomized controlled trial Enrollment between 4/95-2/97 with 2 years of followup	Mean age: Usual 57+/- 8; NCM 59+/-11 CHW 59+/-9; NCM/CHW 60+/-7 % Female: Usual 74; NCM 76; CHW 78; NCM/CHW 78 Duration DM (years): Usual 9+/- 8; NCM 8+/-8 CHW 8+/-8; NCM/CHW 12+/-8 Uses BP meds (%): Usual 62; NCM 84; CHW 68; NCM/CHW 78 Uses cholesterol meds (%): Usual 18; NCM 18; CHW 22; NCM/CHW 25 Mean BMI: Usual 34+/- 8; NCM 33+/-8 CHW 33+/-5; NCM/CHW 33+/-7 Mean HgA1c: Usual 8.5+/- 2; NCM 8.8+/-2.2 CHW 8.4+/-2; NCM/CHW 8.6+/-1.9	DM-II	

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
Gary 2004[34] Gary 2005[35] Gary 2009[36] (Fair)	To determine the effectiveness and cost-effectiveness of primary care and community-oriented interventions in managing HgbA1c, BP, lipids, and reducing ED and hospitalization visits over 2 years.	Patients were initially identified through the managed care organization database, using the following criteria: 1. Age ≥25 years 2. African-American 3. Diagnosis c DM (by ICD-9) Patients were then screened by telephone to confirm eligibility criteria: 1. DM-II 2. African-American 3. Living in inner-city Baltimore 4. Receiving care at one of 6 included clinic sites 5. Member of managed care organization or included fee-for-service plans 6. Able to provide contact info for 2 family members not living in the home 7. No current enrollment in the managed care organizations other disease management programs.	1. Have significant comorbid condition(s) likely to lead to death within 3-5 years (ex: cancer, AIDS, ESRD, active TB, Alzheimer’s, CHF - all by ICD-9) 2. Unable or unwilling to give informed consent 3. Unable to complete baseline assessment 4. Likely to move from Baltimore City in the next 24 months 5. Have severe psychiatric condition that would limit participation in the intervention (ex: schizophrenia)	Randomized controlled trial Enrolled between Oct 2000-June 2002 and followed up for 30 months	Mean age: Minimal intervention: 56.3+/-10.8 Intensive intervention: 58.8+/-11.3 % Female: Minimal intervention: 74 Intensive intervention: 72.1 Tobacco use current: Minimal intervention: 27.1% Intensive intervention: 32% BMI: Minimal intervention: 34.9+/-8.6 Intensive intervention: 34+/-8.2 Mean HgA1c: Minimal intervention: 8+/-2.2 Intensive intervention: 7.9+/-2.2 Mean SBP: Minimal intervention: 137+/-20 Intensive intervention: 137+/-21 Mean DBP: Minimal intervention: 80+/-11 Intensive intervention: 80+/-11 Mean HDL: Minimal intervention: 51.3+/-15 Intensive intervention: 51.1+/-14.9	DM-II	Triglycerides

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
Krein 2004[47] (Fair)	To evaluate the effects of a collaborative CM intervention for patients with poorly controlled T2 diabetes on glycemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization. Hypothesized that case managers would facilitate more timely and appropriate changes in medication treatment, prompt detection of potential problems, and better patient self management.	Identified potential study subjects had at least one prescription for an oral hypoglycemic agent, insulin, or blood glucose monitoring supplies filled in the previous 12 months. Most recent HbA1C level was 8.5% (within the last year) and had a general medicine clinic visit scheduled between May 1999 and January 2000. During screening visit, patients were eligible if HbA1C $\geq$7.5%.	Persons <18 years, never diagnosed with diabetes or before the age of 30 years; no telephone; did not speak English; were not competent for interview; reported primary source of diabetes care outside the VA; current treatment for cancer (other than nonmelanoma skin cancer); had kidney failure, symptomatic heart failure, liver disease, or blindness; spent winter at another residence or planned to move.	Randomized trial Duration: 18 months	Age: 61 years of age 97% Men 51% White	Diabetes	Intervention 254.4+/-270.5; Comparator 209.4+/-187.8

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
Shea 2002[98] Shea 2006[158] Trief 2006[102] Trief 2007[103] Shea 2007[99] Shea 2009[100] Palmas 2010[101] (Fair)	Hypothesis: A telemedicine intervention will improve outcomes among Diabetics in medically underserved areas via 1) more rapid behavior changes, 2) changes in treatment regimen, and 3) more rapid achievement of glucose and BP control.	Patients must: -be age 55+ -be a current Medicare beneficiary -have DM -live in a federally designated medically underserved area (MUA) or health professional shortage area (HPSA)	Moderate or severe cognitive impairment Severe impairments in areas that would preclude ability to utilize telemedical intervention including: -vision -mobility -fine motor coordination -hearing Severe comorbid conditions (likely to result in death/disability during study) No free electrical outlet Spends more than 3 months at location other than home	Randomized controlled trial Randomized 1:1 Randomized within clusters defined by PCP panels Duration: 2 years by original methods	Mean age 71 in both usual care and intervention groups 36.5% men and 37.9% men in intervention and usual care groups respectively 15.3% and 14.5% Black in intervention and usual care respectively 35.8% and 34.6% Hispanic in intervention and usual care respectively ≥13 years education in 16.1% and 17.5% in intervention and usual care respectively Annual household income of <$10,000 in 50.8% and 47.8% in intervention and usual care respectively	Diabetes DM duration ≥15 years in 30.8% and 32.2% in intervention and usual care respectively DM management with insulin alone in 14.5% and 14.4% in intervention and usual care respectively Mean HgbA1c of 7.36 and 7.40 in intervention and usual care respectively	

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population	Other Medical Comorbidities and/or Coexisting Mental Illness
Wolf 2004[111] (ICAN) Wolf 2007[112] (Good)	The objective was to compare the efficacy of lifestyle case management to usual care given in the primary care setting measured by clinical, HRQOL, and economic outcomes. Hypothesized that a modestly priced, RD-led case management approach to lifestyle change would be more effective than usual medical care for patients with obesity and T2 Diabetes.	> 20 years of age, T2 diabetics confirmed by a physician, diabetes medication use, body mass index of $\geq$27, ability to comprehend English, and primary health insurance is Southern Health Services health plan	Pregnancy, cognitive limitations, or other medical reasons preventing diet or exercise modifications.	Randomized trial 12 months	Age: Mean=53 years 60% Female 80% White SES: NR	Obese, T2 diabetics	History of MI

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Babamoto 2009[6] (Fair)	% less than 6th grade education: CHW 67; NCM 58; Standard 57 % income less than $25K/year: CHW 55; NCM 50; Standard 56	NR	No	The NCM was described as being a registered nurse with "linguistic competence" (presumably in Spanish). No information on education or experience reported.	NCMs interacted with patients in clinic. NCMs saw patients monthly and as needed. They also performed followup calls with patients as needed. NCMs followed a "standardized clinic protocol for MD education and monitoring based on ADA clinical recommendations." NCM responsibilities included patient assessment, development of treatment plan incorporating provider treatment, coordination and referral of community resources, and participation in multi-disc conferences to discuss patient status.	NR	NR

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Brown 2011[14] (Poor)	1. Rural community 2. One of the poorest counties in the United States	NR	NR	NCM was certified as a DM educator and had been an intervention team member with this group prior to this study.	Goal of NCM was to provide individualized guidance. 1. Contact patients at least 5 times (including appointments, telephone calls, home visits) 2. NCMs also attended weekly DSME group sessions During interactions with patients, NCM was to provide additional info and answer to questions on DM self-management, as well as to provide individualized health guidance and assistance in overcoming cultural and environmental barriers to improving health. NCM also to provide enhanced coordination of health care and communication with physicians and other providers.	NR	NR

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]: (subset analysis to determine risk of retinopathy in type 2 diabetics) (Fair)	Patients were recruited from three clinical sites in three counties, all of which served racial/ethnic minorities, and low-income Medicare populations (Medi-Cal) in California. Education level was relatively poor in these populations, with approximately 40% in each group having an educational level of 8th grade or less. % education beyond 12th grade: Intervention 20.8; Comparator 19.4 % education 12th grade: Intervention 16.3; Comparator 23.6 % education 9-11th grade: Intervention 21.9; Comparator 17.6 % education 8th grade or less: Intervention 41; Comparator 39.4	Medicaid	One of the three recruitment sites was part of a county-wide managed care plan for Medi-Cal recipients. Also, one of the other two sites recruited patients from hospitals and outlying clinic and those patients could be fee for service or part of a managed care plan.	Not entirely clear, but it seems per the study that case managers can be either registered nurses or registered dietitians. No other information on education or experience is provided.	Case managers used evidence-based practice guidelines and algorithms for medicine and insulin adjustment in collaboration with the primary care providers. Case mangers specifically identified patient barriers to care and then individualized treatment and education strategies to address these barriers. Case managers followed a study protocol which included basic guidelines for glucose and medication management for DM as well as HTN and dyslipidemia.	NR	NR (suspect "no" as the CMs worked in conjunction with primary care providers).

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Ishani 2011[42] (Good)	Patients were diabetic with poorly controlled risk factors	NR	NR	Nurse case managers	After the initial study visit, case manger and patient established lifestyle modification goals (weight loss, dietary changes, physical activity and smoking cessation, as appropriate) and developed personal action plans. All patients provided with validated home blood pressure monitor and instructions.	NR	Yes. Case manager reviewed diabetes, blood pressure and lipid medications and made adjustments to those medications according to protocols established for the study.
Gary 2003[33] (Fair)	Included only African-Americans in East Baltimore. Years of education (Mean): Usual 10+/-3; NCM 10+/-2 CHW 9+/-3; NCM/CHW 10+/-3 Percent yearly income ≤$7500: Usual 44; NCM 42; CHW 61; NCM/CHW 43 Percent receiving medical assistance: Usual 50; NCM 34; CHW 46; NCM/CHW 36	NR	NR	Registered nurse with bachelors in training to be a certified diabetes educator. Years of experience NR.	The NCM coordinated patient care using ADA practice guidelines. NCM provided patient care, management, education, counseling, followup, referrals, and physician feedback. Regimen changes were implemented under physician's orders.	NR	No. Regimen changes were implemented under physician's orders.

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Gary 2004[34] Gary 2005[35] Gary 2009[36] (Fair)	Urban, African-American Annual income <$7500: MI: 35.5% II: 33.5% Education (years): MI: 11.5 +/-2.8 II: 11.5+/-2.5 Unemployed: MI: 4.4% II: 4.8% Per Gary 2005, poor glycemic control and poor BP control were present in 43% and 72% "respectively" (can't tell which group has which by this statement).	Either managed care or fee-for-service	Yes (some)	Registered nurse with bachelor's degree and "relevant case management experience." Years of experience not specified.	The intensive intervention arm included NCM and CHW collaborative involvement. The NCM specifically trains and supervises CHWs, oversees the baseline assessment and plan formation for each patient, prompts physicians about sub-optimal care patterns, and is involved in insulin titration. The CHWs are African-American women familiar with the setting and without prior health care training. They have a high-school education. They also participated in a 6 week training process. CHWs participate in the intake assessment and plan formation, identify non-medical barriers (ex: illiteracy) and work to find solutions to those barriers. Some visits in project office or by phone, some in patient's home, some in community.	6 weeks training process. Gary et al 2009 further describes the 6 weeks of training as having 6 phases including guidelines, practical info, patient self-management education, home-based assessment and education, field experience, skill reinforcement, and maintenance and quality control.	Unclear

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Krein 2004[47] (Fair)	Average length of diabetes onset= 11 years; 45% if participants rated health as poor or fair (see previous cell, average number of comorbidities= 4)	100% VA; 60% had other insurance besides VA	Yes, VA	NP case manager	Case managers were allowed to schedule followups according to individual patient needs (e.g., someone newly started on a medication; encouraged patient self-management (e.g., diet and exercise); provided reminders for recommended screenings/tests; help with appointment scheduling; monitor home glucose and blood pressure levels; and identified and initiate medication and dose changes as needed. To facilitate treatment changes, medication treatment algorithms were used, modified to correspond with the National VA Diabetes Guidelines. Providers were notified by internal e-mail if a medicine change was recommended and could opt to have the case manager make the adjustment or to address the issue directly.	2-day training for case managers included instruction on collaborative goal setting, with case examples and role-playing used to familiarize them with the treatment algorithms.	Yes

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Shea 2002[98] Shea 2006[158] Trief 2006[102] Trief 2007[103] Shea 2007[99] Shea 2009[100] Palmas 2010[101] (Fair)	Older (age 55+) Significant % with annual household income <$10,000 (50.8% and 47.8% in intervention and usual care respectively)	Medicare	No	Described only as "nurse care manager."	Video-conference between patient and NCM every 2 weeks and as needed -followup CBGs and BPs remotely via telehealth system discussed with endocrinology if medication adjustment felt needed (after which recommendation made to PCP) -resource referral for individualized patient needs	Nurse care manager -trained in diabetes management -trained in use of computer-based case management tools	Not clearly stated, but believe "no." Stated that NCM discussed care with endocrinologist, and if treatment recommendations then message was sent to primary care provider.

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Describe Case Management Intervention	Describe Preintervention Training	Did case manager have the ability to adjust medications?
Wolf 2004[111] (ICAN) Wolf 2007[112] (Good)	1) Average of 7 years with diagnosis of diabetes 2) Average body mass index=37.5 3) Average waist circumference=117 cm 4) Average of 2.6 other conditions besides diabetes 5) Average of 6 meds per day	Southern Health Services medical plan	Yes, Southern Health Services	Registered Dietician	Overall: One RD CM met with participants individually, in groups, and by phone for assessment, goal setting, education, and referrals to community resources. Clinical care: RD CM reviewed lab results and discussed patient-care issues with physicians when appropriate. Individual sessions: occurred 6 times throughout the year (total= 4 hours). Followup visits reassessed if goals met and if not, discussed ways to overcome barriers; goals were reset. Monthly calls: provide support. Participants were given the LEARN (Lifestyle, Exercise, Attitudes, Relationships, Nutrition) manual.	NR	No

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services
Babamoto 2009[6] (Fair)	Primary care clinic	Primarily in-person appointments (monthly and as needed), but also followup calls as needed. Frequency of followup calls is not reported in results.	53 patients per NCM **Note, this refers to 53 patients with DM. These same NCMs were also monitoring patients with other diseases, such as asthma.**	Monthly in-person followup and as needed. Telephone calls were as needed. Actual frequency experienced was NR.	Primary are clinic.	Only description provided is that "patient assessment and development of a treatment plan" were part of the NCM's responsibilities.	All patients, regardless of study group, received a packet of diabetes education materials (in Spanish and English and tailored for local Hispanic population) during the initial study visit.	NR	One of the NCM responsibilities is listed as "coordination and referral to community resources" - but no additional information is provided.
Brown 2011[14] (Poor)	NR	Mixture of appointments, telephone calls, and home visits	NR (number of NCMs is unclear, but there were 48 individuals in the "intervention" group.)	NR (goal for 5 times total; study period ~6 months)	Clinic visits or home visits	NR	Patient education as part of both comparator and intervention groups. 8 weeks consecutive curriculum followed by support group sessions at 3 and 6 months.	As per previous description, NCMs to provide individualized health guidance. Additional information on this intervention not reported.	Not specifically reported, although authors note that NCM is hoped to enhance coordination of health care and communication with providers.

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]: (subset analysis to determine risk of retinopathy in type 2 diabetics) (Fair)	Primary care clinic	Unclear. Study reports that "interactions" between patients and CMs occurred in-person at clinic site and via telephone between visits as needed.	NR	NR	Primary care clinic	"Study staff" (presumably CMs) met with patients "at study entry and exit to assess overall health status, glycemic control, DM self-care behaviors, and presence of DM-related complications." Presumably, the individualized treatment and education strategies were formed at that time - but that is not explicitly stated.	Education strategies are mentioned as one facet of the CM intervention, but no specifics are provided. More detail on CM interventions in table 2 mentions education specifically with regard to nutrition.	Not specifically reported but patient goals are mentioned in Table 2 with regards to nutrition education.	NR
Ishani 2011[42] (Good)	VA hospital	Initial in person visits followed by phone calls	NR	Goal was for case managers to contact patients every 2 weeks initially and for the frequency of contact to decrease as patient achieved home blood pressure and glucose goals. Median of 15 phone calls. Median of 3 visits in both groups, p=0.96	VA hospital	As part of intervention, lifestyle modification goals were established and personal action plans were developed for each patient.	NR	Patients monitored blood pressure, HbA1c and LDL	Registered dietician presented information on dietary choices for diabetes and hypertension including carbohydrate counting, label reading, and the Dietary Approaches to Stop Hypertension (DASH) low-sodium diet.

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services
Gary 2003[33] (Fair)	Clinic	Goal was for three 45-minute face-to-face contacts a year or telephone contacts. Face-to-face was preferred, but telephone was supplemented as needed.	NR	Goal was for three 45-minute face-to-face contacts a year or telephone contacts.	Goal was for three 45-minute face-to-face contacts a year or telephone contacts. Face-to-face contact was preferential, but telephone contact was substituted in patients missed their in-person appointments. In-person contact occurred in clinic. 25% in the NCM-alone group received at least 3 visits. 50% received at least one telephone intervention.	NCM determined needs of patients through baseline assessment. Patients were asked to prioritize three domains related to their DM care for initial attention.	Education is listed as part of NCM's interventions, but no additional information is provided.	NR	Summaries of intervention visits were provided to primary care providers.

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services
Gary 2004[34] Gary 2005[35] Gary 2009[36] (Fair)	Primary care clinic appointment	Not entirely clear, but seems primary NCM contact is through clinic appointment.	1:269. N = 269 in the intensive intervention arm. Per Gary et al 2005, there was one NCM.	NCM conducts (minimum) 1 face-to-face clinic visit with each patient each year. CHW has at least 3 contacts with each patient annually.	NCM: face-to-face time occurs in clinic. CHW: Some visits in project office or by phone, some in patient's home, and some in community.	Plan is formed by NCM with input from CHW at initial baseline assessment.	Patients in the intensive intervention group received DM-specific education (pamphlets, newsletters) via the mail. In addition, Gary 2009 specified that both NCMs and CHWs utilized clinical algorithms and interactive action plans to help direct education and followup for patients.	NR	At the end of the baseline assessment and as needed, a written summary is sent to each patient's primary care provider.
Krein 2004[47] (Fair)	VA Clinic	Face to face visits, and followup phone calls	120/case manager (60 patients per 20 hour week case manager)	3 visits per year, followup calls as needed	Not clearly stated.	Yes	Ongoing	Yes	Yes, with primary care via summary statements and direct discussions.

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services
Shea 2002[98] Shea 2006[158] Trief 2006[102] Trief 2007[103] Shea 2007[99] Shea 2009[100] Palmas 2010[101] (Fair)	2 locations (to accommodate urban and rural population components) -Berrie Diabetes Center at Columbia University -Joslin Diabetes Center at SUNy Upstate Medical University in Syracuse	Telemedicine videoconference.	1 NCM for 200 subjects	Not entirely clear. Shea et al, 2002 implied NCM contact with patient every 2 weeks and as needed (pg 52) Trief et al, 2007 reported that videoconference occurred every 4-6 weeks routinely, and every 2 weeks for "significant need." Trief et al 2006 reported that, over the first year, mean home televisits was 28.3 +/- 15.2 (median 28) In addition, a physical exam and in-person survey was completed at baseline and at 1 year. Examiners were NOT NCMs and were blinded to patient's intervention vs. usual care status.	Not clearly stated, but I believe zero. Two exams were performed (baseline and 1 year), but these exams were NOT performed by NCMs.	Not clearly stated. Trief et al, 20007 noted that role of NCMs via videoconference was to educate patients, facilitate goal-setting/self-management, and discuss concerns. Shea et al, 2009 reported that the goal for NCM interventions were based on clinical practice guidelines. (pg 447)	Shea et al, 2002 stated that education and information are available in "small pieces" via the project Web site. "NCMs actively invite and coach patients to use these information resources."	Not specifically reported	NCMs assess patients via telemedicine. If intervention or changes are felt to be needed, NCMs may d/w endocrinologist and make recommendations to PCP.

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services
Wolf 2004[111] (ICAN) Wolf 2007[112] (Good)	Clinic	Sessions with RD and monthly telephone calls.	All participants in intervention group (n=72).	Unclear about study visits; monthly followup calls.	Six times per year, a total of four hours.	Yes, over phone	Participants attended six, 1-hour small group (10 or more people per group) sessions designed to educate subjects about diet and physical activity to improve glucose control and weight loss.	NR	Yes, but unclear

Author Year (Quality)	Medical Monitoring	Medication Adjustment	Integrated within Primary Care	Health Information Technology	Others	Comparator	Patient Health Outcomes Included
Babamoto 2009[6] (Fair)	HgA1c and BMI were measured at baseline and 6 months.	NR	Yes - NCM's saw patients in primary care clinic and participated in multi-disc meetings to discuss patient status.	NR		Two comparators: Standard provider care: standardized clinical care by physicians and NPs. CHW care: CHWs were recruited from the community if they were bilingual and had DM or had experienced it through a family member or friend. Each CHW saw between 1-35 patients (3 were utilized full-time). CHWs were required to have high school degree or GED; they were paid clinical staff. Each CHW received a formal 6-week training program. The CHWs conducted individual educational sessions based on ADA standards (conducted with participants and their families). CHWs made "routine" followup calls to monitor progress and assist in problem solving and barrier identification. CHWs utilized program education materials based on a standardized curriculum.	1. Self-reported quality of health 2. 2+ servings of fruit a day 3. 2+ servings vegetables a day 4. Exercise 3+ times a week 5. Mean HgA1c 6. Mean BMI

Author Year (Quality)	Medical Monitoring	Medication Adjustment	Integrated within Primary Care	Health Information Technology	Others	Comparator	Patient Health Outcomes Included
Brown 2011[14] (Poor)	Measured at baseline, 3, and 6 months: 1. HgA1c 2. Fasting blood glucose 3. Lipids 4. Blood pressure 5. DM-related knowledge 6. Health behaviors (physical activity, dietary intake, glucose monitoring) 7. BMI	NR	Setting not clearly reported	NR		Comparison was between DSME alone vs. DSME + NCM. Education intervention of DSME described previously.	HgA1c BMI Fasting blood glucose
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]: (subset analysis to determine risk of retinopathy in type 2 diabetics) (Fair)	In the intervention group, HgA1c was measured quarterly. In the usual care group, the HgA1c was measured every 6 months.	NR (suspect "no" as the CMs worked in conjunction with primary care providers).	Yes (already described)	NR		Usual care Included: HgA1c every 6 months and presumably usual MD appointments (although not specifically reported)	Primary outcome: changes in glycemic control (measured by change in HgA1c) Secondary outcomes: 1. weight 2. BMI 3. BP 4. lipids Post-hoc: risk of developing retinopathy

Author Year (Quality)	**Medical Monitoring**	**Medication Adjustment**	**Integrated within Primary Care**	**Health Information Technology**	**Others**	**Comparator**	**Patient Health Outcomes Included**
Ishani 2011[42] (Good)	During telephone contacts the case manager reviewed the following: self-monitoring values for blood glucose and blood pressure, difficulties experienced in measuring home blood glucose or blood pressure progress toward achieving lifestyle modification goals and any adverse events associated with therapy.	Yes, Case manager reviewed diabetes, blood pressure and lipid medications and made adjustments to those medications according to protocols established for the study.	Primary care provider notified of any medication changed using the electronic medical record system, for providers outside the VA medical system, letter sent informing them of medication changes.	NR	NR	Usual Care: patients asked to continue managing diabetes, blood pressure and lipids under the direction of own primary care provider.	Percentage of patients with control of all three cardiovascular risk factors, defined as: BP < 130/80 mmHg, LDL < 100 mg/dL, and HbA1c < 8.0%. Percentage of individuals achieving individual treatment goals and the change in absolute values for BP, LDL, and HbA1c between the intervention and usual care groups at 1 year.

Author Year (Quality)	**Medical Monitoring**	**Medication Adjustment**	**Integrated within Primary Care**	**Health Information Technology**	**Others**	**Comparator**	**Patient Health Outcomes Included**
Gary 2003[33] (Fair)	HgA1c, lipids, and BP were monitored as part of the baseline assessment and the 2-year followup assessment.	No. Regimen changes were implemented under physician's orders.	Yes. NCMs provided intervention summaries to PCPs.	NR		Usual care: continued ongoing care from their own health care providers. They also received a quarterly newsletter on DM-related health topics. CHW: CHWs were high school graduates attending college part time. No formal health care training prior to the study. Goal for three 45-60 minute in-home meetings a year or telephone contacts (face-to-face preferred) and as needed. CHWs monitored patient and family behavior, reinforced adherence to therapy, mobilized social support, and provided physician feedback. NCM and CHW combined: Similar to as described. Goal for each NCM and CHW to have approximately 3 visits per year with patients and as needed.	1. HgA1c 2. LDL cholesterol 3. HDL cholesterol 4. Triglycerides 5. SBP 6. DBP 7. Dietary risk scores 8. Physical index scores 9. BMI

Author Year (Quality)	Medical Monitoring	Medication Adjustment	Integrated within Primary Care	Health Information Technology	Others	Comparator	Patient Health Outcomes Included
Gary 2004[34] Gary 2005[35] Gary 2009[36] (Fair)	At baseline and at 24 months, HgA1c, HDL, creatinine, and urine albumin are measured. Vitals (including BP) are also measured during this time. A questionnaire is also administered.	Unclear	Yes - patient care summaries are sent to PCPs. Also, NCMs may act to coordinate between patient and PCP (e.g., prompting physician to suboptimal care patterns).	NR		The comparator is the "minimal intervention" group. This involves every 6-12 month phone calls by a lay health educator. The LHE also took part in a 6 week training session related to project operations, teamwork, and DM knowledge. During each phone call, the LHE reminds patients about important preventive diabetes-related health care activities. The LHE provides a summary of patient health-care utilization and general recommendations (based on ADA guidelines) to the patient's primary care provider.	HgA1c Blood pressure Lipids BMI
Krein 2004[47] (Fair)	Yes	Yes, as NP with permission of physician.	Yes, sent summary statements and consulted about medication adjustments (also gave PCP the choice to defer to the NP case manage).	No, not part of intervention.		All study participants were given an A&D Medical semiautomatic blood pressure monitor, home blood pressure monitoring guidelines, a lay version of the VA Diabetes Clinical Guidelines, and a periodic study newsletter. Patients in comparator group received usual care from their PCP.	A1C, BP, cholesterol and general satisfaction

Author Year (Quality)	Medical Monitoring	Medication Adjustment	Integrated within Primary Care	Health Information Technology	Others	Comparator	Patient Health Outcomes Included
Shea 2002[98] Shea 2006[158] Trief 2006[102] Trief 2007[103] Shea 2007[99] Shea 2009[100] Palmas 2010[101] (Fair)	Home telemonitoring system had ability to upload and store blood pressures and blood glucose values. Per Trief et al, 2006, mean number of blood glucose uploads in 1st year was 560.2, and blood pressure uploads was 184.6	NCM communicated with PCP for any suggested medication adjustment.	Yes. Patients are recruited from primary care clinics. PCPs retain autonomy in decision making for their patients; NCMs only make suggestions based on their telemedicine patient interactions.	The home telemonitoring unit provided each patient access to their own clinical data as well as access to an educational web page for this project (created by ADA). Patients were able to upload blood glucose and blood pressure values via their home telemonitoring unit. This information was then available to patients and NCMs.		Usual care Patients in the usual care group were cared for by their PCPs. PCPs received a mailing with current guidelines for patients with DM. No other guidance from study personnel was provided to PCPs for usual care group.	Primary: -HgA1c -Blood pressure -Cost Secondary: -lipids -quality of life -depression
Wolf 2004[111] (ICAN) Wolf 2007[112] (Good)	No	No	Unclear	No, not part of intervention.		Usual care group received written educational material including the LEARN manual. Patients seen by research associate every 3 months for weight measurements and to complete questionnaires. The RA answered questions but did not assess, set goals, or have an ongoing dialogue about a participant's diet or physical activity level.	Primary outcomes: weight and waist circumference. Secondary measures included glycemic control (HbA1c), lipid levels, use of prescription medications, and HRQOL.

Author Year (Quality)	Results by Patient Health Outcomes	List Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included
Babamoto 2009[6] (Fair)	1. NSD within group for change in self-reported health for NCMs or standard care, but was significantly improved in CHW group ($p<0.05$). 2. Within group significant improvement was seen for fruit and vegetable intake for the CHW and NCM groups but not for standard care ($p<0.05$). The difference between groups was also significant ($p<0.05$). 3. There was significant improvement in exercise in CHW and standard care but not NCM ($p<0.05$). The difference between groups was also significant ($p<0.05$). 4. All groups had significant improvement in HgA1c ($p<0.05$). Between group differences NR. 5. There was NSD in BMI within or between groups.	1. ED admission in previous 6 months (study period)	1. There was NSD in ED visits among CHW and NCMs, but ED utilization increased significantly in the standard care group ($p<0.05$). The difference between groups was also significant ($p<0.05$).	1. Never forgetting to take medications
Brown 2011[14] (Poor)	HgA1c: no significant differences between groups. Of note, individuals in the intervention group had increased HgA1c over time. Fasting blood glucose: no significant differences between groups. BMI: no significant differences between groups.	NR	NR	Changes in physical activity and diet Intervention attendance
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]: (subset analysis to determine risk of retinopathy in type 2 diabetics) (Fair)	Although both usual care and intervention groups experienced declines in HgA1c during the study period, the reduction in the intervention group was greater at each time point ($p<0.01$). Patients in the intervention group achieved their target HgA1c more often than those in usual care, regardless of HgA1c target ($p<0.01$). NSD between groups for any of the secondary outcomes (weight, BMI, SBP, DBP, LDL, HDL, Cholesterol, Triglyceride). Patients in the intervention group showed statistically significant within-group decline in diastolic Bps, LDL, and total cholesterol and increase in HDL during the study period. Patients in the usual care group showed statistically significant within-group improvement in HDL during the study period. Risk of development of retinopathy in comparator vs. intervention groups: OR 5.35 [95% CI 1.14 –2.12], $p=0.034$	NR	NR	NR

Author Year (Quality)	**Results by Patient Health Outcomes**	**List Resource Utilization Outcomes Measured**	**Results by Resource Utilization Outcomes**	**Process Measure Outcomes Included**
Ishani 2011[42] (Good)	Intervention group vs. usual care: Patients with BP < 130/80 mmHg, HbA1c < 8.0%, and LDL < 100mg/dL: 21.9% vs. 10.1%, p<0.001 HbA1c < 8.0% in those with baseline HbA1c > 9.0%: 40.5% vs. 24.6%, p=0.047 LDL < 100 mg/dL in those with baseline LDL > 100 mg/dL: 40.9% vs. 27.7%, p=0.017 BP < 130/80 mmHg in those with baseline BP > 140/90mmHg: 40.6% vs. 15.9%, p<0.001	NR	NR	NR

Author Year (Quality)	Results by Patient Health Outcomes	List Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included
Gary 2003[33] (Fair)	For all comparisons between groups, usual care was the comparator. When p value not provided, assume not significant (based on Figure 1). Reported decline in A1c for NCM group compared to comparator, but no p-value provided. P-value was <0.05 for NCM+CHW compared to comparator for decrease in HgA1c. Reported improvement in DBP (p<0.05) for NCM+CHW, but NSD for NCM intervention alone. Reported worsening of SBP in the NCM group vs. usual care (no p value given) LDL appeared to worsen in all intervention groups because LDL improved in usual care compared to all intervention groups. HDL improved (increased) in NCM+CHW but not in NCM alone; no p values provided. Reported significant improvement in triglycerides for NCM+CHW (p<0.05) but not for NCM alone. Significant (p<0.05) within group differences included the following: 1. HgA1c decreased significantly in the NCM+CHW group. 2. LDL increased in all groups (significantly in NCM and NCM+CHW) compared to usual care because LDL declined in the usual care group. 3. SBP increased significantly in the NCM group. There were no significant between group changes for dietary scores, physical activity index, or BMI. All intervention groups had increase in BMI compared to usual care.	NR	NR	NR

Author Year (Quality)	Results by Patient Health Outcomes	List Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included
Gary 2004[34] Gary 2005[35] Gary 2009[36] (Fair)	HgA1c: no significant within group or between group differences. NSD between group differences for blood pressure, BMI, HDL, or total cholesterol. HDL cholesterol: significant within-group increase in HDL in favor of the intensive group ($p<0.05$) Significant within-group decline in DBP for intensive intervention group ($p<0.05$) When intensity of meetings with CHW/NCM was considered, those patients who had more visits with a CHW/NCM had a statistically significant decline in HgbA1c compared to the minimal intervention group ($p=0.03$).	ED visits Hospitalizations	At 24 months, the intensive intervention group had fewer hospitalizations compared to the minimal care group (RR 0.77, 95%CI 0.59; 1.0) but this was not statistically significant. Those individuals with more NCM/CHW visits had significantly fewer ED visits ($p<0.05$, RR 0.66, 95%CI 0.43; 1.0). Although a similar trend was seen for frequency of hospitalizations, the 95%CI crossed 1 (RR0.91, 95% CI 0.64; 1.19). At 36 months, those who had higher frequency of CHW had significantly fewer ED visits or hospitalizations compared to minimal intervention but this result was NOT DEPENDENT on NCM intervention frequency ($p<0.05$, RR 0.53, 95%CI 0.36; 0.80 and 0.44, 95%CI 0.27; 0.73 respectively).	NR

Author Year (Quality)	Results by Patient Health Outcomes	List Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included
Krein 2004[47] (Fair)	Absolute difference of CM-comparator (95% CI) with p values: 1) A1C: 0.13 (0.40 to 0.68), p=0.13 2) Change in SBP: 2 (4 to 8), p=0.53 3) Change in DBP 0.85 (2 to 4), p=0.61 4) Change in LDL: 5 (17 to 6), p=0.37 5) General satisfaction: 0.47 (0.2 to 1), p=0.04	Hospitalizations at the VA, with VA PCP and outside the VA	Intervention vs. Comparator 1) VA Hospitalizations: 21 (19%) vs. 25 (24%) p=0.42 2) VA PCP visits: 6 (4%) 6 (4%) p=0.39 3) Received care outside VA: 24 (22%) 41 (39%) p=0.007	Eye exams Aspirin use Statin use

Author Year (Quality)	Results by Patient Health Outcomes	List Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included
Shea 2002[98] Shea 2006[158] Trief 2006[102] Trief 2007[103] Shea 2007[99] Shea 2009[100] Palmas 2010[101] (Fair)	<u>Shea et al, 2006</u> 1 year results, HgbA1c: -net adjusted reduction in HgbA1c in the intervention group was 0.18% lower than in the usual care group (p=0.006). 1 year results, HgbA1c subgroup (pts with HgbA1c >7): -net adjusted reduction in HgbA1c was 0.32% greater in intervention vs. usual care (p=0.002) 1 year results, blood pressure: -Net adjusted reductions for SBP and DBP were lower in the intervention group (p=0.001 for SBP and p<0.001 for DBP); BP changes in the usual care group are reported as "small." No intergroup comparisons noted. 1 year results, LDL cholesterol: -Net adjusted differences in LDL were significant in both intervention and usual care groups (p<0.001); no intergroup comparisons noted. <u>Trief et al, 2006</u> Prospective analysis of depression as predictor of HgA1c: -baseline depressive symptoms did not predict change in HgA1c (estimate = 0.016, p>0.35); neither for comparator or intervention (p>0.911 and p>0.769 respectively). -NSD when depression was treated as a dichotomous variable or when depression was defined by antidepressant use. <u>Trief et al, 2007</u> NSD between intervention vs. usual care for change in depression (p=0.30) or "diabetes distress" (p=0.77, p=0.98). <u>Shea et al, 2009</u> 5 year results, HgbA1c Intervention group had net improvement relative to usual care (p=0.001), with net adjusted difference of 0.29 (95% CI 0.12; 0.46). 5 year results, LDL cholesterol Intervention experienced improvement compared with usual care (p<0.001). Statistically significant differences noted in favor of intervention for years 1-4. 5 year results, blood pressure Intervention group achieved greater reductions in SBP and DBP compared to usual care (p=0.024 and p<0.001 respectively) 5 year results, mortality NSD between intervention and usual care (HR 1.01, 95% CI 0.82; 1.24)	Cost was listed as an outcome in original methods paper (Shea et al, 2002)	No formal analysis or comparisons of costs were provided. Shea et al, 2006 did report a breakdown of costs: -total cost each home telemedicine unit was $3,425. -Specifically, $3000 for patient station, $225 for BP cuff, $75 for cables, $125 for cart, and $110 for Glucometer.	Secondary process-of-care outcomes -receipt of recommended DM specific health care services -compliance -education and knowledge -health beliefs Trief et al, 2007 Changes in diabetes self-efficacy. (Definition not clearly stated). Shea et al, 2007 Examined patient and provider satisfaction

Author Year (Quality)	Results by Patient Health Outcomes	List Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included
Wolf 2004[111] (ICAN) Wolf 2007[112] (Good)	Intervention vs. Comparator (at 12 months, 95% CI) Primary 1) Weight: – 4.0 kg (-5.6 to -2.5) at 12 months p<0.001 for between group comparison of weight loss in favor of intervention group 2) Waist: 5.5 cm (7.4 to 3.6) vs. 1.4 cm (3.1 to -0.4) p<0.001 for between group comparison of decrease in waist circumference in favor of intervention group Secondary 1) A1C values: a) 4 months: 0.57%, 1.0 to 0.2; p=0.008 b) 8 months: 0.35%, 0.8 to 0.1; p=0.10 c) 12 months: 0.20%, 0.7 to 0.3; p=0.45 2) Total cholesterol: -8.6 mg/dl (22.6 to 5.5); p=0.23 3) LDL cholesterol: – 0.07 mg/dl (9.4 to 9.3); p=0.99 4) 4) HDL cholesterol: 0.40 mg/dl (1.9 to 2.7); p=0.73 5) Triglycerides: 36.0 mg/dl (–106 to 34); p=0.31 6) Quality of Life: a) Emotional 15.1 (3.4–26.8) b) Physical 10 (1.2–24.7)	Utilization defined as the number of claims during the year; hospital admissions, length of stay, and 12-month change self reported number of prescription medications taken daily.	Prescription meds: 0.8 (0.05–1.1) fewer total medications per day vs. usual care group (p=0.03). 95% CI and p-value for absolute cost difference of intervention vs. comparator: 1) Mean health care cost: -8,374 to -353 (p<0.05) 2) Mean pharmaceutical cost: -70 to $280 (NS) 3) Cost of ED visits: 862±1,488 vs. 849 ± 662 (p=0.97, NS)	NR

Author Year (Quality)	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Babamoto 2009[6] (Fair)	1. There was significant within-group improvement the percent of patients who never forgot to take medications among NCM and standard care groups ($p<0.05$), but not for CHWs. The difference between groups was also significant ($p<0.05$).	NR	1,352 screened 354 eligible 318 randomized	They report patients who "did not complete the program" as a lump number of 129 or 41%. This number included patients who moved out of the area, withdrew, or were lost to followup.	NR	No sample size calculation
Brown 2011[14] (Poor)	Self reported changes in physical activity and fat intake improved for both intervention and comparator, but intervention did not "appear" to affect self-reported improvements beyond DSME alone (statistics NR) Analyzed data from individuals who attended > or = 50% of DSME sessions; HgA1c improvements were larger in comparator individuals who attended this percentage of sessions compared to intervention who also attended this percentage of sessions.	NR	Screened: NR Eligible: NR Enrolled: 83 participants	NR	NR	

Author Year (Quality)	**Results by Process Measure Outcomes**	**Harms Reported**	**Number Screened/ Eligible/ Enrolled**	**Number Withdrawn/ Lost to Followup/ Analyzed (overall)**	**Total Withdrawals; Withdrawals due to Adverse Events**	**Notes**
California Medi-Cal Type 2 Diabetes Study Group 2004[15] Pettitt 2005[16]: (subset analysis to determine risk of retinopathy in type 2 diabetics) (Fair)	NR	The incidence of severe hypoglycemia was greater in the intervention group compared to usual care, but this different was not statistically significant (p=0.28).	Number screened: 1,597 Number eligible: 362 Number randomized: 362	Withdrawn: NR (appears they did not keep track of withdrawals as patients only needed one followup HgA1c after baseline to be included in the analysis). Lost to followup: 41 total (15 in intervention and 26 in usual care) Analyzed: 317 (171 intervention, 146 usual care)	NR	
Ishani 2011[42] (Good)	NR	NR	729/556/556	7 withdrawals 10 deaths 19 randomized in error 431 analyzed: 223 intervention vs. 208 usual care, p=0.13	No participant withdrew from the study as a result of an adverse event.	
Gary 2003[33] (Fair)	NR	NR	Screened: 3,800 Eligible: 666 Enrolled (randomized): 186	Authors report that roughly 84% did followup. That 84% included the 149 who completed both baseline and 2year followup visits, and the 9 who died. That leaves 28 patients (~16%) who did not followup - but why (lost, withdrawn, etc) is not discussed.	NR	
Gary 2004[34] Gary 2005[35] Gary 2009[36] (Fair)	NR	NR	Screened: 120,000 Eligible: 2,064 Enrolled: 542	Not reported in this way. Authors reported 18 deaths, and 36 "lost" - but why lost was not discussed. Lost vs. withdrawals also not clarified.	NR	

Author Year (Quality)	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Krein 2004[47] (Fair)	Dilated eye exam <12 months: 96 (87%) 84 (79%) p=0.11 NSD in aspirin use (p=0.15) NSD in statin use (p=0.20)	NR	691 screened 246 randomized	Lost to followup: 11 Withdrawals: NR Analyzed: 209	NR	Collected qualitative data via semistructured telephone interviews with 40 intervention patients; 20 from each site.
Shea 2002[98] Shea 2006[158] Trief 2006[102] Trief 2007[103] Shea 2007[99] Shea 2009[100] Palmas 2010[101] (Fair)		NR Shea et al 2009 did mention that "no serious adverse events" were experienced related to the intervention.	Screened: 9,597 Eligible: 1,927 Randomized: 1,665	Withdrawn/lost: 248 (144 intervention, 104 usual care) Analysis of patients who completed baseline and 1-year followup examination: 1,417 (717 usual care, 700 intervention) Analysis of all randomized subjects (baseline data carried-forward if 1-year exam not completed): 1,657 (815 usual care, 842 intervention) **Discrepancy between number randomized and number in this second analysis not explained.** Note: power calculated indicated 750 per group needed.	Total withdrawals: *Withdrawals vs. lost not entirely clear - these numbers extrapolated from Figure 2 of Shea, 2006.* Usual care withdrawals: 31 (15 due to death) Intervention withdrawals: 160 (18 due to death) Total withdrawals: 191	

Author Year (Quality)	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Wolf 2004[111] (ICAN) Wolf 2007[112] (Good)		None reported	NR/NR/147	29/0/147	29	

Abbreviations: ADA=American Diabetes Association, BMI=body mass index, BP=blood pressure, CHW=community health worker, CI=confidence interval, CM=case management, DBP=diastolic blood pressure, DM=diabetes mellitus, DSME=diabetes self-management education, HRQL=health-related quality of life, HTN=hypertension, MI=myocardial infarction, ICAN= Improving Control with Activity and Nutrition Study, NCM=nurse care manager, NR=not reported, NS=not significant, NSD=no significant difference, OR=odds ratio, RD=registered dietitian, SBP=systolic blood pressure, SD=standard deviation, SES=socioeconomic status, VA=Veterans Affairs.

Evidence Table 10. Observational Studies of Case Management for Diabetes Mellitus

Author Year (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Curtis, 2009[120] (Fair)	American Indian and Alaska Native patients with diabetes	Having contact with nurse case managers to adjust antihyperglycemic medications	Per group (PCP;NCM;MA) Age mean: 52.4 ; 48.6; 50.1 N (%) female:1008 (64); 465 (65) ;42 (70) Race: American Indian/ Alaska Native	Retrospective Cohort	Demographics: Patients with high adherence profile (seen at least 2 times during the study period) or having at least 2 A1C values separated by 30 days, patients with baseline A1C at least 7.0% , CM patients younger, ($p<0.0001$) insurance type: PIMC United States Department of Health and Human Services, Indian Health Service.	Incidence of hypoglycemia: hypoglycemia incidence rates: 0.0046, 0.017, and 0.046 per person per year, significant Btw groups ($p=0.035$); In patients taking insulin, a sulfonylurea, or both: incidence rates of hypoglycemia: 0.0049, 0.019, and 0.049 per person per year, ($p=0.035$)	A1C rate

Author Year (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Dorr 2005[121] Dorr 2007[122] (Good)	Patients with Diabetes	Contact with a generalist care manager	(Exposure, comparator, registry groups) Age mean: 59.9,59.8,60.; % Female: 50.9,50.9,50.2 Race-% White: 89.4, 88.5,81.5	Prospective Cohort Study	Variables: demographics: patient age (in 10-year age categories), sex, comorbidities, history of testing regularity, race, history of HbA1c and LDL comparator; high risk behaviors (% with risk score >3) 4.2,4.5,3.7: insurance type: NR; selection of comparators: matched on utilization, demographics, testing, and baseline glucose control	NR	HbA1c or LDL level; Previous HbA1c or LDL control;

Author Year (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Wilson 2005[154] (Fair)	American Indian and Alaska Native patients with diabetes	Enrollment in a nurse case management program	Age mean: 50±13 vs. 52 ±14 Percent Female: 63% female vs. 61% female Race: American Indian/ Alaska Native	Retrospective Cohort	Adjusted variables: age, sex, demographics and clinical characteristics (treatment type, BMI) high risk behaviors (e.g., drug use): NR, insurance type: Indian Health Service, selection of controls: Patients with high adherence profile--Individuals with at least 3 PCP visits, two HbA1c test and one patient education in the 1 year evaluation (entire cohort)	NR	HbA1c

Author Year (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration
Curtis 2009[120] (Fair)	Absolute A1C changes by group PCP, NCM, MA: -0.14, -0.48, -1.00 percentage points per month, (p<0.05 for each); A1C rate changes: PCP group (-0.082% per month; 95% CI -0.107 to -0.057), case management services without medication adjustment (-0.135% per month; 95% CI -0.172 to 0.099), case manager medication adjustment group (-0.264% per month; 95% CI -0.387 to -0.140).	Prescribed insulin rate and prescribed metformin rate	CM patients prescribed insulin at a higher rate (p=0.002) and prescribed metformin at a lower rate (p=0.003)	NR	NR	Confounders: Confounding by indication--enrolled patients referred for management of hypoglycemia, duration of diabetes unknown, undocumented hypoglycemia Intensity of CM: three groups of management, PCP, case manager with no medicine adjustment, CM and medication adjustment, services unrestricted by cost or out of pocket patient expenses Duration: Study period, 2 years
Dorr 2005[121] Dorr 2007[122] (Good)	HbA1c or LDL level: Exposure group 21 % less likely to be overdue for HbA1c testing (OR 0.79, 95% [CI] 0.72–0.85), 31% more likely to have an HbA1c under 7.0 %; Previous HbA1c or LDL control; odds HbA1c controlled significantly higher for exposure group (OR 1.19, 95% CI 1.10 to 1.28)	Previous regularity of testing for HbA1c or LDL	Patients with irregular or nonexistent past testing 2.5 and 10.9 times the odds of being overdue, than pts with regular past testing (no previous tests: OR 10.85, 95% CI 8.47 to 13.87; irregular testing: OR 2.48, 95% CI 2.28 to 2.71; p<0.01).	Timeliness of testing	Exposure CM increased odds of testing once the patient overdue for HbA1c (OR 1.49; 95% CI 1.3 to 1.71) and LDL (OR 1.26; 95% CI 1.02 to 1.57)	Confounders: Race, severity of disease, Intensity of CM: Care manager encounters with patients= 4.5 + 1.8 times per year; 6,876 visits total; 39.4% via phone, 36% in person visit, 11.9% care conf. and 5.5% group education Duration: NR

Author Year (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration
Wilson 2005[154] (Fair)	HbA1c at baseline higher in those who subsequently received case management (8.7±2.2 vs. 8.3±1.9,±SD p=0.03)	Hyperglycemia treatment type; Treatment of hypertension with ACEI or ARB; treatment of elevated LDL cholesterol with lipid-lowering agents; use of daily aspirin	CM patients less likely to be treated with diet alone for glucose control [OR 0.5, 95% CI (0.3, 0.9)]; CM group less likely to use daily aspirin therapy [OR 0.4, 95% CI(0.3, 0.6)]	Eye examination Diet instruction by a registered dietitian Self monitor blood glucose Dental examination Comprehensive foot examination Screening for nephropathy	Patients with nurse case managers more likely to have eye examination: [OR 2.9, 95% CI (2.1, 3.8)], diet and exercise instruction by dietitian: [OR 2.8, 95% CI (1.9, 4.1)], self monitor blood glucose: [OR 2.1, 95% CI (1.5, 3.1)], dental examination: [OR 1.7, 95% CI (1.3, 2.3)], foot examination: [OR 1.6, 95% CI (1.2, 2.1)], nephropathy screening: [OR 1.6,95% CI (1.2, 2.1)]	Confounders: potential unmeasured differences in patient groups? Intensity of CM: 4 case managers, fluent in native language, CDE, active outreach, referrals and in person visits, staffing ratio was 1 : 365, at least one intervention Duration: 1.8 face-to-face encounters per patient per year

Abbreviations: CI=confidence interval, CM=case management, NR=not reported, OR=odds ratio.

Evidence Table 11. Trials of Case Management for Cancer

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)
Engelhardt 2006[28] (Fair)	To evaluate coordinated care program for patients with advance illnesses and its impact on patient satisfaction with health care and provider communication, AD wishes and health care costs	VA patients with cancer (e.g., esophagus, trachea, colon, liver, Hodgkin's disease, or multiple myeloma) who also had COPD or CHF and with 1 ICU admissions or > 2 or more acute-care admissions within 6 months	NR	Clinical Trial, 6 months	Mean Age: Intervention: 70.3; Usual care: 70.8 Gender (% Female) Intervention: 18.8% Usual care: 23.9% Race and/or ethnicity Intervention: 88% White, Usual care: 85% White SES Intervention: 37.8% lower middle Usual care: lower middle 38.4%	Patients with advanced cancer and patients with COPD and CHF 1) Population had cancer with COPD and CHF 2) NR
Goodwin 2003[37]; Jennings-Sanders 2003[38]; Jennings-Sanders 2005[39] (Fair)	To evaluate the effect of NCM on the treatment of older women with breast cancer	Women aged 65 and older, newly diagnosed with breast cancer	Patients identified more than 2 months after diagnosis	Randomized prospective trial, 12 months	1) Comparator: Age, mean: 72.9 + 7.4, Mean education years, Mean:10; currently married, 35.1% Income <$15,000/year, 56.5 % Supplemental insurance, 60.2 %; Medicaid,11.1 %; Ethnicity, % Non-Hispanic white, 68.1; Black, 22.3 ; Hispanic, 7.2; Other, 2.4; Lives alone, 33.3%; MMSE score, mean: 27.2 + 3.1; Local or regional stage, 93.9% ; Seeing male surgeon, 75.9% ; Seeing board certified surgeon, 97.1%; Seeing low-volume surgeon, 32.1% 2) Intervention: Age, mean: 71.8 + 6.6; Mean education, years: 11; Currently married, 42.5 %; Income <$15,000/year, 49.6%; supplemental insurance, 58.9% Medicaid, 10.6%; Ethnicity, Non-Hispanic white 72.6%; Black 19.6; Hispanic 6.0 Other 1.8; Lives alone, 36.7%; MMSE mean: 27.3 + 3.2; Local or regional stage, 93.3%; Seeing male surgeon, 81.4%; Seeing board certified surgeon, 96.2%; Seeing low-volume surgeon, 36.5%	Breast Cancer NR

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)
McCorkle 1989[63] (Poor)	To compare the effect of two different home care treatment regimens to usual care on the psychosocial well-being of patients with lung cancer.	Lung cancer patients with Stage I lung cancer or higher; lived in King County, WA, and met Medicare criteria for being homebound, capable of cooperating with study requirements and completed informed consent.	Patients receiving home nursing care within 6 months of study and/or enrolled in home health agency.	Randomized trial, 6 months	1) Sample: (n=166) Age (No., %) 60-69: 71, 43% Gender (% Female) 31% Race and/or ethnicity :white 89% SES income <15,000 year: 14% 2) Subsample: (n=78) Age (No., %) 60-69: 35, 45% Gender (% Female) :47% Race and/or ethnicity: White 72% SES income <15,000 year: 12%	Lung cancer NR
Moore 2002[71] (Fair)	The aim of this study was to assess the effectiveness of a nurse-led follow up in the management of patients with lung cancer	Patients with lung cancer expected to live at least 3 months.	Patients receiving cancer treatment, close medical supervision, or had a poor prognosis or performance status.	Randomized trial, 12 months	Age mean (SD): 67 years 8.8, (range 4589) Female: 25%	Lung cancer 1) COPD (8%), cardiac disease (29%), pleural effusion (2%), hypertension (18%), arthritis (22%), GI disease (28%) 2) Emotional, cognitive functioning
Mor 1995 (Fair)	To assess a short term, educationally oriented approach tested in a randomized trial of cancer patients undergoing outpatient chemotherapy.	RI residents; at least 21 years of age; initiating a new course of chemotherapy at one of two hospital based clinics or 8 private oncology practices.	Patients receiving only hormonal therapy	Randomized trial, 6 months.	Comparators: Age (%) 21-54: 43.8; 55-74: 50.8; 75+:5.5l Gender (% Female) 64.1White: 95.3% Case managed: Age (%) 21 54-65.4; 55-74: 39.4; 75+:11.0Gender (% Female) 65.4White: 96.0%	Cancer (Breast, lung, colorectal, lymphoma and other) NR

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type; Duration	Demographics: Age Gender Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)
Ritz 2000[92] (Poor)	To evaluate the quality of life and cost outcomes of CM on women with newly diagnosed breast cancer. Hospital-to-community "standard medical care"	Women, 21 years or >, newly diagnosed with breast cancer.	NR	Randomized trial, 2 years	Intervention: Range (35-85 years) Age (Mean) 55.7 Gender (% Female) 100 Race and/or ethnicity -White 97% SES Income under 31,000 23% Comparator: Range (35-85 years) Age (Mean) 55.3 Gender (% Female) 100 Race and/or ethnicity -White 97% SES income under 31,000 25%	Breast Cancer 1) NR 2) Mental illness NR but mood/wellbeing assessed

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager:	Describe Case Management Intervention	Describe Preintervention Training
Engelhardt 2006[28] (Fair)	Poor (27% low middle income) Elderly > 65 years (46% and 53%)	Medicare: 60%, 62%; Medicaid: 5.8%, 3.5%	Yes, VA	Nurses, NPs, or social workers familiar with institutional policies and who had ongoing relationships with providers	"Advanced Illness Coordinated Care Program" in which a care coordinator provided assistance with provider communication, care coordination and support; clarified patient preferences for care using worksheets; provided emotional and social support.	Reviewed assigned readings; AICCP training manual and training courses
Goodwin 2003[37]; Jennings-Sanders 2003[38]; Jennings-Sanders 2005[39] (Fair)	NR	Medicaid, comparators: 11.1 %; intervention group: 10.6%	"Supplemental insurance", unnamed.	BS degree registered nurses with previous experience with CM in other settings	NCM interacted with client via home visits, telephone appointments, visited client if hospitalized, and at other community locations. Nurse roles: educator, counselor, advocate, and coordinator of care; services provided for 12 months; also employed standard assessment instruments: activity of daily living scale, instrumental activity of daily living scale, MMSE, Geriatric Depression Scale	40 hours of training from advance practice nurses in oncology and geriatrics on treatment and complications of breast cancer, availability of community resources, assessment of older patients, and methods of communicating with treating physicians; educated in the evaluation and treatment guidelines (National Cancer Institute) and given patient-education brochures produced by the American Cancer Society and the National Cancer Institute.

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager:	Describe Case Management Intervention	Describe Preintervention Training
McCorkle 1989[63] (Poor)	Low SES, social dependency	Eligibility criteria included meeting Medicare criterion so possibly, yes.	NR	Nurses with master's degrees, training in providing personalized care to advanced cancer patients and families.	Two intervention groups: OHC nurses, or a regular home care group (SHC) consisting of a team of: team consisted of registered nurses, physical therapists, home health aides, medical social work, occupational therapist, and speech pathologist (both compared to no home care).	OHC nurses: specialized training in: symptom management, cancer treatments, pain management, physical and psychosocial assessment, grief and mourning theory, communications systems, community resources and agencies, systems analysis, self-support, professional role development, pathophysiology of death, and research theory and methodology.
Moore 2002[71] (Fair)	See previous cell	NA (UK)	NA	Clinical nurse specialists	Provided information, support and coordination with agencies or other services; telephone assessment or clinic appointment 2 weeks after enrollment; followup clinic assessment every 4 weeks or telephone assessment; provided weekly, open access nursing clinics and same day appointments.	Observing outpatient lung cancer clinics and shadowed medical consultants; nurse academics provided regular clinical supervision sessions.
Mor 1995[72] (Fair)	High unmet need status:" transportation, housekeeping, forms, financial, any activity"	NR	NR	Phone interview conducted by "trained research reviewer"	Short-term case management intervention including: 1) initial home visit, 2) initial needs assessment, 3) development of an intervention plan 4) followup phase, 5) termination visit; patients received 2 visits and intervening phone calls with individualized information services	NR

Author Year (Quality)	Describe Factors of Complex Care Needs	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager:	Describe Case Management Intervention	Describe Preintervention Training
Ritz 2000[92] (Poor)	NR	NR	NR	Two advanced practice nurses registered nurses with master's degree in nursing and in-depth knowledge and skill in the care of the patient population	Patients received "advanced practice" nurse interventions based on Brooten's cost quality model and Oncology nursing model and follow care with an APN.	NR

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Face: Face Time: Location	Planning and Assessment	Patient Education	Self-Management Support
Engelhardt 2006[28] (Fair)	Unclear; likely VA clinic	In person	NR	6 sessions	During AICCP program sessions	Provided help with AD planning, coping with loss of ability; addressing family conflict and EOL decisions; promoted advance planning.	NR, part o the six sessions presumably	Provided information to guide patients through the medical information available and treatments; enhancing self-management skills.
Goodwin 2003[37]; Jennings-Sanders 2003[38]; Jennings-Sanders 2005[39] (Fair)	Hospital	Telephone, in person visit	Three nurses, 169 patients; 56-57 subjects per CM	Patient need determined frequency of contact-- minimum contact during intervention period included at least one in-person assessment and monthly telephone calls	At least one in-person assessment, duration NR	Assessment activities: assessed understanding of and adherence to medications, assessed social support, and assessed emotional and cognitive status, monitored surgical wound healing; Planning: goal setting, decision-making, and planning with health care professionals.	NR	Checklist outlining steps in the case management and the specific activities (available to patient by request)
McCorkle 1989[63] (Poor)	Unclear, "19 hospitals and one radiation outpatient clinic used for recruitment", probably hospital based staff.	Interviews	NR	Interviews, 1 per month	5 interviews in 6-month; depending on intervention group either in home or in office/clinic	Patient needs assessed during home visit interviews.	NR	NR
Moore 2002[71] (Fair)	Specialist cancer hospital and three local cancer units.	Clinic, monthly calls and weekly open access clinic	NR	Monthly, mean = 3 calls per month; length of contact =23 minutes (range 2120)	Clinic	Notes from nurse led clinic sent to general practitioner, home care team or hospice.	NR	NR

Author Year (Quality)	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls	Face: Face Time: Location	Planning and Assessment	Patient Education	Self-Management Support
Mor 1995[72] (Fair)	NR	Initial home visit, telephone calls and termination home visit	Unclear, from the context it seems there was only 1 CM for 127-128 patients.	One initial visit, one termination visit; phone calls at two-week intervals. Average number of phone calls: 5.2, average duration: 34 minutes	Initial home visit: average 80 minutes	CM telephoned patients at two week intervals to assess new unmet needs requiring intervention.	Per protocol CM to function as a "patient educator," provided disease, treatment and nutritional information as part of the intervention plan.	NR
Ritz 2000[92] (Poor)	Hospital	Clinic visits, hospital, telephone, and home visits	2 APN : 106 patients	Patient, family and CM need-determined. CM on-call all days during the daytime, mean time per patient over study period: 1,377 minutes.	In person during assessments and therapy, duration NR	pre and post operative assessment; and during therapy	NR	Therapy included motivational interviews for patient well being and coaching; health promotion

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Engelhardt 2006[28] (Fair)	Yes	NR; NR (unlikely)	NR	VA medical centers records	NR	NR	AD: mean number ADs per patient for intervention significantly higher (mean = 1.2, SD = 1.0) than usual care (mean = 0.8, SD = 1.1 at 3 months (p=0.01); more intervention patients completed AD (69.4% vs48.4%; p=0.006); Intervention group had increased patient satisfaction with care, communication (p=0.03) and fewer reported problems with provider support (p=0.03).
Goodwin 2003[37]; Jennings-Sanders 2003[38]; Jennings-Sanders 2005[39] (Fair)	Planning with health care professionals	Monitored surgical wound healing; assessed understanding of and adherence to medications; No	Yes; planning with health care professionals; attended medical appointments with patient.	NR	NR	NR, only described as comparators not receiving intervention.	In women undergoing breast-conserving surgery, more in the NCM group received adjuvant radiation (78.3% vs. 44.8%; p=0.001) and auxiliary dissection (71.4% vs. 44.8%; p=0.057). Women in the NCM group with advanced cancer more likely to receive chemotherapy (72.7% vs. 30.0%, p=0.057). Two months after surgery, more in the NCM group had normal arm function (93% vs. 84%; p=0.037) and were more likely to state" that they had a real choice in their treatment" (82.2% vs. 69.9%, p=0.020).
McCorkle 1989[63] (Poor)	Yes, specialized services by other disciplines coordinated as needed	Yes; NR but for physicians in office group, yes	Unclear	A MR Review Instrument used to collect utilization information and health stats	NR	The OC group received usual care from their physician but no home care.	Symptom Distress scores: significant difference between time profiles home care nursing groups and OC. (p=0.03); Enforced Social Dependency: home care groups independent longer than CP (p=0.02)

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Moore 2002[71] (Fair)	Yes, made referral to medical team if new symptoms or rapid worsening of condition reported, and to social services	Yes, monitored patient. symptoms and condition; NR	Yes, "rapid and comprehensive communication" with general practitioner and primary health care team by telephone, fax, or letter; (documentation sent to patient caregiver and PCP)	NR	NR	"Conventional medical followup" (with MD), details NR	Quality of life: less severe dyspnea 3 months (p=0.03) ; better emotional functioning (p=0.03) less peripheral neuropathy(p=0.05) at 12 months patients overall satisfaction at 3, 6 and 12 months: no difference between groups (p=0.08)
Mor 1995[72] (Fair)	Provided information on the service resources needed by the patient that were located near the patients' homes.	Patients' ratings for severity of symptoms (e.g., pain, nausea, dry mouth, appetite) at 3 and 6 months; NR	NR	NR	NR	Comparator Group, details NR	Comparators: (Mean, SD)1) 3 month: QOL 7.2, SD 2.2; treatment disruption: 5.4, SD 4.6; mental health index 71.68 SD 16.80; Symptom comparator outcomes: pain (none 55.1, mild: 15 , moderate: 17 severe: 13), nausea (none 58, mild: 18, moderate:12 severe: 12), dry mouth (none 66 , mild: 20, moderate: 8.3 severe: 5.6), constipation (none79.6 , mild: 11.1 , moderate:6.5 severe: 2.8), poor appetite (none 62.0 , mild:8.3, moderate:16.7 severe:13.0); 2) 6 month: Mean QOL 7.2, SD 2.4 treatment disruption 4.2 SD 4.4; mental health index 75.5, SD 13.2; Intervention (Mean, SD): 3 month: QOL 7.0 SD 2.0; treatment disruption 5.1 SD 4.1; mental health index 74.7, SD 13.2; 6 month: Mean QOL, 7.1, SD 2.3, treatment disruption 3.4, SD 4.2; mental health index 74.4, SD 15.0; Symptom comparator outcomes: pain (none 46.2,mild: 17.6, moderate: 24.2 severe: 12.1), nausea (none78.0,mild: 15.4, moderate:3.3 severe: 3.3), dry mouth (none 71.4 , mild: 17.6 moderate: 7.7 severe: 3.3), constipation (none 85.7, mild 7.7, moderate: 4.4 severe: 2.2), poor appetite (none 72.5 , mild:9.9 , moderate: 7.7 severe: 9.9)

Author Year (Quality)	Coordination of Services	Medical Monitoring; Adjustment	Integrated Within Primary Care	Health IT	Others	Describe Comparator	Results by Patient Health Outcomes
Ritz 2000[92] (Poor)	Coordination of social services, financial services, community support groups, etc.	Wound care, labs; NR	Yes	NR	NR	“standard medical care”	No difference in POMS scores (p=0.93); mood disturbance decreased in unmarried women (p=0.011), decreased mood disturbance in women with no history of birth control (p=0.004 at 6 months); well being at 1 month better in intervention group (p=0.036)

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Engelhardt 2006[28] (Fair)	Health care Costs of Patient Participants by Treatment Group and Time T1: 6 months pre baseline, usual care and intervention p<0.01 T2: 3 months pre baseline, usual care p=0.3650 ; intervention p=0.9727	NA	NR, did report that the intervention helped avoid adverse events.	Number screened: NR eligible: NR , enrolled: 275 (intervention: 133 usual care: 142)	(AICCP= 86, UC=100) completed study	NR	
Goodwin 2003[37]; Jennings-Sanders 2003[38]; Jennings-Sanders 2005[39] (Fair)	More women in the NCM group received breast-conserving surgery (28.6% vs. 18.7%; p=0.031) and radiation therapy (36.0% vs. 19.0%; p=0.003). NCM group also received more breast reconstruction surgery (9.3% vs. 2.6%, p=0.054)	NR	NR	Number screened: NR eligible/enrolled: 335; 169 to intervention group, 166 to comparator group	Number withdrawn: Lost to followup: Analyzed (Overall): 335	Total withdrawals:14	Only 155 from intervention group analyzed.
McCorkle 1989[63] (Poor)	Hospitalizations: 194 hospitalizations total OHC mean no. = 2.1 hospitalizations, SHC= 2.8, OC = 2.6; Length of hospitalization: OHC = 258 day SHC = 3 17 days OC group OC = 272 days (reported not significant but p-value NR)	OC group reported better health perceptions over time compared to HC groups (p<0.005)	NR	900 eligible, 166 enrolled	66% (n = 111) died; relocated (n=3); unknown (n=2)	11 patients too sick for interviews	Tables only report no. and % or means (see footnotes for p-values).

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Moore 2002[71] (Fair)	CM at 3 mos) : Fewer medical consultations with a MD at (p=0.04); fewer radio graphs taken (p=0.04); more likely to have radiotherapy treatment (p=0.01) ; no significant difference in cost of care (p=0.66)	Among 144 (73%) of the 197 general practitioner surveyed, NSD in satisfaction were reported between the patient groups.	NR	203 of 271 of eligible patients enrolled; nurse led follow up (n=100); conventional follow up (n=103)	68 (25%) declined to participate 43 (16%) eligible patients preferred a MD; died intervention (n=20) ; comparators (n=17)	"unwell" (n=30) in each group	
Mor 1995[72] (Fair)	Patterns of health, social and transportation use(avg): 3 months (comparator vs. CM) physician visits 9.6; hospital days10.0; home care services: agency hours 2.8; nurse hours NR; transportation services agency hours:1.3 vs. CM group: physician visits9.6; hospital days14.6; home care services: agency hours 6.0; nurse hours 3.0; transportation services agency hours:2 6 months (comparators vs. CM): physician visits 7.7; hospital days7.8; home care services: agency hours0; nurse hours 3; transportation services agency hours:4.5 vs. CM group: physician visits 8.6; hospital days 10.7; home care services: agency hours NR; nurse hours 3.6; transportation services agency hours: 1.5	Treatment disruption: Mean, (SD) 3 months- Comparators: 7.23 (2.16) Experimental group: 6.96 (2.01) 6 months- Comparators: 7.18 (2.42) Experimental group: 7.12 (2.27)	NR	414 eligible; 11 not contacted (at physicians discretion)	Abstract reports 257 patients participated; Attrition: 40 lost at 3 months (217 participated); 32 additional lost at 6 months (185)	NR	

Author Year (Quality)	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Ritz 2000[92] (Poor)	Cost data: no significant difference in distribution of charges (p>0.05 for all); no significant difference in cost measures (p>0.05 for all)	NR	NR	588 screened, 210 enrolled	analyzed for cost data: 141	NR	

Abbreviations: AD=advance directive, AICCP= Advanced Illness Coordination of Care Program, APN=advanced practice nurse, CHF=congestive heart failure, CM=case management, COPD=chronic obstructive pulmonary disorder, ICU=intensive care unit, MMSE=Mini-Mental State Examination, NCM=nurse case management, NR=not reported, OC=office care, OHC=oncology home care, SD=standard deviation, SES=socioeconomic status, QOL=quality of life, VA=Veterans Affairs.

Evidence Table 12. Trials of Case Management for Serious Chronic Infections

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of Intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Describe Factors of Complex care Needs**	**Payer/ Insurance Carrier**
Hsieh 2008[40] (Fair)	To explore the efficacy of hospital-to-community level case management with DOTS to monitor the adherence of patients with pulmonary TB in Taiwan. Hypothesis: adherence, rate of completion, treatment success, sputum conversion, and chest X-ray improvement in experimental Group1 who received CM with DOTS would be significantly improved compared with experimental Group 2 and comparator group.	18 years of age or older, no cognitive impairment, spoke Mandarin or Taiwanese, did not have atypical or extrapulmonary TB, chronic hepatic or renal disease, and were willing to participate in the study for the entire 6 months.	Not specified	quasi-experimental design, using age and gender as matching factors, subjects were randomly assigned to one of three groups; May 2002 to July 2003	Mean age 68 years, 81% male, 80% lived with family or friends SES: NR (85% unemployed/ retired)	TB	Unclear (rate of TB medicine completion with DOT in Taiwan in 2001 was 74% according to authors)	NR
Husbands 2007[41] (Poor)	Among people living with HIV/AIDS, who and with what characteristics and circumstances, benefit most from case management vs. self-directed access to support services? Also what are the comparative costs to society?	HIV+, ≥ 16 years of age, new or current user of support services at the AIDS Committee of Toronto in Canada, able to understand spoken English themselves or with an interpreter, in touch with reality.	NR	Singled-blind randomized trial Duration 6 months	Age Mean 42.27 +/- 8.92 13% female; 1% transgender 70% Caucasian/ white 84% spoke English 89% ≥ high school education	HIV/AIDS Comorbidities: 1) 73% depressed at baseline, mean CESD score of 28.4 (±13.1). 2) Means years since HIV/AIDS diagnosis 8.72 (±13.1)	80% with annual income < $20K; 72% on disability10% worked full or part time51% lived alone	National Health Care Insurance (Canadian)

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex care Needs	Payer/ Insurance Carrier
McCoy 1992[64] (Poor)	Is case management superior to one-timereferrals to services on demand as needed by HIV-positive IDUs? Will thecase-managed group receive higher numbers of services than the comparatorgroup?	HIV-seropositive IDUs who were involved in other studies at University ofMiami Comprehensive Drug Research Center	NR	Randomized trial (Demonstration project) Duration: 1-year	Age range: <25 (9%); 26-30 (22%), 31-35 (27%); 36-40 (29%), 41 (13%); 36% Female86% Black76% without regular employment	HIV+Comorbidities: NR	Low income IVDUs	South Florida AIDS Network (a program within the Public Health Trust of Dade County)
Nickel 1996[79] (Poor)	To assess whether nurse case management, as compared to usual care, affects the QOL of AIDS patients on home care.	AIDS diagnosis; referred for home care to one of the seven participating agencies.	< 21 years; those determined to be near death at the time of the CM first visit; refused home care.	Randomized trial Duration: 2.5 years (Jan 1990- June 1992) Note: Subjects followed throughout the course of home care or until project closure in August1992.	Age ranges: 20-29 (23%); 30-39 (53%); 40+ (24%)93% male79% white 63% were participating in Medicaid	AIDS Comorbidities: NR	NR	NR (63% were participating in Medicaid either at study entry or during followup)

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex care Needs	Payer/ Insurance Carrier
Nyamathi 2006[80] Nyamathi 2007[81] (Fair)	1) To compare the effects of an intervention program (conceptually based on ComprehensiveHealth Seeking and Coping Paradigm; Nyamathi, 1989), employing nurse case management against a comparator program with standard care on LTBI treatment completion in a homeless population, and 2) To compare the effectiveness of the two programs in improving TB knowledge over a 6-month treatment period.	Spent the previous night in one of the study's homeless shelters; no self-reported history of completing TB prevention therapy; between the ages of 18 and 55, or >55 years of age, reported risk activation factors for active TB (diagnosis of immune compromising diseases or taking immunosuppressant medications), and willing to undergo further diagnostic testing at the John Wesley Community Health Medical Clinic at the Weingart Center LA.	Cognitive impairment (e.g., active hallucinations or stupor, refused chest x-ray, missed physical exam, excluded by PCP, refused DOT	Randomized trial (conducted from 1998-2003) Duration= 6 months	Age mean (SD): 41.5 (8.5) 80% male Race/ethnicity: Black (81%), Hispanic (9 %), White (7%)	LTBI 1) Comorbidities: NR	Homeless; 75% without health insurance	10% Medicare

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of Intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Describe Factors of Complex care Needs	Payer/ Insurance Carrier
Sorensen 2003[106] (Fair)	To address the question of the utility of CM in a population of substance abusers with HIV/AIDs.	Adults who met DSM-IV criteria for substance dependence, hadHIV infection as verified by their medical charts with CD4 ≥ 50 in the last 6months, willing to provide informed consent and urine specimens.	Currently enrolledin substance abuse treatment or case management, diagnosed with medical conditions indicating they would likely be deceased within 6 months, nonresidentsof San Francisco, or in police custody.	Randomized trial Duration: 1 year	Age: NR73% menRace: 43% African American, 7% Hispanic, 8% other/mixed ethnicity, 42% Caucasian7% employed	HIV+ Comorbidities: NR Coexisting mental illness: NR	Most with unstable living situations (e.g., homeless, living with friend/relative, halfway house, hotel/motel); substance abuse.	NR
Wohl 2006[109]; Sansom 2008[110] (Fair)	To evaluate the impact of a DAART program and IACM intervention onvirologic and immunologic response to HAART among patients at 3 public HIV clinics in Los Angeles County, California.	Treatment-naïve and treatment-experienced persons for whom no more than 1 prior Cregimen had failed; MMSE score=23, live or work within the DAART workers' catchment areas.	Those with advanced liver or kidney disease, were receiving directly observed therapy for TB, or were participating in clinical trialsthat prohibited participation in an adherence-support program.	Randomized trial Duration: 6 months	82% >30 years 75% Men 64% Latino; 24% were African American) 56% self-identified as heterosexual 73% Unemployed; 64% reported annual incomes of <$10,000	HIV+ Comorbidities: NR	Challenges to HAART adherence (*authors note that adherence barriers were not assessed before randomization*)	LA County public-health HIV clinics

Author Year (Quality)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Hsieh 2008 [40] (Fair)	NR	NR	Group 1: DOT under direct supervision of the case manager7 days/week for 2 months, self-administration after the second month with one unscheduled home visit per week by a case manager; Group 2: self administered medicine with a monthly unscheduled home visit by a case manager. Both groups were offered clinical medical care and nursing instructions according to the clinical pathway for TB during hospitalization.	NR	unclear	in person	NR	Group 1: DOT daily times 2 months; weekly home visit times 6 months; Group 2: monthly home visit times 6 months
Husbands 2007[41] (Poor)	Yes, National Health Care Insurance (Canadian)	NR	Strengths-based model of CM where case manager works with the client to assess and prioritize the range and mix of their challenges and strengths in the areas of daily living, housing, finances, social supports, vocation, health, leisure or meaningful activity); The CM attempts to actively link the PLHAs with a range of services as needed.	Manual used to train CM in of the strength-based model of case management.	AIDS service organization	NR	NR	NR

Author Year (Quality)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
McCoy 1992[64] (Poor)	No	Bachelor-level health educators with no social work training	3 CMs with specific assigned caseload; CM model: needs identification through screening; regular, ongoing HIV prevention education; identified need for health and mental health care, social and economic services, and addiction treatment services; CM program used regular and frequent (every 2 weeks) monitoring of patients' use of the above-identified services to determine access, compliance with treatment, and the reassessment of any needs or problems for treatment or intervention.	In-service training programs wereheld with CMs to familiarize them with the relationshipbetween drug addiction and HIV transmission and to demonstrate risk-reductioncounseling and behavioral skills, such as needle cleaning, for this population.	South Florida AIDS Network (a program within the Public Health Trust of Dade County)	Unclear	1:30 to 1:35 (CM: clients)	NR
Nickel 1996[79] (Poor)	No	Nurses specialized in HIV care	Direct services by the NCM and consultation to the agency nurse assigned to the patient; intervention protocol included: patient assessment, careplanning with monthly care review by an interdisciplinary team consisting of the NCMs, agency home care nurse and other specialists (e.g., infections disease, public health, social worker, clergy member); twice monthly review of subject needs by CM team and directed patient to community network for and authorization of services; ongoing case manager observation and monitoring of subject reports of service quality.	Training of the case manager *in study protocols* was conducted by thestudy investigators.	NR	Weekly phone calls, monthly visits.	1:12 or less	Weekly phone

Author Year (Quality)	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload	Frequency of Visits and Phone Calls
Nyamathi 2006[80] Nyamathi 2007[81] (Fair)	No	CM included a research nurse (community-based nurse trained in thecare of homeless patients) and a trained outreach worker.	8, 1-hour TB education sessions, by their nurse and outreach worker over the 24 weeks of treatment; provided with community resources; escorted to their medical and social service appointments; tracked by the outreach worker when they missed a DOT dose.Note: identical LTBI medical treatment, medical monitoring and incentives as the comparator group	The research nurses and outreach workers received special training as extended care providers to ensure optimal skills in providing the intervention.	Unclear likely at the Weingart Center)	8, 1-hour TB education sessions by their nurse and outreach worker over the 24 weeks of treatment; outreach worker tracked patients when they missed a DOT dose; escorted to their medical and social service appointments.	NR	8, 1-hour TB education sessions by their nurse and outreach worker over the 24 weeks of treatment (otherwise number, length, and location of contacts not specified)
Sorenson 2003[106] (Fair)	No	Paraprofessionals who were former consumers of HIV or substance abuse treatment services with a high school equivalency degree, certified chemical dependency counselors with a successful work history in treatment programs.	CM program was in place when the study began and included: service brokerage (advocating for client entry to programs) and counseling (continuingcontact with patients through a 1-year period); focused on linking patients with services; made appointments forevaluation and followup care and accompanied patients to appointments.	1-week orientation to policies and procedures upon joining the CM program. Supervised by a licensed clinical social worker through direct observation, daily supervisory meetings, and weekly case presentations that were observed by the clinical social worker and a consulting psychiatrist.	CM program based out of a public teaching hospital.	Mode of overall contact: 57% calls; 43% visits	1 per 20	Phone calls and visits forthe year of treatment: 43.8 (SD = 50.3); median=30. *Seven participants had 100 or more activities. CMs provided 12 or fewer activities to about a fourth of the participants.* Total: 49% of activities (phone calls and visits) occurred in months 1–3, and 72% of activitiesoccurred in months 1–6.

Author Year (Quality)	**Managed Care (Yes/No)**	**Characteristics of the Case Manager**	**Case Management Intervention**	**Preintervention Training**	**Primary Location of Case Manager**	**Primary Mode of Case Manager Contact with Patient**	**Caseload**	**Frequency of Visits and Phone Calls**
Wohl 2006[109]; Sansom 2008[110] (Fair)	No	Described as "trained case manager"	IACM patients self administered their HAART and met weekly for 6 months with a trained case manager to overcome barriers to HAART adherence while also engaging in traditional case-management activities including: referrals for health care payment issues, housing support, drug abuse treatment, legal services, and nutritional support.	NR	HIV clinic where participant received care	In-person clinic visits	NR	Scheduled to meet weekly for 6 months; *Average number of meetings with CM = 14*

Author Year (Quality)	**Location of Face: Face Time**	**Planning and Assessment**	**Patient Education**	**Self-Management Support**	**Coordination of Services**	**Medical Monitoring and Adjustment**	**Integrated within Primary Care**	**Health IT**	**Describe Comparator**
Hsieh 2008[40] (Fair)	Group 1: DOT daily times 2 months; weekly home visit times 6 months; Group 2: monthly home visit times 6 months	CMs responsible for offering counseling, DOT, following up on the patient's treatment status, and corresponding and communicating with public health nurses.	Hospital clinic staff were responsible for providing health education information to subjects in Group 1 and 2	"CMs responsible for offering counseling"	CMs responsible for offering counseling, DOT, following up on the patient's treatment status, and corresponding and communicating with public health nurses.	yes (see coordination of services)	hospital-based program	NR	Comparator group: routine hospital care without any additional intervention and a clinic followup visit with a case manager once per month

Author Year (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health IT	Describe Comparator
Husbands 2007[41] (Poor)	NR	"Case management records were developed for each client and served as evidence that strengths-based case management for each domain of life was indeed provided. Records included notes on intake, assessment and reassessment, service planning, coordination and referral, monitoring and followup and discharge and transition planning."	NR	NR	(See Planning and Assessment)	Both NR	No	NR	Usual care: Self-directed Use of Support Services Program which included psychosocial counseling, employment counseling, social support and support groups with or without practical assistance as needed (e.g. meals, furniture, good food box, buddies, drives to medical appointments, congregate dining, and referrals to other agencies). These services are provided if a PLHA asks; that is, services are provided on demand or at the request of the PLHA.
McCoy 1992[64] (Poor)	NR	Occurred during intake (details not specified)	Educated patients about risk reduction strategies (average= 30 minutes)	NR	NR	NR; No adjustment	No	NR	The comparator group utilized the services of a bachelor-level, experienced social worker on staff at Comprehensive Drug Research Center who, on request and without a formalized needs assessment, during a brief intervention session, referred study participants to health and social services.

Author Year (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health IT	Describe Comparator
Nickel 1996[79] (Poor)	Monthly in-person visits	Yes	NR	NR	Yes	Yes, monitoring; no adjustment	Communication with PCP at least monthly	NR	Usual care was provided by agency home care nurses who provided care toAIDS patients through procedures comparable tothose for patients with other diagnoses (e.g., needs assessment, care planning and revision, and delivery of care as needed). Included 24-hour on-call services.

Author Year (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health IT	Describe Comparator
Nyamathi 2006[80] Nyamathi 2007[81] (Fair)	See previous cell	Unclear	8, 1-hour TB education sessions by their nurse and outreach worker over the 24 weeks of treatment.	Included 1) self esteem and attitudinal readiness for change; 2) TB and HIV risk reduction education; 3) coping, self management,and communication skills; 4) cognitive problem solvingto implement behavior change; and 5) positive relationships and social networks to maintain behavior change.	Provided with community resources and escorted medical and social service appointments.	LTBI treatment = twice weekly doses of 900 mg INH 50mg vitamin B6 over 6 months at a common medical clinic, monthly monitoring of side effects . Note: unlike comparator group, NCMI participants were tracked when they missed a DOT dose.	Those requesting assistance with non-TB health care problems were referred to the medical clinic located on site.	NR	Standard of care included (received by both study groups) DOT at the research clinic twice a week over a period of 6 months administered by research nurses; a 10-min question and answer session regarding LTBI treatment before receiving the INH dose and time devoted to individualized needs, such as referral to treatments or services; a detailed directory of community resources and services of local agencies; $5 for each dose of INH received; referral on request to the medical clinic located on site; Comparator participants: received a single 20-min factual presentation on TB and the importance of being compliant with the LTBI treatment.

Author Year (Quality)	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring and Adjustment	Integrated within Primary Care	Health IT	Describe Comparator
Sorenson 2003[106] (Fair)	Community (64%), hospital (16%), office (20%).	NR	Description of CM activities included risk reduction education	NR	73% of programs contacted/ referrals made were defined as non-drug, 27% defined as drug. *Case managers focused on linking patients with services that included medical care, psychiatric treatment, legal assistance, and social service entitlements such as low-income housing and Supplemental Security Income (SSI).*	No; No	No	NR	Brief contact with the department of psychiatry at SFGH provided brief contact and referral through ASAP. When ASAP workers (included both professionally trained individuals (e.g., social workers) and paraprofessionals (former consumers of substance abuse or HIV services)) received a referral from the research project, they met with the patient at the hospital program. They provided education about reducing the risk of HIV transmission, information about HIV services, and referrals to substance abuse treatment, social services, and HIV services in the community.

Author Year (Quality)	**Location of Face: Face Time**	**Planning and Assessment**	**Patient Education**	**Self-Management Support**	**Coordination of Services**	**Medical Monitoring and Adjustment**	**Integrated within Primary Care**	**Health IT**	**Describe Comparator**
Wohl 2006[109]; Sansom 2008[110] (Fair)	In person during clinic visit; A*verage meeting duration =30 minutes; Total time spent with CM = 7 hours.*	Yes (met weekly with CM to discuss)	Yes, regarding adherence to HAART	Yes, support to adhere to HAART	Referrals for health care payment issues, housing support, drug abuse treatment, legal services, and nutritional support.	No; decisions were made by the medical staff in the clinics.	Yes	NR	Self-administered their HAART and continued to receive the services that were available to all clinicpatients, including quarterly contact with a case manager. DAART: received daily delivery of HAART, specially-trained, bilingual community worker observed the participant take 1 daily HAART dose. Community workers delivered evening, weekend, and holiday doses for self administration. At the next meeting, patients were queried about the self-administered doses, and empty packages were collected. Adherence problems were addressed by the community worker when possible, and participants were referred to the clinic staff when necessary.

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Hsieh 2008[40] (Fair)	At 2 months, statistically significant difference in sputum conversion (87% vs. 75% vs. 53%) and CXR improvement rates (62% vs. 59% vs. 32%); treatment success rates were significantly better in Group 1 than in Group 2 or Comparator (94% vs. 69% vs. 69%);	NR	Statistically significant adherence rate differences among the three groups for the third, fourth, fifth and sixth months (< 80% adherence (range for 3rd through 6th months)): Group 1 (0-0%), Group 2 (13-22%), Comparator (19-28%); treatment completion rates were significantly better in Group 1 than in Group 2 or Comparator (97% vs. 69% vs. 69%)	NR	Screened: NR; eligible 114; enrolled 114; each group n=38	96 analyzed (32 in each group); (10 died, 8 not included because of the match procedure)	NR	

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Husbands 2007[41] (Poor)	1) Depression: (CES-D scale scores divided into very depressed and less depressed) a) Mental Health Function Index Scores for very depressed (CM vs. usual care): 31% improvement vs. 1% deterioration (p=0.015) b) Social Function Index Scores for very depressed (CM vs. usual care): 45% improvement vs. 27% deterioration (p=0.001) c) Physical Health Summary Score (CM vs. usual care): 16% improvement vs. 7% deterioration (p=0.009) d) Mental Health Summary Score (CM vs. usual care: 30% improvement vs. usual care = 4% deterioration (p=<0.0001)	1) Cost among the very depressed (CM vs. usual care): $17,901 vs. $20,839 (p=0.19) 2) Among females (CM vs. usual care): $10,548 vs. $27,379 (p=NR)	NR	NR	128 screened/ NR/ 99 enrolled	Attrition and loss to followup (not differentiated) 20; completed 6-month followup = 79 (80%)	NR	91% had used this AIDS service organization before; Those who completed the study (n=79) had, on average at baseline, a clinically significant 8-10 point higher (better) QOL score than those who did not complete the study (n=20). Unable to tell from data reported how many were randomized to each group/attrition rates from each group.

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
McCoy 1992[64] (Poor)	NR	NR	Number of services received (CM vs. comparator) 193 vs. 42 servicesChange in high risk behaviors:a) Number of different people with whom the study participant injected and had sex (fewer compared with baseline for CM/more compared with baseline for comparator); (p<0.01)	NR	Screened, eligible unclear; 100 enrolled in CM vs. 40 enrolled in usual care (randomization suspended "to fill case loads" and the reinstituted; project expired before number in comparator group could be equalized)	NR	NR	

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Nickel 1996[79] (Poor)	NSD in QOL or Quality of Well-Being between groups at 3 and 6 months	NR	NR	NR	A total of 130 of the estimated 394 people with AIDS living in the catchment area (Columbus-Franklin County, Ohio) were referred for home care to one of the seven participating agencies at some time during the 2.5 years of the project. 45 were ineligible; 28 of the 85 eligible chose not to participate; 57 (67% of those eligible) enrolled (29 CM; 28 usual care)	NR/NR/57	NR	Duration of involvement in the interventionprotocols varied by individual, with suchevents as death (range: 5 to 815 days)

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Nyamathi 2006[80] Nyamathi 2007[81] (Fair)	NR	NR	64% of NCM group completed LTBI treatment; 42% of comparator completed their LTBI treatment (OR 3.01 (CI 2.15-4.20); treatment completion was significantly associated with the NCM intervention (r=0.22, p<0.001; TB knowledge: At baseline, the mean knowledge scores were 7.3 and 7.6 for standard care and NCM groups, respectively (p>0.05). At followup, mean knowledge scores were 9.3 for standard care and 11.4 for NCM (p<0.001).		Screened 5442/ eligible 980 (PPD+); enrolled 520 (CM, n=278; comparator, n=242)	5% overall lost to followup/followup data available for 494	NR	

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Sorenson 2003[106] (Fair)	The sex risk index was greater (i.e., more risk) for the brief contact group. NSD in substance use, HIV risk behaviors, physical and psychological status, quality of living situation.	NSD were found in self-reporting of treatment services received.	NR	NR	371 screened; 281 eligible; 190 (68% of eligible) enrolled; randomized to either brief contact (n = 98)or CM (n = 92);	A total of 160 participants (84% of total, 90% of living) were interviewed at 6 months, 150 (79% of total, 90% of living) at 12 months, and 151 (79% of total, 95% of living) at the 18-month followup.	NR	The study occurred at San Francisco General Hospital, a public teaching hospital. Study recruitment occurred 1994–1996. Participants recruited from: inpatient medical wards (44%), outpatient heroin detox clinic (25%), and emergency department (22%); no other unit accounted for more than 4% of participants.

Author Year (Quality)	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to followup/ Analyzed (Overall)	Total Withdrawals; Withdrawals due to Adverse Events	Notes
Wohl 2006[109]; Sansom 2008[110] (Fair)	6 months: <400 copies/mL (NSD)1) DAART group, 54%2) IACM group, 60%3) Usual care group, 54% at 6 months: Co treatment analyses (NSD) of undetectable viral loads:1) 71% of the DAART patients2) 80% of the IACM patients3) 74% of the usual care undetectable viral loads at 6 months (P > .05). Note: NSD in viral load reduction, median CD4+ cell count, change in CD4+ cell count from baseline, or percentage of patients with a CD4+ cell counts <200 cells/mm3 or patients with new or recurrent opportunistic infections.	Study group vs. usual care: 1) IACM participants: 2.3 vs. 6.7 days/1000 person–days; incidence rate ratio [IRR]: 0.34, 97.5% CI 0.13–0.87, p<0.025; 2) DAART participants: 44.2 vs. 31.5/1000 person–days, IRR: 1.4; 97.5% CI 1.01–1.95) p<0.025. 3) Average participant health care utilization costs were $13,127, $8,988, and $14,416 for DAART, IACM, and SOC	At 6 months no missing dose:1) 97% DAART arm2) 92% IACM arm3) 97% Usual care AL6	NR	2797 screened; 416 (15%) eligible; 166 (40%) declined to participate; 250 enrolled: DAART arm (82), IACM arm (84), SOC arm (84);	78% (194/250) completed 6 months in the study, with equal rates of retention among the3 arms: DAART 79% (65/82), IACM 80% (67/84), SOC 74% (62/84); All were included in analysis of health outcomes.	NR	Recruited from3 public HIV clinics in Los Angeles County from November 2001 through March 2004; In addition to primary care services, the study clinics adherence support included provider adherence counseling at the time of clinic visits, meetings with a case manager every 3–4months, and access to community-based social support services, including adherence support provided by community based pharmacies and others.

Abbreviations: ASAP=AIDS and Substance Abuse Program, CI=confidence interval, CM=case management, DAART=directly administered antiretroviral therapy, DOT=directly observed therapy, HAART=highly active antiretroviral therapy, IDU=intravenous drug user, IACM=intensive adherence case management, LTBI=latent tuberculosis infection, NR=not reported, NSD=no significant difference, QOL=quality of life, SD=standard deviation, SES=socioeconomic status, TB=tuberculosis.

Evidence Table 13. Observational Studies of Case Management for Serious Chronic Infections

Author Year Data Source (n) (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Andersen 2007[113] (n=51) (Poor)	HIV+ women living in inner city Detroit, currently using heroin and/or acknowledging mental health problems	Receipt of ancillary services (weekly transportation service and nurse CM for 6 months, then 6 months of transportation service only) from outreach clinic	Age: Mean 44.4 years (SD 8.58), Median NR, Range NR; 90% Black; 78% on Medicaid; urban-dwelling (Detroit)	Pre/post measurement; 1-year intervention	NR	NR	NR
Bouey 2000[116] (n=132) (Poor)	HIV-positive Native Americans	Enrolled in the Ahayala case management program according to the National Native American HIV/AIDS Client Database	Mean age: 34.3 years Sex: 74% male Race/Ethnicity: 67.7% American Indian, 3.1% Alaskan Native, 25.2% Native Hawaiian, and 3.9% Other Indigenous Group	Cross-sectional	NR	NA	Patient satisfaction, QOL
Fleishman 1991[125] (n=988) (Fair)	Patients over 18 years of age having been enrolled in the Robert Wood Johnson Foundation's AIDS Health Services Program for at least one month.	Participants either received Community based case management (CBO) or clinic based case management (clinic)	Direct service providers (usually the client's case manager or a clinic nurse) made the initial request to participate in the study.	Age 18 years and older. 90% male 66% white	Observational	NR	NR

Author Year Data Source (n) (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Kushel 2006[134] (n=280) (Good)	Probability-based community sample of HIV-infected homeless and marginally housed adults in San Francisco, California; cohort assembled through HIV screening in 3 San Francisco neighborhoods during April 1996-Dec 1997 and April 1999- April 200	CM, defined as none or rare (any CM in 25% or less of quarters in the study), moderate (from 25% to 75%), or consistent (more than75%)	Age at baseline: Mean 43 years (+/- 8.3), Ranges: <40 years (36%), 40 years or older (64%); Male 83%; Race/ethnicity: White (41%), African American (43%), Latino (6%)	Prospective observational cohort	Sex, age, race/ethnicity, housing status, CD4 cell count nadir, physical and mental health status, crack or methamphetamine use within last 30 days, level of case management use	In the screening portion of the study, 411 persons had test results positive for HIV infection and 330 (80%) agreed to participate in the cohort. Before the start of the study, 35 individuals died, 13 were lost to followup, and 2 dropped out, leaving a total of 280 eligible participants. 23 lost to followup.	Increase in CD4+ cell count of 50% or greater; undetectable HIV load at followup
Lehrman 2001[135] (n=588) (Poor)	Clients from 28 agencies (14 located in NY city [data collected Aug 1995-Mar 1996], and 14 located in Albany, Syracuse, Rochester, and on Long Island [data collected Sept 1997 - Mar 1998])	Enrolled in CM program for at least 6 months: mean (SD) 19.9 months (10.6 months)	Age mean (SD) 40 (8.1); Gender: 54% male, 46% female; Race/ethnicity: White (21%), Black (41%), Hispanic (38%)	Retrospective chart review	Gender, race/ethnicity, disease stage, mode of transmission, education level, children living with client, housing status, substance abuse status, place of residence, age, months in case management	NR	To what extent is CM successful in identifying clients' needs?

Author Year Data Source (n) (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Lin 2006[136] (n=369) (Poor)	Reported cases of TB from one hospital in Taiwan Feb 2003 to Jan 2004	received hospital based case management for duration of TB treatment	Age mean (SD): 53 (21), median and range NR; Gender: 64% male; Race/ethnicity: NR;	Register-based cohort study	Age, sex, diagnosis (pulmonary vs. extrapulmonary TB), cohort	Taiwan nationwide rate (confirmed/ reported) pulmonary or extrapulmonary TB in 2003 was 15,042/22,362 (67.3%); hospital rate for study period 369/524 (70.4%)	Successful treatment (cure) defined as completion of therapy and smear negative in last month of treatment; (outcome compared between patients with and without CM and with nationwide surveillance data)
Mangura 2002[139] (n=343) (Good)	TB patients treated by the NJMS NTBC during 1994–1996;	Treated for TB via one of three different treatment strategies: 1) cohort 1-- self-administered with occasional SAT and DOT, 2) cohort 2-- UDOT, or 3) cohorts 3, 4, 5, 6—UDOT with NCM.	Age mean (range among cohorts): 33-41 years; Male: 62%; Race: 78% Black; HIV+ 43%; 34% substance abusers (alcohol, IV and non-IV drug use); homeless: 8%; foreign-born 26%;	Retrospective Cohort	Age, race/ethnicity, sex, HIV status, drug use, foreign born, previous TB, cohort	343 TB patients treated by the NJMS NTBC during 1994–1996; *Study Clinic serves an estimated population of 258,751. Unemployment, poverty, high crime, low education, poor housing, injection drug use, HIV infection/AIDS, and cultural barriers in the foreign-born are prevalent (US Census Data 1990).*	Treatment completion; duration of treatment

Author Year Data Source (n) (Quality)	Population	Categorization of Exposure	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)	Incidence (if cohort study)	Patient Health Outcomes Included
Pugh 2009[146] (180) (Fair)	HIV positive patients living in the North West, US.	As clients attended standard clinic appointments with physician and case manager, participation was voluntary. Categories: Men who have sex with men IDU MSM/IDU Heterosexual Other/unknown	Age 50+: state 6%, EMA 5%, QOL sample 28.2%. Gender, female: state 13%, EMA 9%, QOL 16.7% Race, white: state 73%, EMA 72%, QOL 76.9%	Pre/post assessment.	NR	NR	Multidimensional quality of life

Author Year Data Source (n) (Quality)	**Results by Patient Health Outcomes**	**Resource Utilization Outcomes Measured**	**Results by Resource Utilization Outcomes**	**Process Measure Outcomes Included**	**Results by Process Measure Outcomes**	**Effects of Confounders, Intensity of Case Management, Duration**	**Notes**
Andersen 2007[113] (n=51) (Poor)	NR	NR	NR	Mean number of HIV clinic appointments and missed appointments measured 6 months prior to intervention, 6 months after start of intensive intervention, and 6 months after transportation-only intervention	Significant contrasts between the prior 6 months and 6 months of major intervention, and between 6 months of major intervention and 6 months of transportation only. The corresponding means were 1.08, 1.60, and 1.04. *(When given both transportation and individualized nursing intervention, the number of HIV medical visits increased. When the nursing component was withdrawn, the number of HIV medical visits decreased)*	NR	Withdrawn or lost to followup = NR Analyzed = 37 at 6 months, 38 at 12 months.
Bouey 2000[116] (n=132) (Poor)	**Program made life better, yes vs. no vs. unsure** 114/130 (87.7%) vs. 4/130 (3.1%) vs. 12/130 (9.2%) **Favorable quality of life, pre-enrollment vs. post-enrollment** 18.3% vs. 60.3%	NA	NA	NA	NA	NR	

Author Year Data Source (n) (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Fleishman 1991[125] (Fair)	NR	NR	NR	Case Manager Evaluations	Case Manager Evaluations: CBO (N=306) vs. Clinic (N=339) strongly agree: CM can be reached easily in an emergency: 24% vs. 26%; Not too busy to spend time with me: 31% vs. 30%; Helped a lot to get benefits and services: 30% vs. 34%; Knows about services I am getting: 34% vs. 33%; Knows a lot about entitlement: 34% vs. 38%; Seems to care about me as a person: 49% vs. 49%; Gives very good advice and information: 34% vs. 39%; Can be counted on when things get tough: 36% vs. 38%	Frequency of contact with case manager: CBO (N=366) vs. Clinic (N=380) 5 or more: 9% vs. 8% None: 19% vs. 26%	

Author Year Data Source (n) (Quality)	**Results by Patient Health Outcomes**	**Resource Utilization Outcomes Measured**	**Results by Resource Utilization Outcomes**	**Process Measure Outcomes Included**	**Results by Process Measure Outcomes**	**Effects of Confounders, Intensity of Case Management, Duration**	**Notes**
Kushel 2006[134] (n=280) (Good)	**(Measured among 219 persons with CD4+ cell count nadir < 350 cells/mL)** compared with no or rare CM, both moderate CM and consistent CM were strongly associated with improvements in CD4+ cell counts: **Moderate**-unadjusted OR 7.1 (1.4–34.8), AOR with adherence 6.5 (1.3–33.0), AOR without adherence 7.3 (1.5–36.7); **Consistent**-unadjusted OR 23.4 11.5 (2.6–51.9), AOR with adherence 10.7 (2.3–49.6), AOR without adherence 11.9 (2.6–54.6); ***no statistically significant association with reduction of viral load to undetectable.***	Receipt of primary care; emergency department visits and hospitalizations;	CM was not independently associated with primary care use, emergency department use, or hospitalization	Antiretroviral therapy adherence (concurrent use of 3 or more antiretroviral medications)	**(Measured among 219 persons with CD4+ cell count nadir < 350 cells/mL)** moderate CM was associated with improved adherence (adjusted B = 0.13; 95% CI, 0.02–0.25), compared with no or rare CM. Consistent CM use neared but did not reach a statistically significant association (adjusted B = 0.13; 95% CI, -0.01 to 0.26)		Case manager defined as a person that (1) worked at an agency, (2) talked with participants about services, and (3) helped participants to get services (could include nurses and social workers , but not money managers or doctors); only considered a person to have a CM when participant reports were confirmed by interviewing the identified case managers; (Author's note: The CM models studied were heterogeneous: some included brokerage models and other models in which the case managers themselves provided mental health counseling or nursing CM.)

Author Year Data Source (n) (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Lehrman 2001[135] (n=588) (Poor)	Clients averaged 15.4 needs during their time in CM (SD10.); on average, clients identified 0.51 additional needs that their CM failed to uncover (SD 0.86)	To what extent are services utilized, once arranged?	Medical needs were arranged at a significantly higher rate than other services (84.9% arrangement rate vs. 72.3% arrangement rate for all services, p<0.05), regardless of where the service was provided. Clients also utilized medical services, once arranged, at a high rate (77% vs. 63%, p<0.05) regardless of the location of the service. However, utilization was even higher for services provided directly by the CM agency (81.2%) than was true for services provided by another agency (75.5%), (p<0.05).	To what extent are arrangements made to meet clients' needs and to what extent are services utilized, once arranged? Does this vary based on client or organizational characteristics?	Across all services, **CMs arranged services** 72.3% of the time; **clients utilized services** 63.0% of the time (*clients failed to utilize services that had been arranged 12.9% of the time*); **Services provided directly by the CM agency** were arranged and utilized more frequently than services provided by another agency (p<0.05) [arranged, 77.6% vs. 71.2%] [utilized, 72.8% vs. 60.7%]	**Place of residence:** the extent to which services were actually utilized, once arranged, varied significantly based on only one demographic characteristic: participants living in NYC accessed services 60.4% of the time, participants living outside of the city accessed services 66.5% of the time (p<0.05); **Months in case management**: 42 % of client needs were identified in the first 3months of CM, 74% of needs had been identified by 1 year (conversely, 58% of client needs were discovered after three months in CM; 26% after a year); **the following groups had more needs** at the p<0.10 level: females (compared to males); those whose mode of transmission was heterosexual (compared to those whose mode of transmission was "men who have sex with men"), individuals who had children in the home (compared to those who did not), and the inadequately housed (compared to the adequately housed). Individuals with a high school diploma had fewer needs than did the comparison group (individuals who did not finish high school).	Only agencies in existence for at least 3 years with stable CM programs were included; Place of residence: NYC (49.5%), outside NYC (50.5)%; Have children: (61%); inadequately housed: 8.1% (included those living in SROs, temporary shelters, and living on the street); substance abuse [currently abusing]: 29%);

Author Year Data Source (n) (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Lin 2006[136] (n=369) (Poor)	Significantly (p=0.002) higher rate of successful treatment with CM vs. without CM (240/277 [86.6%] vs. 67/92 [72.8%]); a significantly higher success rate excluding all patients who died (95.6% vs. 88.2%, p=0.027); overall treatment success rate (pooled CM and non-CM groups) was 83.2% compared with nationwide successful treatment rates of 78.3% in 2002 and 69.4% in 2003	NR	NR	NR	NR	CM was the single independent predictor of successful treatment either including (RR 2.82 [CI 1.53-5.19]) or excluding patients who died (RR 2.77 [CI 1.09-7.02])	

Author Year Data Source (n) (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Mangura 2002[139] (n=343) (Good)	UDOT/NCM (Cohorts 3, 4, 5, and 6), significantly increased the TB treatment completion rates by 3 to 6 times compared with Cohort 1 (SAT/DOT) (*no significant difference between Cohort 2 (UDOT) and Cohort 1)*. A cohort-specific stepwise reduction in duration of treatment from a median of 11.6–7.5 months and an increase in completion rates from 57–81%. *The most desirable and optimal (shortest) duration of treatment completion coincided with the application of universal DOT combined with NCM.*	NR	NR	NR	NR	Variables significantly associated with treatment completion: **HIV status** (HIV+ cases (85%), HIV- cases (60%) p<0.0001; **substance use** (non-substance users (83%), substance users (68%); p=0.005; **Cohort** *(Trend analysis revealed a significant change over time:* Cohort 1 (57%) and by Cohorts 5 and 6 (86% and 81%) p=0.0004; CM model: Patients assigned to a NCM team; staff matched to ethnicity of the patient population; CM performs baseline and followup assessments and is directly responsible/ accountable for day-to-day patient management; Multi-disciplinary interventions ongoing and discussed at team meetings. DOT by outreach worker or clinic nurse.	Incremental changes (from SAT/DOT to UDOT to ODOT/NCM) at NJMS NTBC during 1994–1996

Author Year Data Source (n) (Quality)	Results by Patient Health Outcomes	Resource Utilization Outcomes Measured	Results by Resource Utilization Outcomes	Process Measure Outcomes Included	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Pugh 2009[146] (Fair)	Mean scores on the MQOL domains at both baselines (T1) and followup (T2, 6 months later) range between 60 and 72 on the 0-to-100 point scale, where higher scores indicate higher QOL.	NR	NR	Mental Health Counseling Harm Reduction Counseling Insurance/Benefits Counseling	Mental Health Counseling n=14: mental health baseline 39.95 vs. 6 months 49.74, change +9.79 index score baseline 46.21 vs. 6 months 55.16, change +8.95 Harm Reduction Counseling n=14: social functioning baseline 54.23 vs. 6 months 65.34, change +11.11 cognitive functioning baseline 63.49 vs. 6 months 71.16, change +7.67 Insurance/ Benefits Counseling n=27: cognitive functioning baseline 71.33 vs. 6 months 64.75, change -6.58	NR	

Abbreviations: DOT=directly observed therapy, EMA=eligible metropolitan area, NA=not applicable, NCM, nurse case manager, NR=not reported, QOL=quality of life, SAT=self-administered therapy, SD=standard deviation, UDOT=universal directly observed therapy.

Evidence Table 14. Trials of Case Management for Other Clinical Conditions

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Allen 2002[4] (Poor)	To test effectiveness of nurse CM program to lower blood lipids in patients with CHD.	Patients with hypercholesterolemia, defined as an LDL-C level >2.59 mmol/L (100 mg/dL) or a total cholesterol level >5.18 mmol/L (200 mg/dL), who underwent CABG or PCI.	Lived >75 miles from the hospital; had a severe, noncardiac life threatening illness; major psychiatric or substance abuse morbidity, or severe cardiac disease with a poor prognosis (NYHA Class IV or preoperative EF <30%); >75 years, BMI >40; participation in conflicting research study; unable to speak/understand English, physician caring for patient refused.	Randomized trial, duration 1 year	Mean age: Intervention group 61.1, usual care 59.6 1) Gender: CM group (70% male/N=70, 30% female/N=34), Usual care (73% male/N=83, 27% female/N=30) 2) Race: CM group (81% white/N=93, 19% other/N=22) Usual care (82% white/N=93, 18% other/N=20) 3) Education: CM group 13.8+/-3.7 years, usual care 13.3 +/- 3.4 years	Adults with hypercholesterolemia and CHD who received CABG or PCI. 1) MI (53%/N=61 CM 54.9%/N=62 usual care); HTN (positive history, or BP >140/90 mm HG)(74.8% CM, 77% usual care); prior revascularization (23.5% CM group, 31% usual care group); CHF (4.4% CM group, 5.3% usual care); Cerebrovascular disease (5.2% CM group, 6.2% usual care); Peripheral vascular disease (10.4% CM group, 14.2% usual care); DM (28.7% CM group, 23% usual care); BMI (28.7 CM group, 28.2 usual care) 2) NR	Majority of population had multiple comorbidities and were considered "high-risk" CABG or PCI. No socioeconomic factors contributing to complex care described by authors.

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Bourbeau 2003[12]; Bourbeau 2006[13] (Good)	A disease-specific self-management program and the ongoing attention and communication by a trained health professional could significantly reduce the number of hospital admissions for patients with advanced COPD.	Stable COPD. > 50 years old. Current or previous smoker.	Previous diagnosis of asthma. Participation in a respiratory rehabilitation program in the past year. Long-term-care facility stays.	Multicenter randomized trial 1 year followup period.	Age, year usual care 69.6±7.4 intervention 69.4±6.5 Sex usual care 41% female intervention 48% female	COPD 1) Comorbid conditions Cardiovascular: usual care 48%, intervention 43% Renal : usual care 4%, intervention 17% Endocrine: usual care 24%, intervention 19% Gastrointestinal: usual care 32%, intervention 26% 2) NR	Old age Education <12th grade: usual care 77% intervention 82%

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Chow 2010[19] (Fair)	To examine the effectiveness of a nurse-led case management program in improving the quality of life of peritoneal dialysis patients in Hong Kong.	Patients were included if: admitted to the renal units of the study hospitals, telephone access after discharge, receiving PD.	Patients were excluded if: received PD only intermittently, transitioned to HD during hospitalization, had an upcoming planned admission, new to PD within 3 months.	Randomized trial with pre and post test Study duration: 12 weeks	Age mean: 56.9 +/- 13.5 years Age range: 23-78 years 38.8% Female Race: NR 1) 14.3% and 7% had no formal education in the comparator and intervention groups respectively 2) 21.4% and 11.6% were unemployed in the comparator and intervention groups respectively 3) 35.8% and 30.3% had financial status that was insufficient or extremely insufficient in the comparator and CM groups respectively.	ESRD Etiology unknown on 57.6%, DM in 24.7%, DM in 10.6%; mean years on PD: 2.6; range years on PD: 0.3-12 1) 41% had diabetes(38.1% and 44.2% in the comparator and intervention groups respectively); 32.9% had heart disease (28.6% and 37.2% in the comparator and intervention groups respectively) 2) 1.2% had psychiatric disease (OF NOTE, 0% in comparator group and 2.3% in the intervention group)	16.5% unemployed, 7% with "extremely insufficient" financial status; 10.6% with no formal education

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Claiborne 2006[21] (Poor)	Investigated efficacy of social work care coordination model for stroke patients; (evaluated cost via MD, ED, and inpatient reimbursements to "evaluate the ability of group membership (intervention or comparator) to affect reimbursement."	Patients surviving stroke and completing and inpatient rehab program; 18 or older.	Severe cognitive impairment, language comprehension problems, or discharged to long term care facility	Trial, randomly assigned pre-post experimental design, 3 months prior data collection, 3 month intervention. (6 months)	Age range: Intervention group: 70 Comparator Group: 65 11.99 ("averaged 65 to 70 years old"--mean age?);Gender (39% Female) Race and/or ethnicity (84% white)	Stroke (CVD) 1) Patient's with moderate, intermediate and high complexity (details NR) 2) Reports trauma and mental health issues	Psychosocial assessment consists of five sections and a total score. A higher score indicates that the patient is experiencing greater stressors. The five sections are (a) family issues and support, with scores ranging from 9 - 45; (b) social issues ranging from 7 to 35; (c) trauma and mental health issues ranging from 6 to 30; (d) legal issues ranging from 2 to 10; and (e) chemical dependency issues ranging from 4 to 20. Total scores range from 28 to 140.

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Fan 2012[29] (Good)	To determine the efficacy of a comprehensive care management program in reducing the risk for COPD hospitalization.	Hospitalized for COPD in the 12 months before enrollment. Postbronchodilator ratio of FEV1 to FVC below 0.70 with an FEV1 below 80% predicted. >40 years old. Current or past history of cigarette smoking (>10 pack-years). At least 1 visit in the past year to a VA primary care or pulmonary clinic. No COPD exacerbation within 4 weeks. English speaking. Telephone access.	Primary diagnosis of asthma. Any medical condition that would impair ability to participate in the study.	Randomized trial, 1 year planned duration. Note: Due to serious safety concerns, the intervention was terminated before the trial's planned completion. Mean followup was 250 days.	Mean Age: 66 years 3% Female Race: 87% White 84% $\geq$ high school degree	COPD 1) Comorbid conditions: Hypertension (61%), Ischemic heart disease (32%), diabetes (27%), CHF (17%). 2) Depression self-reported (17%).	Severe COPD with high risk for hospitalization.

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Ma 2009[55]; Berra 2007[56]; Ma 2006[57] (Good)	To evaluate a nurse- and dietitian-led CM program for reducing major CVD risk factors in low-income, primarily ethnic minority patients in a county health care system, 63.0% of whom had T2DM.	Men and women aged 35 to 85 years who had moderately to severely elevated levels of major modifiable CVD risk factors with or without a history of atherosclerotic CVD or DM.	No elevated CVD risk, leaving area, difficulty coming to visits Enrolled in another study Age < 35 or > 85 years Serious comorbidities, family member already enrolled, language.	2-arm randomized trial	Mean age (55.1 overall, 54.4 CM group, 55.8 usual care) Female (65.6% overall, 64.6% CM group, 66.7% usual care) Hispanic (63% overall, 63.2% CM group, 62.8% usual care) African American (9.6% overall, 9.9% CM group, 9.2% usual care) Asian (11.9% overall, 11.3% CM group, 12.6% usual care) Education less than 8th grade (44.9% overall, 50.7% CM group, 39% usual care); Unemployed, disabled, retired (60.5% overall, 63.2% CM group, 57.7% usual care); Unable to speak, read or understand English (49.1% overall, 50.5% CM group, 48.1% usual care).	Patients at elevated risk for cardiovascular disease. 1) Hyperlipidemia/ hypercholesterolemia (Overall 63%, CM group 64.2%, usual care 61.8%); Metabolic Syndrome (overall 59.2%, CM group 59.0%, 59.4% usual care); Elevated BMI (overall men 33, women 35.4, men in CM 33.1, men in usual care 32.9, women in CM group 35.2, women in usual care 35.5) 2) NR	Sizable low income population, most of whom have Medicaid or a county sponsored indigent care plan.

Author Year (Quality)	**Study Purpose and/or *A Priori* Hypothesis (if stated)**	**Eligibility Criteria**	**Exclusion Criteria**	**Study Design/Type Duration of intervention**	**Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status**	**Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)**	**Factors of Complex Care Needs**
Mayo 2008[62] (Good)	Determine whether persons newly discharged into the community following an acute stroke would report better health related quality of life (HRQL) and have fewer emergency room visits and non-elective hospitalisations if assigned to a stroke case manager who would interact with the patients personal physician to coordinate and provide continuity of care in comparsion to those receiving usual procedures for post-hospital care	Returning home directly from the acute-care hospital following a first or recurrent stroke with any of the following criteria indicating a specific need for health care supervision post-discharge; lives alone; mobility problem requiring assistive device, physical assistance or supervision; mild cognitive deficit, dysphagia; incontinence; social service consultation during acute hospitalisation; or need for post-discharge medical management for diabetes, congestive hear failure, ischemic heart disease, arthritis, COPD, atrial fibrillation, kidney disease, perihperal vascular disease	Discharged to an in-patient rehabiitation facility or to long-term care	Randomised trial, 6 week intervention with 6 month followup	Intervention mean age: 70 33% female Comparator meage age: 72 45% female	Stroke patients	Hypertension; ischemic heart disease; dabetes; atrial fibrillation; cardiovascular condition; lives alone; no primary care physician

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Rice 2010[86]; Dewan 2011[87] (Good)	Determine if a simpler disease management program, with a focus on early recognition and self-treatment of COPD exacerbations, would improve outcomes in patients with severe COPD.	Spirometrically confirmed COPD at high risk for hospitalization as predicted by one or more of the following during the previous year: hospital admission or ED visit for COPD, chronic home oxygen use, or systemic corticosteroids for COPD.	Spirometry	Randomized trial, 1 year	disease management vs. usual care Age (SD): 69.1 (9.4) vs. 70.7 (9.7) Gender % female: 2.4% vs. 1.6%	COPD, current smoker, hypertension, cardiac, gastrointestinal, musculoskeletal, endocrine, genitourinary, neurologic.	Number of comorbidities

Author Year (Quality)	Study Purpose and/or *A Priori* Hypothesis (if stated)	Eligibility Criteria	Exclusion Criteria	Study Design/Type Duration of intervention	Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or ethnicity Socioeconomic Status	Primary Disease of Population (and other medical comorbidities and/or coexisting mental illness)	Factors of Complex Care Needs
Sadowski 2009[94] (Good)	To assess the effectiveness of a case management and housing program in reducing use of urgent medical services among homeless adults with chronic medical illnesses.	Patients ≥ 18 years without stable housing 30 days prior to hospitalization, referred at least 24 hours before hospital discharge and not the guardian of minor children needing housing. Also had ≥1 chronic medical illnesses confirmed in medical record: HTN or diabetes requiring medication; thromboembolic disease; renal failure or cirrhosis; CHF, MI atrial or ventricular arrhythmias; seizures in past year or needed medication for comparator; asthma or emphysema with ≥ 1 ED visit or hospitalization in past 3 years; cancer; HIV; GI bleeding (not peptic ulcer disease) or chronic pancreatitis	Hospital physician determined them incapable of self-care on hospital discharge.	Randomized trial	Mean Age: 47 years 22% Female 95% did not graduate from high school	≥1 Chronic medical illness (see eligibility criteria cell) 1) Unclear 2) 43% with major depression; 17% with panic disorder	Median duration of homelessness= 30 months 55% without medical insurance

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Allen 2002[4] (Poor)	NR. States that some patients received insurance coverage for prescriptions and others paid out of pocket.	NR	NP	NP and PCP and/or cardiologist participated in a partnership to manage patient's lipids. NP provided 1 outpatient visit 4 to 6 weeks after discharge to initiate a plan for lipid management. Plan included counseling for lifestyle modifications and prescription or adjustment of appropriate lipid lowering medications. Followup telephone calls to the patient reinforced counseling and recommended appropriate adjustments in medications based on results of blood tests.	NR	Primary care clinic	1 outpatient visit 4 to 6 weeks after discharge to initiate management plan. Followup telephone calls to reinforce counseling and recommend medication adjustments.	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Bourbeau 2003[12]; Bourbeau 2006[13] (Good)	Provincial universal health care program	No	Experienced nurse or respiratory therapist.	Standardized education on the COPD self-management program as well as ongoing supervision by a case manager, in addition to management by usual specialist and/or family physician.	Specific training was provided for the application of the program. Case managers had to become familiar with the content of the COPD self-management program and competent to educate patients in regards to all aspects of the disease. CMs had first to identify their specific learning needs in regards to COPD and patient education through a questionnaire and a group discussion. Half-day training sessions were dedicated to interactive lecturing session on each aspect of COPD given by different members of the multidisciplinary team. The rest of the training days included workshops oriented toward how to assess patient needs and the acquisition of motivational and teaching skills using group discussion, demonstration and practice of techniques, case scenarios, and role modeling. CMs were handed a reference guide to assist in educating their patients that includes general and specific objectives, material resources	Health Centers	Initially in health center, followup by phone calls.	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Chow 2010[19] (Fair)	Non-US	Non-US	All care managers are referred to as "nurses" (no specific educational background info provided)	1) Discharge planning 2) Weekly nurse phone followup after discharge for 6 weeks discharge planning included: discussion with patient and family and OMAHA evaluation of patient's physical, social, cognitive, emotional status, individualized education program, development of shared objectives.	24 hours training required for each NCM. All required to complete training with a simulated patient.	Not explicitly stated, but probably a call center.	Telephone	NR
Claiborne 2006[21] (Poor)	Medicare, Medicaid	Yes, organizations not named.	Care coordinators were master's-level social workers	A social worker made an initial home visit within 1 to 2 weeks after the patient was discharged from an inpatient stroke program at a physical rehabilitation hospital. Depending on patient need, subsequent contacts with the patient were made via telephone or home visits. Most patients received one home visit and weekly telephone appointments ranging from 20 minutes to 1 hour. Home visits were rare after the initial visit. A few patients received two home visits. One patient with aphasia required weekly home visits.	NR	Physical rehabilitation hospital	1 home visit; weekly telephone appointments	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Fan 2012[29] (Good)	VA coverage	Yes	Respiratory therapist (8 sites); RN (5 sites); Physician assistant (2 sites); MD (2 sites); Certified medical assistant (1 site); NP (1 site); Study coordinator (1 site)	COPD education during four individual sessions and one group session, an action plan for identification and treatment of exacerbations, and scheduled telephone calls for case management.	Three-day training course with workshops covering detailed aspects of the self-management program.	Outpatient clinic	Initially in-person (CM taught the educational sessions), subsequently by phone (scheduled CM calls).	20 sites/ 1 CM at each site: caseloads ranged from 2 to 32.
Ma 2009[55]; Berra 2007[56]; Ma 2006[57] (Good)	Most Medicaid or a county sponsored indigent care plan.	No	Nurse and dietitian.	CM participants received a 1:1 nurse- and dietitian-led CM intervention Heart to Heart program that differed by focusing on high-risk patients served by public health primary care clinics. Principal CM strategies included (1) intensive, individualized care; (2) continuity of care and coordination with primary and specialty care; (3) self-management support; (4) implementation of evidence-based treatment guidelines for primary and secondary CVD prevention15,16; and (5) behavioral counseling to improve physical activity, nutrition, weight management, stress reduction, and medication adherence.	Nurse and dietitian CM were trained and supervised by a senior nurse practitioner and the principal investigator.	Clinic	Face-to-face clinic visits supplemented by telephone consultations, as needed	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Mayo 2008[62] (Good)	NR	No	Two nurses with extensive experience with geriatric nursing, including stroke	Establish contact with patients existing personal physican and arrange for an appointment and for documentation about the stroke to be fowarded to the physician. For persons without personal physicians, the local community health centre (CLSC) was contacted for physician follow-up. Stroke patient were also provided with a 24-hour contact number for the nurse, which was used sparingly mostly on weekends on in the early evening mostly propted by visits from family members	Establishing guidelines for assessments to be carried out and creating a documentation system for recording the interaction	NR	In home visits, telephone	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Rice 2010[86]; Dewan 2011[87] (Good)	NR	NR	NR, disease management	Patients attended single 1 to 1.5 hour group education session conducted by a respiratory therapist case manager. Session included general information about COPD, direct observation of inhaler techniques, review and adjustment of outpatient COPD medications, smoking cessation counseling, recommendation concerning influenza and pneumococcal vaccinations, encouragement of regular exercise, and instruction in hand hygiene.	NR	NR	Mail, telephone	NR

Author Year (Quality)	Payer/Insurance Carrier	Managed Care (Yes/No)	Characteristics of the Case Manager	Case Management Intervention	Preintervention Training	Primary Location of Case Manager	Primary Mode of Case Manager Contact with Patient	Caseload
Sadowski 2009[94] (Good)	Of the 55% insured, 37% Medicaid, 8% Medicare	No	Case managers social worker with master's-level training.	Case management was one of three integrated components of intervention (after hospital discharge transitional housing at respite care centers, placement in stable housing, and case management). Functions of CM included: hospital CM facilitated discharge planning during hospitalizations and placement in respite care or back in stable housing sites; respite and housing CM facilitated the participant's housing placement and coordinated appropriate medical care with substance abuse and mental health treatment referrals as needed. On-site CM had contact with participant at least biweekly.	Intervention designed by developed by a consortium of 14 hospitals, respite care centers, and housing agencies in Chicago. Note: no description of duration.	Hospital, respite location and study sites.	Appointments and followup phone calls	No more than 20 subjects per case manager

Author Year (Quality)	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring; Adjustment	Integrated within Primary Care	Health IT
Allen 2002[4] (Poor)	NR. 1 outpatient visit 4-6 weeks after discharge to initiate plan. Average of 7 contacts per patient over 1 year.	Single outpatient baseline followup visit for 1 hour in clinic.	Nurse practitioner and primary provider and/or cardiologist participated in a partnership for managing the patient's lipids. 1 outpatient visit 4 to 6 weeks after discharge to initiate lipid management plan that included counseling for lifestyle modifications and prescription or adjustment of appropriate lipid lowering medications. Followup telephone calls to the patient reinforced counseling and recommended appropriate adjustments in medications on the basis of the results of followup blood tests.	All patients received standard discharge teaching and physical therapy instructions administered by the hospital. Instructions included general guidelines for activity, monitoring pulse, temperature, and diet, and personalized exercise instructions for the first few weeks after discharge.	Followup telephone calls to the patient reinforced counseling.	Standard discharge care for all patients	Repeat measures of plasma lipids and liver function tests at 6 weeks after initiation or dosage adjustment; When the serum concentration of LDL cholesterol was >2.20 mmol/L (85 mg/dL), the nurse practitioner initiated or adjusted drug therapy with the use of lipid management algorithms.	Care plans, results of lipid testing, and adjustments of medications communicated to the primary provider and/or cardiologist regularly by letter.	NR

Author Year (Quality)	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring; Adjustment	Integrated within Primary Care	Health IT
Bourbeau 2003[12]; Bourbeau 2006[13] (Good)	Weekly for first 8 weeks, monthly afterwards	Hospital	Weekly skill-oriented teaching at home for 6-7 weeks, depending If the patient needed home oxygen and agreed to perform the home exercise program. Monthly followup phone calls after each session. Audiotape given to every patient to be used at home in order to assist him/her in implementation of relaxation techniques; deep breathing, progressive muscular relaxation, and visualization.	1 hour a week for 7 to 8 weeks, taught at home.	7 skill-oriented patient workbooks covering 1) basic information about COPD; breathing and coughing techniques, energy conservation during day-to-day activities, and relaxation exercises; 2) preventing and controlling symptoms through inhalation techniques; 3) understanding and using a plan of action for acute exacerbation; 4) adopting a healthy lifestyle (smoking cessation, nutrition, sleep habits, sexuality, managing emotion); 5) leisure activities and traveling; 6) simple home exercise program, not supervised, except for an initiation visit; and 7) long-term oxygen therapy when appropriate.	No	Medication was monitored but not adjusted.	Yes, intervention was in addition to management by usual family physician.	No

Author Year (Quality)	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring; Adjustment	Integrated within Primary Care	Health IT
Chow 2010[19] (Fair)	1) Weekly phone followup for 6 weeks starting 72 hours post discharge 2) Face to face interviews at discharge, 6 weeks post discharge, and 12 weeks post discharge.	3 interviews; time utilized for each interview not specified. Location: unclear (presumably a clinic)	Planning: as stated, included discharge planning (outlined previously); during followup calls, the nurse checked and reinforced patient's progress towards meeting shared objectives and identified new or potential complications including any problems encountered on returning home.	Individualized education plan developed for each patient by nurse care manager at time of discharge.	Patient goal-setting, as described	During followup calls, additional services could be utilized if felt necessary by nurse care manager. Those additional services included: community nurse home visit, referral to renal nurse clinics or wards, referral to renal doctor's clinic, medical treatment, referral to ED for emergent treatment	NR; Unclear. Nurse had ability to refer patient to renal nurse evaluation or MD evaluation or ED. Nurse also had an option for "medical treatment" but that is not described.	Not reported. NCM did have ability to refer patient to nephrologist office or ED - but primary care not explicitly stated.	NR

Author Year (Quality)	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring; Adjustment	Integrated within Primary Care	Health IT
Claiborne 2006[21] (Poor)	Most patients received one home visit and weekly telephone appointments; telephone appointments ranging from 20 minutes to 1 hour.	Face time: 1 in home visit at patients home; Home visits were rare after the initial visit. A few patients received two home visits. One patient with aphasia required weekly home visits.	Intervention group followup data were collected by the social worker during the last care coordination appointment at the end of 3 months.	NR	NR	Provided service needs assessment, service coordination, assisting, and advocating for services (e.g., new medical appointments, additional care, transportation issues, financial issues, housing, heating and repair assistance).	"Monitoring patient care and progress" No, did not adjust medications.	Possibly; "providing brief patient/ caregiver counseling."	No
Fan 2012[29] (Good)	Four individual educational sessions plus a group session at start of study. Phone call to patient once per month for 3 months then every three months thereafter.	Hospital-based outpatient clinics	Initial needs assessment by CM; written, individualized action plan for flare-ups that included prescriptions for prednisone and an antibiotic (chosen in consultation with the primary care physician)	Four individual 90-minute weekly sessions plus a group session	Followup telephone calls to the patient reinforced self-management teaching; Pts instructed to call CMs after initiating action plan; CMs available by phone during regular working hours.	CMs contacted PCP if an exacerbation occurred.	CMs contacted PCP if an exacerbation occurred.	Yes. PCPs for patients in both groups were advised to manage their patients according to published guidelines	NR

Author Year (Quality)	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring; Adjustment	Integrated within Primary Care	Health IT
Ma 2009[55]; Berra 2007[56]; Ma, 2006[57] (Good)	After initial visit, 4 to 6 week intervals during the initial 6 months and every 2 to 3 months thereafter with per-patient target of 8 to 10 visits during 15 months.	Clinic visits	Each visit began with a brief physical examination and a review of the patients risk reduction plan, progress, and problems. Counseling was then provided and referrals made as needed.	NR	NR	Yes, as needed	NR	Yes.	No
Mayo 2008[62] (Good)	Average of 4.8 home visits and 7.8 telephone contacts	In home	NR	NR	NR	Case managers worked with personal primary care physicians or local community health centres for those without personal primary care physicians	NR	Yes, case managers worked with primary care physicians	NR
Rice 2010[86]; Dewan 2011[87] (Good)	Monthly phone calls	Clinic	NR	Disease management and education sessions as part of intervention.	Each received an individualized written action plan that included refillable prescriptions for prednisone and an oral antibiotic, contact information for a case manager, and the telephone number of the 24-hour VA helpline.	NR	NR	NR	NR

Author Year (Quality)	Frequency of Visits and Phone Calls	Location of Face: Face Time	Planning and Assessment	Patient Education	Self-Management Support	Coordination of Services	Medical Monitoring; Adjustment	Integrated within Primary Care	Health IT
Sadowski 2009[94] (Good)	At least bi-weekly.	NR	Yes, assessed medical, mental health and substance abuse needs.	No	No	Yes, housing services	No; No	No	No

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Allen 2002[4] (Poor)	None	Patients in usual care group observed by usual primary providers and/or cardiologists. Enhanced usual care included written results of full lipid profiles sent to patients and their physicians at 4 weeks, 6 and 12 months post-discharge; received recommendations about goal levels for lipoproteins and general recommendations for diet and physical activity at baseline and again at the time of followup examinations. Note: All patients received standard discharge teaching and physical therapy instructions by the hospital and include: general guidelines for activity, monitoring pulse, temperature, and diet, and personalized exercise instructions for the first few weeks after discharge.	After 1 year of CM the average TC, LDL cholesterol, and triglyceride levels were significantly lower in intervention group. 1) Mean HDL level increased modestly in both groups. Significantly more patients in CM group than usual care group achieved LDL levels <2.59 mmol/L (65% vs. 35%, p=0.0001). 2) No significant difference in proportion of patients achieving these goals at baseline. At 1 year, 87% of patients in intervention group and 79% of patients in usual care group were on lipid-lowering drugs. 97% in both groups were taking a single statin. 3) NS changes in BMI in either group.	NR	Compared with usual care group, patients in CM group reported a greater reduction in dietary consumption of calories from total fat (p=0.0004), saturated fat (p=0.0004), and cholesterol (p=0.02) and increase in dietary fiber (p=0.13). Significantly higher proportion of patients in the intervention group (40%) reported exercising at a level of 6 MET hours per week compared with patients in the usual care group (26%, p=0.02).	NR	Of the 337 patients eligible, 228 (68%) consented/115 randomized to intervention group and 113 to usual care group. 158 (69%) completed 12 month followup (77% of intervention patients and 62% of usual care patients).	Loss to followup: inconvenience or loss of interest (58); changed providers (4); unable to contact (3); death (3); moved (2).	NR

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Bourbeau 2003[12]; Bourbeau 2006[13] (Good)	NA	Usual care: management by usual specialist/family physician.	Usual care group, mean±SD FEV_1 was 0.98±0.31 L at baseline and 1.01±0.36 L at 12 months. Intervention group FEV_1 was 1.0±0.33 L at baseline and 0.96±0.32 L at 12 months. Lung function did not change significantly from baseline to the end of the study. Walking distance on the 6-minute walking test did not change significantly within or between groups at 4 and 12 months. 362 acute exacerbations of COPD were reported in the usual care group and 299 in the intervention group (p=0.06).	Usual care group, 32.5% of acute exacerbations resulted in hospital admission compared with 23% in intervention group. Usual care group 44.4% of acute exacerbation resulted in an emergency department visit compared with 31.7% in the intervention group. Admissions during 1 year followup: acute exacerbations; usual care 118, intervention 71 other health problems; usual care 49, intervention 21	NR	NR	NR/469/191	25/1/165	

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Chow 2010[19] (Fair)	None	Usual care included routine discharge care: standard information, telephone hotline service, self-help materials.	1) No significant difference between comparator and study group overall for all quality of life measures. 2) Statistically significant ($p<0.05$) interaction effects were noted for sleep, staff encouragement, patient satisfaction, and social function. 3) By three time intervals, participants in the intervention group showed greater improvement in their scores during the first 6 weeks after intervention. Participants in the comparator group displayed slight improvement during first 12 weeks, but to a lesser degree than in intervention group.	NA	NA	NR	Number screened: NR/Number eligible: 120/ Number enrolled: 100	Lost to followup: 9 (4 in intervention group and 5 in comparator group). Withdrawn, unclear. A total of 6 were listed as having "discontinued intervention" due to death, transplant, or change of treatment regimen (3 in each group). Analyzed: 85 (43 in intervention group and 42 in comparator group). Note: 45 in each group required to meet sample size calculations.	Total withdrawals unclear (see previous). Adverse events NR.

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Claiborne 2006[21] (Poor)	None	"Both groups received subsequent treatment as determined by physicians and patients." However, the intervention patients received additional social work care coordination services that the comparator group did not.	NR	"Outpatient reimbursement higher for Intervention group (p<0.05), ED reimbursement lower for intervention group(p<0.05); Total reimbursement lower for intervention group (p<0.05)"	NR	NR	28 patients participated; 16 were assigned to the intervention group and 12 were assigned to the comparator	Report 28 analyzed. Four comparator-group patients were removed from the study due to 2 dying, 1 entering a skilled nursing facility after a rehospitalization event, and 1 left the study; One patient from the intervention group voluntarily left the study	Unclear; one patient from the CM group left the study.

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Fan 2012[29] (Good)	NR	Usual care. Both the intervention and usual care groups received a COPD informational booklet and PCPs for both groups received a copy of COPD guidelines and were advised to manage their patients according to these guidelines.	No significant difference between intervention and control groups in number of COPD exacerbations, rate of antibiotic use, or the timing of prednisone or antibiotic treatment. Treatment. Exacerbations treated with prednisone: 2.5 per patient-year in the intervention group vs. 2.1 in the usual care group (rate ratio, 1.25 [CI, 1.05 to 1.48]; p=0.011). Deaths from all causes: intervention 28, usual care 10 (hazard ratio, 3.00 [CI, 1.46 to 6.17]; p=0.003). Deaths due to COPD: intervention group 10, usual care 3 (hazard ratio, 3.60 [CI, 0.99 to 13.08]; p=0.053).	1-year cumulative incidence of COPD-related hospitalization: intervention 27%, usual care 24% (HR, 1.13 [95% CI, 0.70 to 1.80]; p=0.62).	No statistically significant improvements in COPD-specific or general health status, depressive symptoms, COPD-related knowledge, or patient satisfaction. Patient self-efficacy: a statistically significant improvement in the intervention group at 1 year (mean difference of 1-year change in self-efficacy score, 0.65 [SD, 2.3] [CI, 0.02 to 1.29]; p=0.044).	Excess mortality (see health outcome results). Due to serious safety concerns, the intervention was terminated before the trial's planned completion.	Screened: 467; Eligible: 426; Enrolled: 426	Lost to followup: 0; Analyzed: 426	Withdrawals: usual care (10), intervention (8); Withdrawals due adverse events: (0)

Author Year (Quality)	**Others**	**Comparator**	**Results by Patient Health Outcomes**	**Results by Resource Utilization Outcomes**	**Results by Process Measure Outcomes**	**Harms Reported**	**Number Screened/ Eligible/ Enrolled**	**Number Withdrawn/ Lost to Followup/ Analyzed**	**Total Withdrawals; Withdrawals due to Adverse Events**
Ma 2009[55]; Berra 2007[56]; Ma 2006[57] (Good)	None	Routine medical care with their primary care physician	Compared with baseline, mean FRS decreased in the CM group (-0.92; 95% CI, -1.28 to -0.57), whereas it remained unchanged in the UC group (-0.19; -0.56 to 0.18). Among patients randomly assigned to receive CM, the amount of change in the FRS was inversely associated with the number of face-to-face visits (r - 0.22; p=0.001). The mean (SD) number of CM visits was 8.0 (5.3), equivalent to 11.2 (6.8) hours of face-to-face contact time.	NR	NA	NR	1005/419	78 lost to followup	5 died

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Mayo 2008[62] (Good)	None	Usual care: patient and family were instructed to make an appointment with the patients personal physician or, if the pation did not have a physician, at their local community health centre as soon as possible.	Intervention vs. comparator: physical component summary at followup 43 vs. 40; mental component summary at followup 51 vs. 48	Intervention vs. comparator: hospital readmission, unplanned 10% vs. 13%; scheduled 5% vs. 11%; emergency without hospitilisation at least on day 16% vs. 23%; general practioner outpatient visit average 1.8 vs. 2.1; specialist outpatient visit average 2.2 vs. 3.4	NR	NR	NR/NR/294/190	NR/NR/190	NR
Rice 2010[86]; Dewan 2011[87] (Good)	NR	Usual care, received one-page handout containing summary of principles of COPD care and the telephone number for 24-hour VA nursing helpline.	36 deaths in the disease management group vs. 48 deaths in the usual care group over the 1 year study period.	Disease management vs. usual care Mean cumulative number of COPD-related hospital admissions and ED visits in 1 year: 0.48 vs. 0.82, p=0.001 Disease management group spent average of 36% less time in the hospital for all causes.	Respiratory health status worsened, disease management vs. usual care average: 1.3 vs. 6.4, p<0.001	NR	761/743	84 deaths	NR

Author Year (Quality)	Others	Comparator	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Harms Reported	Number Screened/ Eligible/ Enrolled	Number Withdrawn/ Lost to Followup/ Analyzed	Total Withdrawals; Withdrawals due to Adverse Events
Sadowski 2009[94] (Good)	Intervention case managers had weekly team meetings to coordinate the housing, social service, and medical care needs of participants.	Participants in usual care group referred back to the original hospital social worker and received the usual discharge planning services with no continued relationship after hospital discharge. Typically patients provided with transportation to an overnight shelter if no other accommodation could be arranged before discharge. Participants with HIV had access to case management after hospital discharge through a Ryan White program while those without HIV had access to general case management services.	NA	Rate Reduction in intervention vs. usual care: (95% CI) Hospitalizations 29 (10 to 44) p=0.005 Hospital days 29 (8 to 45) .01 Emergency department visits 24 (3 to 40) For every 100 homeless adults offered the intervention, the expected benefits over the next year include: 1) 49 (95% CI, −20 to 119) fewer hospitalizations; 2) 270 (95% CI, −23 to 563), fewer hospital days; 3) 116 (95% CI, −3 to 235) fewer emergency department visits.	NA	Death (no other harms reported)	604/455/407	76/61/405	76/0

Abbreviations: BP=blood pressure, BMI=body mass index, CABG=coronary artery bypass grafting, CHD=coronary heart disease, CM=case management, COPD=chronic obstructive pulmonary disorder, CVD=cardiovascular disease, HD=heart disease, HTN=hypertension, NA=not applicable, NP=nurse practitioner, NR=not reported, NYHA=New York Heart Association, PCI= percutaneous coronary intervention, PD=pulmonary disorder.

Evidence Table 15. Observational Studies of Case Management for Other Clinical Conditions

Author Year	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Jowers 2000[131] (Fair)	Patients at least 18 years old with severe asthma that were unstable or in need of intensive specialist observation and evaluation.	Following screening, development of individual treatment plans and asthma education, nurse CMs used telephone interaction and a pre-specified individual treatment plan to guide patients in health related decisions. Over the course of two years, CMs made 8 to 12 proactive calls to patients. CMs were also available to patients via telephone; patients averaged 6 calls to CMs.	NR	≥18 years old. Other NR.	Prospective cohort lasting 2 years	NR
Okin 2000[142] (Poor)	5+ visits to the San Francisco General Hospital ED during the previous 12 months; age ≥ 18 years; ability to give informed consent; willingness to receive case management services	Provide and coordinate all needed services including: crisis intervention, individual and group supportive therapy, arrangement of stable housing and financial entitlements, linkages to primary care providers, harm reduction services and referral to substance abuse treatment, liaison with other community agencies and extensive, persistent outreach. 12 months	Referred by San Francisco General Hospital Emergency Department staff and screened for study admission by clinical case managers.	Age: 45(14.4), Range 19-82 years Gender: 13% female Race: 49% Black; 23% White; 19% Hispanic; 6% Native American; 4% Asian Unemployed: 100%	Pre-post design, 12 months between the start of the study and the post-test. Pre-test measures were obtained through self-report of behaviors 12 months prior to the start of the study.	NR

Author Year	**Population**	**Categorization of Exposure**	**How Subjects were Referred to Case Management**	**Demographics (age, gender, race)**	**Study Design/Type**	**Adjusted Variables, Selection of Controls (for case-control studies)**
Poole 2001[159] (Poor)	Sixteen patients receiving intervention (case management) vs. sixteen patients receiving usual care for COPD.	Case-management by a clinical-nurse specialist	All patients who had been admitted to Auckland Hospital for COPD four or more times in the previous two years, where two or more of these admissions had been in the previous 12 months, were considered for case management	Case-managed group: 63% male, mean age: 70 years race: NR vs. comparator group: 56% male, mean age 75.4 years, race: NR	Cohort. Not randomized	NR
Shah 2011[150] (Fair)	Patients aged 18 to 64 years, below 200% of the Federal Poverty Level, uninsured, not eligible for public insurance programs, and frequent users of hospital services. n=98 Intervention n=160 Comparator	Case management included goal creation and support, assistance with care navigation, arranging support services, care transitions, and communication with providers. Care managers met with patients at least monthly.	Patients were referred to CM when they were identified as frequently utilizing ED and inpatient admissions. Frequent use defined as: 4 or more ED visits or admissions, 3 or more admissions, or 2 or more admissions and 1 ED visit within 1 year.	Mean age: 46.4 (Intervention), 46.0 (Comparator) Sex: 59.2% male (Intervention), 46.9% male (Comparator) Race: 46.9% Caucasian, 37.8% Hispanic, 12.2% Black, 3.1% Asian/Pacific Islander (Intervention); 50% Caucasian, 38.8% Hispanic, 11.3% Black (Comparator)	Cohort	NR

Author Year	Population	Categorization of Exposure	How Subjects were Referred to Case Management	Demographics (age, gender, race)	Study Design/Type	Adjusted Variables, Selection of Controls (for case-control studies)
Tatum 2008[152] (Poor)	Low income patients with epilepsy	Receiving 1 year of CM services from 2002 to 2003	Patients were referred by their neurologist or through self-referral, usually based upon financial inability to obtain a primary physician or neurologist for care of their seizures;	Age: Mean 41 years, Range 3 - 67 years (13 pts were under 18 years, 2 pts were older than 65 years); Male 58%; Race NR; Married 14%; 67% without health care coverage; Medicaid/Medicare 20%; 68% reported transportation problems; 86% being treated with at least one antiepileptic drug;	Pre/post survey	NR
Wetta-Hall 2007[153] (Poor)	Low income, uninsured patients with at least three ED visits in a six month period	Community Case Management model paired four sets of registered nurses and social workers to help uninsured patients access community resources, navigate the health care system, and find permanent physicians or clinics for medical care.	Patients of four area hospitals were given the option to contact Community Case Management team.	Mean age: 35 years Gender: 70% female Race: 67% Caucasian	Pre-post intervention design	NR

Author, Year	Incidence (if cohort study)	List Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Jowers 2000[131] (Fair)	NR	NA	NA	At 12 and 24 months, major reductions in (p values for 12 and 24 months): 1) Unscheduled doctor visits (p<0.001; p<0.001) 2) ED visits (p<0.001; p<0.001) 3) Hospital visits (p=0.005; p<0.001) 4) ICU admissions (p=0.004; p=0.359) 5) Oral steroid bursts (p<0.001; p<0.001) 6) Days missed from work (p=0.010; p=0.112)	Estimated net savings due to reduced utilization and employee absenteeism at 12 months of CM: $280,369	NR	Values reported graphically; no actual numbers reported.
Okin 2000[142] (Poor)	NR	NR	NR	Pre vs. post intervention ED visits 15 vs. 9 p<0.01 Medical inpatient admissions 1 vs. 1 p=0.99 medical inpatient days 5 vs. 2 p=0.95 medical outpatient visits 2 vs. 4 p<0.01	Median total hospital service cost decreased from $21,022 to $14,910, p=0.06. Median medical emergency service costs decreased from $4,124 to $2,195, p<0.01 Median medical inpatient costs decreased from $8,330 to $2,786, p<0.01	NR	

Author, Year	Incidence (if cohort study)	List Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Poole 2001[159] (Poor)	NR	number of hospital admissions; death; mean chronic disease questionnaire scores	One death in the case-managed group (died suddenly at home during sleep) and three deaths in the comparator group (all respiratory failure or pneumonia from COPD)	Median length of stay fell from 5.6 days to 3.5 days for the case-managed group but did not change in the comparator group.	Chronic disease questionnaire scores after 6 months demonstrated an average improvement of 20 points (p=0.03)	Duration of follow up was one year. The intervention group received education about the COPD disease process, the correct us of their medicines, smoking cessation, and how to recognize and manage exacerbations. They were encouraged to obtain a yearly influenza vaccination and to see their GP both on a regular basis and when they were unwell. Eight patients received a supply of prednisone and antibiotics to commence at home if they had an exacerbation. The clinical nurse specialist kept in contact with patients with weekly telephone calls and by visiting the patients at home each month (or more as needed). When a patient was admitted to the hospital, the medical staff notified the clinical nurse specialist, who saw the patient daily and helped in discharge planning. In the period immediately after discharge, the patients were visited more frequently at home.	In the period immediately after discharge, the patients were visited more frequently at home. One patient had administration of his medicine supervised by the clinical nurse specialist. Five patients were assessed by a liaison psychiatrist because the clinical picture and Hospital Anxiety and Depression score suggested a significant anxiety disorder.

Author, Year	Incidence (if cohort study)	List Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Shah 2011[150] (Fair)	NR	NR	NR	**Median ED visits per year** 6.0 (IQR 1-11) pre-enrollment vs. 1.7 (IQR 0-5) post-enrollment (p<00001) **Median inpatient hospital admissions** 0 (IQR 0-1) pre-enrollment vs. 0 (IQR 0-0) post-enrollment (p<0.0001) **Relate risk of ED visits, intervention vs. comparator** 0.68 (p<0.0001)	NR	NR	
Tatum 2008[152] (Poor)	737 epilepsy pts received CM from this epilepsy service subserving a four-county region in southeastern Florida, during 2002-2003;	*measured at 1 year after CM intervention and compared to initial survey data (pre-intervention)*: seizure control; QOL measures;	**Seizure contro**l: 87% vs. 47% (p<0.0001); **QOL**: Most pts (81%) self-assessed an improved QOL. Fewer pts reported difficulty with friends, employers, problems socializing, and feelings of anger (p<0.05).	ED Admissions	Number of pts with ED visits: 95% vs. 5% p<0.0001; ED admissions per patient dropped from 2.0 (1.8 +- 1.18) to 0.0 (0.1 +- 0.69) p<0.0001	NR	NR

Author, Year	Incidence (if cohort study)	List Patient Health Outcomes	Results by Patient Health Outcomes	Results by Resource Utilization Outcomes	Results by Process Measure Outcomes	Effects of Confounders, Intensity of Case Management, Duration	Notes
Wetta-Hall 2007[153] (Poor)	NR	Physical health status Mental health status Internal HLOC Powerful others HLOC Chance HLOC	Preintervention vs. postintervention (vs. US population norm) mean: Physical health status, 35.5 vs. 41.3, p<0.001 (vs. 49.2) Mental health status, 41.8 vs. 43.4, p=0.59 (vs. 49.2) Internal Health Locus of Control (HLOC), 26.0 vs. 26.1, NS (25.6) Powerful others HLOC, 21.8 vs. 22.4, NS (19.2) Chance HLOC, 19.4 vs. 18.9, NS (16.2)	ED visits prior to enrollment: 3999 ED visits postenrollment: 2096 48% reduction, p<0.001	NR	CCM process followed a cycle of assessment, planning, implementation, and evaluation. The first client visit encompassed both nursing and social needs assessment, goal setting with the client, initial coordination of referrals, and client education. Intervention planning and implementation included direct health and social service interventions, as well as supporting client connections to informal support networks. Direct intervention included activities such as careful matching of client to agencies, initial agency contacts, client orientation to services and form completion and visiting agencies and providers on behalf of the client to facilitate the development of informal social support, the teams structured time into client visits to provide the necessary orientation, training, and consultation with natural helpers (friend, neighbors, and community groups) in a culturally sensitive manner.	

Abbreviations: CM=case management, COPD=chronic obstructive pulmonary disorder, HLOC= Health Locus of Control, NA=not applicable, NR=not reported, QOL=quality of life.

Appendix J. Appendix References

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