

D.3 Service configuration

| Item | Details |
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| Key issue in the scope | Models for delivery of care and multidisciplinary teams. |
| Review question in the scope | What is the most effective model for delivery of care for people with CF (including multidisciplinary teams of various compositions, shared care, centre care, community care, home care and telemedicine)? |
| Review question for the protocol | What is the effectiveness of different models of care (for example, specialist centre, shared care [delivered by a Network CF Clinic which is part of an agreed designated network with a Specialist CF Centre], community, telehealth and/or home care for people with CF? [This issue in the scope has been divided into 2 review questions. See protocol D.4 for multidisciplinary teams] |
| Objective | CF is a multi-system chronic disease that affects the respiratory tract and lungs, digestive system, sweat glands and reproductive organs. The condition is typically identified in infancy and care is required throughout an individual's lifetime through to end of life. The care aims to address the biological and psychosocial needs of the patient and their families/carers and, in the UK, is primarily provided by a specialist CF Centre. As CF is associated with poor quality of life and clinical outcomes, it is important that care adequately addresses the needs of patients by allowing flexibility for individual circumstances. |
| Language | English |
| Study design | <ul style="list-style-type: none"> • SR • RCTs • Conference abstracts of RCTs (only if RCTs unavailable) • Comparative prospective and retrospective cohort studies • Registry and audit data (UK only, if no other information available) |
| Population and directness | <p>Infants, children, young people and adults with CF, diagnosed clinically and by sweat test or genetic testing. No minimum sample size.</p> <p>Population size and indirectness:</p> <ul style="list-style-type: none"> • No sample size specification. • Studies with indirect populations will not be included • To include RCTs and observational studies from Western countries. |
| Stratified, subgroup and adjusted analyses | <p>The following groups will be assessed separately if possible:</p> <ul style="list-style-type: none"> • Children • Adults <p>Sensitivity analysis: Sensitivity analysis: including and excluding studies with a high risk of bias</p> |
| Intervention | <ul style="list-style-type: none"> • Specialist centre • Telemedicine • Shared care (network of clinic) • Home care (e.g. Hospital at home) • Outreach care • Community care (primary care health care professionals, i.e. Gp) |

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| | <ul style="list-style-type: none"> Any combination of the models above <p>See notes section for details on each of the below.</p> |
| Comparison | <ul style="list-style-type: none"> Specialist centre Shared care (network of clinic) Community care Telemedicine Home care Outreach care Any combination of the models above Usual care |
| Outcomes | <ul style="list-style-type: none"> Lung function: FEV1 LCI Time to next pulmonary exacerbation Mortality Nutritional status (eg BMI, Height, weight, SDS) Quality of life (CF-QOL, CFQR) Patient and carer satisfaction Frequency of cross-infections (pseudomonas, b.cepacia) Staff experience Adherence to treatment <p>Note: change from baseline will be prioritised over absolute values</p> |
| Importance of outcomes | <p>Critical outcomes for decision making:</p> <ul style="list-style-type: none"> FEV1 Mortality Patient satisfaction |
| Setting | <p>All settings in which NHS-commissioned health and social care is provided.</p> |
| Search strategy | <p>Sources to be searched: Medline, Medline In-Process, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Database of Abstracts of Reviews of Effectiveness, Health Technology Database, Embase, CINAHL</p> <p>Limits (e.g. date, study design): All study designs. Apply standard exclusions and English language filters.</p> <p>Supplementary search techniques: No supplementary search techniques will be used.</p> <p>See appendix E.3.1 for full strategies</p> |
| Review strategy | <p>Appraisal of methodological quality:</p> <ul style="list-style-type: none"> The methodological quality of each study will be assessed using an appropriate checklist as per NICE guidelines manual and the service guidance methods guide 2014 (The Cochrane Risk of Bias tool for RCTs and the Newcastle and Ottawa scale for observational studies). The quality of the evidence will be assessed by GRADE for each outcome according to the process described in the NICE guidelines manual (2014). <p>Synthesis of data:</p> <ul style="list-style-type: none"> Meta-analysis will be conducted where appropriate. If comparative cohort studies are included, the minimum number of events per covariate to be recorded to ensure accurate multivariate analysis. Final and change scores will be pooled and if any study reports both, change scores will be used in preference over final scores. |

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| | <ul style="list-style-type: none"> • If studies only report p-values from parametric analyses, and 95% CIs cannot be calculated from other data provided, this information will be plotted in GRADE tables, but evidence may be downgraded. • If studies only report p-values from non-parametric analyses, this information will be plotted in GRADE tables without downgrading the evidence, as imprecision cannot be assessed for non-parametric analyses <p>MIDs:</p> <ul style="list-style-type: none"> • FEV1: 5 percentage points • LCI: GRADE default • Time to next pulmonary exacerbation: any change will be considered clinically significant • Mortality: any change will be considered clinically significant • Nutritional status (BMI, Height , weight, SDS): GRADE default • Quality of life: CF-QOL = 5; CFQ-R = 8.5 • Patient and carer satisfaction: GRADE default • Frequency of cross-infections (pseudomonas, B. cepacia): GRADE default • Staff experience: GRADE default • Adherence to treatment: GRADE default <p>Default MIDs: 0.8 and 1.25 for dichotomous outcomes; 0.5 times SD for continuous outcomes.</p> <p>Review process:</p> <ul style="list-style-type: none"> • A list of excluded studies will be provided following weeding. • Evidence tables and an evidence profile will be used to summarise the evidence. |
| Equalities | <ul style="list-style-type: none"> • Psychological and behavioural issues are more likely in people with a lower socioeconomic status • Gender- outcomes are worse for women although there is no evidence that this is a consequence of difference in care • Geographical issues – care is given through specialist centres and this may be a problem if a person with CF is living in an isolated location. |
| Notes/additional information | <p>2012, Telehealth in cystic fibrosis: a systematic review (adults and children services) www.ncbi.nlm.nih.gov/pubmed/22198961</p> <p>Full, shared and hybrid paediatric care for cystic fibrosis in South and Mid Wales – be mindful of responses to this article: www.ncbi.nlm.nih.gov/pubmed/21317431</p> <p>Specialist centre:</p> <ul style="list-style-type: none"> • Normally with >100 patients and minimum of >50 patients • Commissioned by NHS England to provide care for people with CF • Will have the core MDT available <p>Shared care/network care:</p> <ul style="list-style-type: none"> • Local hospital looking after a small number of people with CF • Has input from a specialist centre at least twice a year • May not have the core MDT and may not be full time. <p>Community care:</p> <ul style="list-style-type: none"> • Community nurses of the region who look after people with CF and will administer treatments such as home IV antibiotics |

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| | <ul style="list-style-type: none">• Normally delivered by health visitors and school nurses.• Might include palliative services <p>Home care:</p> <ul style="list-style-type: none">• Care that would normally be given at hospital which is given at home• Delivered by CF specialist (e.g. nurse, dietician, physiotherapist) <p>Outreach:</p> <ul style="list-style-type: none">• Specialist team conduct a clinic in a local hospital <p>Telemedicine:</p> <ul style="list-style-type: none">• Involves skyping with patients and remote monitoring• More frequent in Scotland |