Table 8: Review protocol for neurosurgical procedures for spasticity

Field (based on PRISMA-P)	Content
Review question	Are neurosurgical procedures (intrathecal baclofen pump and selective dorsal rhizotomy) effective in adults aged 19 and over with cerebral palsy to reduce spasticity and or dystonia?
Type of review question	Intervention review
Objective of the review	The aim of this review is to determine the relative effectiveness of intrathecal baclofen pump and selective dorsal rhizotomy compared with standard care or placebo in reducing spasticity and or dystonia in adults with cerebral palsy
Eligibility criteria – **population**/disease/condition/issue/domain	Adults aged 19 and over with cerebral palsy and spasticity with or without dystonia (median age in studies should be at least 18 years)
Eligibility criteria – **intervention**(s)/exposure(s)/prognostic factor(s)	• Intrathecal baclofen pump • Selective dorsal rhizotomy
Eligibility criteria – **comparator(s)**/control or reference (gold) standard	• Usual care (including, for example: oral drugs, botulinum toxin and physiotherapy) • Placebo
Outcomes and prioritisation	**Critical outcomes** • Walking (for ambulant people only) • Gross motor function (both upper / lower limb) ○ posture • Tone (for example Ashworth scale) • Health related quality of life

Field (based on PRISMA-P)	Content

	Important outcomes
	• Pain
	• Adverse events:
	  ○ CSF leakage
	  ○ infection
	  ○ respiratory depression
	  ○ baclofen withdrawal
	  ○ baclofen overdose.
	• Satisfaction (patient or carer reported)
	• Use of concurrent medications
	
	Minimally important differences
	• Goal Attainment Scale: 7 units
	• Modified Ashworth Scale: 1 unit
	• Quality of Upper Extremities Test: 5 units
	• ICF - Measure of Participation and Activities Screener: 2 units
	• Community Balance and Mobility Scale: 10 units
	• Five Times Sit to Stand Test: 2.5 seconds
	• Seated Shot-Put: 40cm
	• Timed Up and Go: 5 seconds
	• Pain: 30% reduction – corresponding to “much improved” or “very much improved” on a global impression of change, or 2 points on a 0 to 11 pain intensity numerical rating scale
	• Other dichotomous outcomes will use default MIDs [RR thresholds of 0.80 and 1.2]
	• Other continuous outcomes will use default MIDs [0.5 times the SD of the control group]

Eligibility criteria – **study design**	• Systematic reviews of RCTs • RCTs • Comparative cohort studies (only if RCTs unavailable or limited data to inform decision making) Consider conference abstracts only related to RCTs.

Field (based on PRISMA-P)	Content
Other inclusion / **exclusion criteria**	• Only published full text papers • Date limit 1980 onwards
Proposed sensitivity/**sub-group analysis**, or meta-regression	Groups that will be reviewed and analysed separately: • Ambulant vs. non-ambulant: GMFCS level I to III vs. GMFCS IV to V) No subgroups were identified for sensitivity analysis in the presence of heterogeneity. Important confounders (when comparative observational studies are included for interventional reviews): • degree of dystonia / spasticity • prior treatment with baclofen pumps (previous pump removed because of the infection) • adjunct medications • presence of scoliosis.
Selection process – duplicate screening/selection/analysis	A random sample of the references identified in the search will be sifted by a second reviewer. This sample size will be 10% of the total, or 100 studies if the search identifies fewer than 1000 studies. All disagreements in study inclusion will be discussed and resolved between the two reviewers. The senior systematic reviewer or guideline lead will be involved if discrepancies cannot be resolved between the two reviewers.
Data management (software)	STAR was used to sift through the references identified by the search, and for data extraction Pairwise meta-analyses and production of forest plots was done using Cochrane Review Manager (RevMan5). 'GRADEpro' was used to assess the quality of evidence for each outcome.
Information sources – databases and dates	Database(s): Embase 1974 to Present, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Cochrane Library; WEB OF SCIENCE
Identify if an update	Not an update
Author contacts	For details please see the guideline in development web site.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014

Field (based on PRISMA-P)	Content
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014 The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual
Methods for quantitative analysis – combining studies and exploring (in)consistency	For details please see supplementary document C for a description of methods.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014
Rationale/context – what is known	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the evidence review. The committee was convened by the National Guideline Alliance (NGA) and chaired by Dr Paul Eunson in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the NGA undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details please see the methods see supplementary document C.
Sources of funding/support	The NGA is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The NGA is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds NGA to develop guidelines for those working in the NHS, public health and social care in England

Field (based on PRISMA-P)	Content
PROSPERO registration number	Not applicable

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; CSF, cerebrospinal fluid; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; GMFCS, gross motor function classification system; HTA: Health Technology Assessment; ICF: International Classification of Functioning, Disability and Health; MID: minimally important difference; NICE: National Institute for Health and Care Excellence; NGA: National Guideline Alliance; RCT: randomised controlled trial; RoB: risk of bias; SD: standard deviation