National Institute for Health and Care Excellence

4-year surveillance (2016) – Spasticity in under 19s: management (2012) NICE guideline CG145

Appendix B: stakeholder consultation comments table

Consultation dates: 06 to19 September 2016

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Royal College of Paediatrics and Child Health	Agree		Thank you for your answer.
Association of Paediatric Chartered Physiotherapists (APCP)	Disagree	APCP is very concerned that the opportunity to not update the guidance will fail to acknowledge the clinical evidence and increasing awareness of the need for a standardized and robust integrated clinical pathway for skeletal surveillance in this population. NICE advised that the spasticity guidance was the appropriate guidance document for this to be included at time of review. The growing body of evidence from Australia, Sweden and Scotland strongly advocates a physiotherapy lead physical examination program with routine radiography at agree interval based on GMFCS and the age of patient for improved long term outcomes through combination of both early and targeted intervention. APCP respectfully asks in the strongest terms that the Spasticity guidance be updated.	Thank you for your comment. We are aware of the physical examination programme that you refer to and we were notified of a study of a population-based hip dislocation prevention programme in Sweden (see Appendix A: Summary of new evidence from surveillance). However, we currently believe that more evidence is needed on which particular parts of the programme make the most difference, as the intensive measurements sessions involved are quite time consuming and potentially costly. Until further evidence is available we are unable to update NICE guideline CG145 which currently recommends a pathway for monitoring children and young people at increased risk of hip displacement, recognising clinical findings as possible indicators of hip displacement, and regular x-rays in high risk groups.
National Guideline Alliance	Disagree	Dear team As part of the process of developing the NICE guideline for Cerebral Palsy the committee felt throughout that careful co-ordination between the CP and Spasticity guidelines was paramount	Thank you for your comment. We agree that co-ordination between NICE guideline CG145 and the in-development NICE guideline on cerebral palsy: diagnosis and management in children and young people under 25 is important. We received expert advice during this 4-year surveillance review from topic

		Much of our early discussion was around which areas were felt to be underdeveloped within the Spasticity guidelines and therefore caused concern for our colleagues within Multidisciplinary teams across the UK We were firmly instructed that we should not be dealing with questions specifically related to aspects of movement and posture including dystonia, movement therapy services and screening of musculoskeletal disorders associated with the Cerebral Palsy population We were asked to consider what extra questions we felt should be incorporated to the revision of 'Spasticity in under 19s' which would be reviewed at this point - in order to plug the major gaps between the guidelines These included • Medical management of dystonia in children • How early motor interventions change outcome • Updating evidence on anti-spasticity treatments • Updating evidence for hip and spinal screening to prevent deformity • Updating evidence on therapy approaches • Scoliosis and spinal monitoring • How treatments for motor disorders (spasticity and dystonia) impact on functional outcomes, including swallowing, speech, pain, sleep etc. The Committee also noted the limited coverage of oral medication in the spasticity guideline – having been devised in 2010-2012 there is no mention of several drugs now in daily use (pregabalin, gabapentin) and also no review of other long term 'usual' treatments of both spasticity and dystonia. There is a huge amount of variation in management across services and perceived conflict in these areas, which detrimentally effects outcome for children, young people and their families.	experts who are on the guideline committees of both NICE guideline CG154 and the in-development guideline on cerebral palsy in children and young people to help ensure that where possible the 2 guidelines complement each other. During a 4-year surveillance review of NICE guidelines, we search for systematic reviews and randomised controlled trials to identify new evidence that could have an impact on current recommendations. We can consider evidence other than systematic reviews and randomised controlled trials if this is alerted to us by topic experts (including those who helped to develop the guideline, and other correspondence we have received since the publication of the guideline) as long as it is within the evidence types specified in the relevant review question. We can also consider issues beyond the scope of the published guideline. However, without evidence, we are unable to recommend that the guideline is updated or review questions are added. To address the specific points on extra questions you felt should be incorporated: • Medical management of dystonia in children – Children with pure dystonia are out of scope of NICE guideline CG145. NICE was aware before the consultation of the cerebral palsy guideline committee's wish to add dystonia to the scope of NICE guideline CG145, however NICE 4-year surveillance found no evidence on management of pure dystonia nor was any evidence identified to us. Additionally, we note that dystonias are not limited to people with spasticity. NICE guideline CG145 may not therefore be the most appropriate place for guidance on dystonia, as this could only discuss dystonia in the population defined in the scope of this guideline. We will monitor this area in future surveillance. • How early motor interventions change outcome – NICE 4-year surveillance found evidence on various physical therapy interventions including task-focused active-use therapy (see Appendix A: Summary of new evidence from surveillance) but concluded that this evidence was unlikely to have an impact on current recommendations.

		In order to get the clearest evidence and development of pathways for services provided for children with movement disorders close inter-relationship between these two guidelines is vital. We would strongly urge NICE to re-consider their wish not to review the guideline on Spasticity management in under 19s.	• Updating evidence on anti-spasticity treatments – NICE 4-year surveillance found evidence on oral drugs, botulinum toxin, baclofen, and selective dorsal rhizotomy (see Appendix A: Summary of new evidence from surveillance) but concluded that this evidence was unlikely to have an impact on current recommendations. • Updating evidence for hip and spinal screening to prevent deformity – NICE 4-year surveillance found no evidence on spinal screening therefore no impact on NICE guideline CG145 is anticipated. We were notified of a study of a population-based hip dislocation prevention programme in Sweden (see Appendix A: Summary of new evidence from surveillance). However, we currently believe that more evidence is needed on which particular parts of the programme make the most difference, as the intensive measurements sessions involved are quite time consuming and potentially costly. Until further evidence is available we are unable to update NICE guideline CG145 which currently recommends a pathway for monitoring children and young people at increased risk of hip displacement, recognising clinical findings as possible indicators of hip displacement, and regular x-rays in high risk groups. • Updating evidence on therapy approaches – NICE 4-year surveillance found evidence on various physical therapy, orthotic, drug-based, and surgical interventions (see Appendix A: Summary of new evidence from surveillance) but concluded that this evidence was unlikely to have an impact on current recommendations. • Scoliosis and spinal monitoring – Management of scoliosis is out of scope of NICE guideline CG145. NICE was aware before the consultation of the cerebral palsy guideline committee's wish to add scoliosis to the scope of NICE guideline CG145, however NICE 4-year surveillance found very limited evidence on scoliosis (1 limited systematic

			review on management of scoliosis; see Appendix A: Summary of new evidence from surveillance). No evidence was found on spinal monitoring. Additionally, we note that scoliosis can be caused by conditions other than spasticity, and most cases are idiopathic. NICE guideline CG145 may not therefore be the most appropriate place for guidance on scoliosis, as this could only discuss scoliosis in the population defined in the scope of this guideline. We will monitor this area in future surveillance. • How treatments for motor disorders (spasticity and dystonia) impact on functional outcomes, including swallowing, speech, pain, sleep etc – NICE 4-year surveillance found evidence on some of these functional outcomes across several of the studies identified (see Appendix A: Summary of new evidence from surveillance) but concluded that this evidence was unlikely to have an impact on current recommendations. • Limited coverage of oral medication in the spasticity guideline – having been devised in 2010-2012 there is no mention of several drugs now in daily use (pregabalin, gabapentin) and also no review of other long term 'usual' treatments of both spasticity and dystonia – NICE 4-year surveillance found no evidence on pregabalin or gabapentin nor was any evidence identified to us. For long-term treatments, surveillance found evidence on various physical therapy, orthotic, drug-based, and surgical interventions (see Appendix A: Summary of new evidence from surveillance) but concluded that this evidence was unlikely to have an impact on current recommendations.
Leeds Teaching Hospitals NHS Trust	Agree		Thank you for your answer.
Medtronic Ltd	Disagree	CG145 covers the management of spasticity in the under 19s including spasticity associated with cerebral palsy. The surveillance review decision is that the CG145 guideline scope should not be extended to include ages up to 25 years.	Thank you for your comment. Age up to 25 years is currently outside the remit and therefore the scope of NICE guideline CG145. NICE 4-year surveillance found no evidence to support the extension of the scope, nor was any evidence

		There is a NICE guideline in development for “Cerebral Palsy Diagnosis and Management in Children and Young People under 25”. This guideline is due to be published in January 2017 and the draft guideline does not cover management of spasticity as this is covered by CG145 however CG145 does not cover “young people” between 19 and 25 years. We are concerned that the inconsistency in the ages covered by the two related guidelines and recommendation not to extend the scope of CG145 to include ages 19 – 25 years leaves a gap in guidance on the management of spasticity in young adults between 19 and 25 years and suggest that the guideline be updated to include this age group.	identified to us. Increasing the age limit of the guideline introduces some questions about managing long-term aspects of spasticity. Currently it is not clear how much evidence is available on this to inform recommendations. As a result, no impact is anticipated at the moment. We recognise concerns that there is a gap in guidance on the management of spasticity in young adults between 19 and 25 years, therefore this area will be monitored by future surveillance, and will be considered when an update to the guideline is needed. Additionally, development of a NICE guideline on cerebral palsy in adults has recently commenced and the management of spasticity in people aged 19 and over with cerebral palsy has been proposed in the first draft of the scope.
Do you agree with the proposal to remove the research recommendation: RR–01 What are the greatest inhibitors of functional ability in children and young people with upper motor neurone lesions?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Royal College of Paediatrics and Child Health	Disagree	We feel that researches bring more useful information to improve the outcome.	Thank you for your comment. We decided to retain this research recommendation based on the feedback on its importance.
Leeds Teaching Hospitals NHS Trust	Disagree	This needs to be investigated so that we can better understand how to develop and target treatments to improve patient quality of life	Thank you for your comment. We decided to retain this research recommendation based on the feedback on its importance.
Do you agree with the proposal to remove the research recommendation: RR–02 What is the optimal postural management programme using a standing frame in children aged 1–3 years?			
Royal College of Paediatrics and Child Health	Agree		Thank you for your answer. We will remove this research recommendation from the NICE version of the guideline and the NICE research recommendations database.

Leeds Teaching Hospitals NHS Trust	Agree	This is too specific and too limited	Thank you for your answer. We will remove this research recommendation from the NICE version of the guideline and the NICE research recommendations database.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Royal College of Paediatrics and Child Health	No		Thank you for your answer.
Medtronic Ltd	Yes	We are concerned that the inconsistency in the ages covered by the two related guidelines and recommendation not to extend the scope of CG145 to include ages 19 – 25 years leaves a gap in guidance on the management of spasticity in young adults between 19 and 25 years.	Thank you for your comment. Age up to 25 years is currently outside the remit and therefore the scope of NICE guideline CG145. NICE 4-year surveillance found no evidence to support the extension of the scope. Increasing the age limit of the guideline introduces some questions about managing long-term aspects of spasticity. Currently it is not clear how much evidence is available on this to inform recommendations. As a result, no impact is anticipated at the moment. We recognise concerns that there is a gap in guidance on the management of spasticity in young adults between 19 and 25 years, therefore this area will be monitored by future surveillance, and will be considered when an update to the guideline is needed. Additionally, development of a NICE guideline on cerebral palsy in adults has recently commenced and the management of spasticity in people aged 19 and over with cerebral palsy has been proposed in the first draft of the scope.

Do you have any comments on equalities issues?

Stakeholder	Overall response	Comments	NICE response

Royal College of Paediatrics and Child Health	No		Thank you for your answer.
Leeds Teaching Hospitals NHS Trust	Yes	The focus of any research needs to include PROMs and Quality of Life outcome measures. We need the perspective of patients and not just what clinicians think that patients want to improve / change.	Thank you for your comment. Section 3.3 'Reviewing and synthesising evidence' in the full version of NICE guideline CG145 states 'The Guideline Committee considered that reduction of spasticity alone without concomitant clinically meaningful improvement in other patient-centred outcomes would be insufficient to recommend an intervention.' The 'Evidence to recommendations' section of each review question has a subsection titled 'Relative value of outcomes' which discusses the specific outcomes agreed to be of particular importance to the review question. The Guideline Committee gave emphasis to patient-centred outcomes and quality of life measures relevant to the interventions examined for each question. NICE's guideline surveillance process is aligned with the approach taken for the original guideline and therefore is also particularly interested in the outcomes originally prioritised by the Guideline Committee. Additionally, NICE's 5 key research recommendations make suggestions for outcome measures that should be examined in future research (many of which are patient-orientated), however NICE can ultimately only analyse the outcomes reported in published evidence.