National Institute for Health and Clinical Excellence

Clinical guideline: Spasticity in children and young people

PRE-PUBLICATION CHECK ERROR TABLE

Number	Organisation	Order number	Section number in FULL guideline	Page number	**ERROR REPORT**	Developers' response
1	Allergan Ltd	1	Footnote *§§§* to recommendation number 67	155	*§§§ "At the time of publication (June 2012), some botulinum toxin type A products had UK marketing authorisation for use in the treatment of focal spasticity in children, young people and adults, including the treatment of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, 2 years of age or older. Other products had UK marketing authorisation only for use on the*	This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is requesting that further detail about botulinum toxin products be added to the guideline

					face in adults or for post-stroke spasticity of the upper limb in adults. Where appropriate, informed consent should be obtained and documented" In relation to this footnote, the Guideline Development need to make clear that the products licensed for the treatment of dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, 2 years of age or older are BOTOX® and DYSPORT®.	
2	Allergan Ltd	2	Throughout to document		Throughout the document it refers to the use of Botulinum toxin type A. At no point does it point out that these products	This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is requesting that further detail about botulinum toxin products be added to the guideline

					vary in licence or that unit doses are not interchangeable. Regulatory agencies have determined the non-interchangeability of botulinum toxins; each product has a unique structure and pharmacology, meaning one cannot use one product in exactly the same way as another and expect the same efficacy or safety.	
3	British Pain Society	1	Section 8	Page 192	*There is no clear reason why the testing with baclofen should be confined to neurosurgical centres as long as a clear pre and post test report from a trained physiotherapist clearly documents the results. Where other centres*	This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is expressing disagreement with the developers' recommendation which took account of the available evidence, the developers' clinical and parent experience, and the comments from stakeholders on the draft guideline for consultation

					within the network have the necessary expertise testing can be performed	
4	British Pain Society	2	Section 8	193	It is important for pump patients and carers to have a single point of contact and that is their therapy maintenance physician who may or may not be based within the neurosurgical centre. Thus point of contact should be changed to therapy maintenance physician not just neurosurgical centre	This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is expressing disagreement with the developers' recommendation which took account of the available evidence, the developers' clinical and parent experience, and the comments from stakeholders on the draft guideline for consultation
5	International neuromodulation society (INS)	1	Spasticity in Children: Care Pathway	8	Intrathecal testing: The guideline prescribes the use of general anaesthesia for IT baclofen testing. This should be left to the team to decide in best interests of child with child and	This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is expressing disagreement with the developers' recommendation which took account of the available evidence, the developers' clinical and parent experience, and the comments from stakeholders on the draft guideline for consultation

					parental consent. Many children can happily manage a simple local anaesthetic procedure with or without sedation. Defining the centre for testing and implantation as a neurosurgical centre is challenged. This is not supported by evidence. There are several fully trained interventional pain physicians who have great expertise in implanting and managing Intrathecal baclofen testing and pump implantations their long term management.. Neurosurgical centre should be replaced by centre of pump implantation expertise	
6	International Society for Prosthetics and	1	5	71	*This is a very negative reflection of*	This is not a matter of factual accuracy (the comment does not identify an objective error of

	Orthotics UK National Member Society				*orthotic intervention. It is true but no more so than if physiotherapy, occupational therapy or ortjhopaedic surgery is performed incorrectly. Suggest that for this reason a experienced orthotists should be involved*	material fact in the guideline). The stakeholder is expressing disagreement with the developers' statement that there are risks and benefits with the use of orthoses, as for other treatments
7	International Society for Prosthetics and Orthotics UK National Member Society	2	5?	71?	Ankle angle at stance phase of gait will determine influence on tibial alignment and knee and hip flexion. Omitted in line 21	Thank you for this comment. The developers have expanded the explanation in the full guideline to take account of the point raised by the stakeholder
8	International Society for Prosthetics and Orthotics UK National Member Society	3	5	71	S AFO is a common abbreviation for silicone AFO	The developers consider that SAFO is a commonly understood abbreviation for solid ankle-foot orthosis, and that its use has been adequately defined in the text of the full guideline and the accompanying list of abbreviations to prevent ambiguity about what is meant. As such, the developers have not made a change to the full guideline in response to this comment
9	International	4	5	71	The rigid AFO	The current description in the full

	Society for Prosthetics and Orthotics UK National Member Society				can only claim to align the tibia in stance phase, it can impact on both knee flexion and hyperextension in stance depending on the childs proximal control and alignment	guideline has not been altered. The developers appreciate that the additional information in the comment provides further explanation, but the text in the guideline is intended only to provide some basic information about possible uses of solid ankle-foot orthoses
10	International Society for Prosthetics and Orthotics UK National Member Society	5	5	71	Line 42 The shin is the tibia. In standing is during stance. It may resist knee flexion	The developers have not altered the wording in the full guideline because they consider that the terms shin and standing will be more widely understood by readers of the guideline than will the more technical terms referred to in the comment
11	International Society for Prosthetics and Orthotics UK National Member Society	6	5	72	Line 4 Knee orthoses may be dynamic in that they may be designed to allow flexion and limit hyperextension	The text of the full guideline has been clarified to state that these devices are usually static when used for the management of spasticity
12	International Society for Prosthetics and Orthotics UK National Member Society	7	5	72	Line 13 incorrect terminology. Spinal orthoses not Trunk orthoses. The rest of the sentence doesn't really make sense or say anything. Lumber sacral orthoses may occasionally be appropriate	The developers' view is that the current terminology in the full guideline and recommendations regarding trunk orthoses is sufficiently clear and will be easily understood by readers of the guideline. They do, however, recognise that it is not accurate to say that such devices are 'classed' as spinal braces or thoracic-lumbar-sacral orthoses, and so this word has been changed to 'termed'

13	International Society for Prosthetics and Orthotics UK National Member Society	8	5	72	Line 18 knee orthoses	The comment refers to the developers' review question. The review question is presented in the full guideline as a historical record of the original wording agreed by the guideline development group, and although the developers recognise that the term 'knee orthoses' may be more accurate the review question cannot be changed at this stage. The remainder of the section makes clear that the developers considered knee orthoses in this chapter of the full guideline
14	International Society for Prosthetics and Orthotics UK National Member Society	9	5	97	Replace body trunk orthoses with Spinal orthoses	The developers' view is that the current terminology in the full guideline and recommendations regarding trunk orthoses is sufficiently clear and will be easily understood by readers of the guideline
15	International Society for Prosthetics and Orthotics UK National Member Society	10	5	100	Line 50 Replace body trunk orthoses with Spinal orthoses	The developers' view is that the current terminology in the full guideline and recommendations regarding trunk orthoses is sufficiently clear and will be easily understood by readers of the guideline
16	Royal College of Paediatrics and Child Health	1	**7 Botulinum toxin**		Use of Botulinum toxin A: I cannot find a dose recommendation in this section. Up to now we have used a dosage of 30 units per Kg max in the young	This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is requesting that further detail about botulinum toxin products be added to the guideline

					child and less where there was a significant degree of central hypotonia with reduced trunk control as this has appeared to be the group most likely to get systemic effects or excessive weakness in our practice.	
17	The Society for Research in Rehabilitation	1		120	*Omitted to include one of the few double blind placebo controlled RCT of BT-A effect on mobility in children with CP.* *Uhbi BST, Bhakta BB, Ives H, Algar V, Roussounnis SH. Randomised double blind placebo controlled trial of the effect of Botulinum toxin on walking in cerebral palsy. Arch Dis Child 2000; 83(6):481-487.*	This study has now been included in the full guideline. The evidence that it contributes supports the current recommendations
18	The Society for Research in	2	2.1	28	An issue with the definition of	The developers are aware that there is considerable ongoing

	Rehabilitation				spasticity - the definition they have used is worse than that provided by Lance and is not related to the entire document (they talk of treating spasticity as problem resulting form muscle activity) yet they define this as one of stiffness (Page 28 Section 2.1) Just a general observation: Whilst the title of this guideline is spasticity the focus of most of the studies reviewed is not spasticity per se but treatment of cerebral palsy - it would help if a line was provided to justify this.	discussion regarding the exact definition of spasticity. The role of the guideline development group was not to define spasticity, and so the group used a recently published definition (Sanger 2003) that was strongly supported by comments from stakeholders on the draft guideline for consultation This is not a matter of factual accuracy (the comment does not identify an objective error of material fact in the guideline). The stakeholder is observing that the although the title of the guideline is spasticity in children and young people, most of the evidence reviewed for the guideline relates to children and young people with cerebral palsy (because this is the condition most commonly associated with spasticity in children and young people)