

National Institute for Health and Clinical Excellence

711 – Combined bony and soft tissue reconstruction for hip joint stabilisation in proximal focal femoral deficiency (PFFD)

Consultation Comments table

IPAC date: 12th February 2009

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
				Please respond to all comments
1	Consultee 1 NHS Professional Specialist Adviser	1	<p>I do not believe that there is any need to inform the clinical governance leads in the Trust. Item 1.3 stating that this procedure should only be carried out in units specialising in limb reconstruction is entirely reasonable and I believe is what is currently undertaken anyway due to the rarity and complexity of the condition. The "super hip" is an evolution of current practice but does not constitute a new procedure requiring additional safeguards.</p> <p>[REDACTED]</p> <p>(The consultees' comments have been blacked out because they relate to confidential discussions held in Part 2 of the Committee meeting.)</p>	<p>Thank you for your comment. This is a standard recommendation in NICE's Interventional Procedures guidance when the committee considers that there is insufficient evidence to support the routine use of a procedure. The Health Service Circular that was issued to support the establishment of the Interventional Procedures Programme (HSC2003/011) refers to the requirement to involve clinical governance leads when new procedures, or those that are of uncertain safety or efficacy are carried out. The scope for this procedure was developed in order to describe a generic group of techniques for treating PFFD of which "superhip" represents one element.</p>

Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
				Please respond to all comments
2	Consultee 2 NHS Professional	1	It would be helpful to add the terminology Congenital Femoral Deficiency which is the preferred description and suggested by Dr Dror Paley, leader in this field. I also think that it is helpful to suggest that 2 or more surgeons are directly involved with the surgery owing to the complexity.	Thank you for your comment. The term PFFD is defined in section 2.1.1 of the guidance as follows: 'Proximal focal femoral deficiency is a congenital syndrome'. Section 1.3 of the guidance states 'the procedure should only be carried out in units which specialise in limb reconstruction'.
3	Consultee 3 NHS Professional	1	When ██████████ submitted this as a new procedure he was referring to the specific procedure described by Dror Paley which involves multiple steps using a mix of well used and new techniques (eg using BMP). Surgery for PFFD has been done in various formats since it was defined. Techniques such as the pelvic support procedure (an old idea adapted by Dror Paley) are done routinely in many specialist units not only for PFFD but also other conditions. It would be extreme to imply use of these techniques requires special permission when it is only a small number of elements of the procedure as advocated by Dror Paley which need scrutiny. <i>(The consultee's reference to the name of the notifier has been blacked out because it is not in the public domain).</i>	Thank you for your comment. The scope for this procedure was developed in order to describe a generic group of techniques for treating PFFD of which "superhip" represents one element.
4	Consultee 2 NHS Professional	2.1	It would be helpful to issue guidance in broad terms on the ages of treatment. Â Soft tissue surgery and deformity is corrected initially at approximately age 2-4 with subsequent lengthening procedures later in childhood.	Thank you for your comment. The guidance is aimed at this specific treatment: overall treatment and management of PFFD, including the timings of interventions, falls outside the scope of the guidance.

Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
				Please respond to all comments
5	Consultee 3 NHS Professional	2.1	The Van Ness procedure may also be used in some cases where amputation is unacceptable.	Thank you for your comment. The Van Ness procedure as a standalone intervention falls outside the scope of this guidance
6	Consultee 3 NHS Professional	2.2	Parts of these procedures are regularly done in various combinations by specialised paediatric orthopaedic surgeons for other conditions affecting the upper femur as well as for PFFD. Tertiary centres may see more cases than [REDACTED] and have more experience, so what is a new procedure for his hospital does not necessarily apply country-wide. <i>(The consultee's reference to the name of the notifier has been blacked out because it is not in the public domain.)</i>	Thank you for your comment. Section 1.3 of the guidance states that 'The procedure should only be carried out in units which specialise in limb reconstruction, by surgeons with specialist knowledge of neonatal dysplasias and expertise in limb lengthening procedures.'
7	Consultee 3 NHS Professional	2.3	Efficacy is almost impossible to determine for PFFD which is rare and very variable in presentation. You will never get a large enough series to make any useful comment on outcome. What is done is to treat each patients individual problem using well tried and tested techniques in various combinations. Complications are routine (as for many procedures such as limb lengthening) but an improved outcome is usual. The techniques are used for other upper femoral problems as well. They should be done by someone familiar with them.	Thank you for your comment. The committee recognised that the evidence is based on a small patient population. Section 1.3 of the guidance requires that the procedure should only be carried out in units which specialise in limb reconstruction, by surgeons with specialist knowledge of neonatal dysplasias and expertise in limb lengthening procedures

Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
8	Consultee 3 NHS Professional	2.4	These are routine complications for any limb lengthening procedure and not specific to PFD. Knee dislocation is also known, because of deficient knee ligaments in many congenital lower limb conditions. Audit of such a rare condition will be impossible and valueless in the face of the widely differing clinical presentations. Patients need the best personalised treatment in a unit which regularly uses all these techniques for conditions other than PFFD as well as for this problem.	Thank you for your comment. Section 1.3 of the guidance states that this procedure should only be carried out in units which specialise in limb reconstruction, by surgeons with specialist knowledge of neonatal dysplasias and expertise in limb lengthening procedures. Audit criteria for this procedure have been prepared by NICE with input from Specialist Advisers, and are based on the outcomes they considered important in relation to the procedure.
9	Consultee 2 NHS Professional	General	I would recommend adding that the surgery should involve 2 or more surgeons directly, owing to the complexity of the operations performed. For interest I work in a unit that performs leg lengthening and treats cases of CFD.	Thank you for your comment. The term PFFD is defined in section 2.1.1 of the guidance as follows: 'Proximal focal femoral deficiency is a congenital syndrome'. Section 1.3 of the guidance states 'the procedure should only be carried out in units which specialise in limb reconstruction'.

Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.