National Institute for Health and Care Excellence

IP358/2 Intramedullary distraction for lower limb lengthening

IPAC date: 9 December 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 5 NHS professional	**General**	There is now plenty of evidence on safe IM lengthening in adults and children- the technique has been improved vastly over the last 10 years and has made a dramatic difference to patients, families and their experience of limb lengthening and deformity correction.	Thank you for your comments.
2	Consultee 5 NHS professional	**Overall comments**	Much of the data cited is obsolete. Comparison between ISKD and External Fixators is no longer useful. There is lots of evidence on comparison of Circular versus mono-lateral external fixators There is little good outcome and patient satisfaction work available as well as poor up to date information on patient function including range of motion etc This needs to be a focussed recommendation and funding for this needs to be recommended. I can make further comment if required especially regarding data security versus national data collection.	Thank you for your comments. IP considers efficacy and safety of a procedure and not comparative effectiveness. Page 39 of the overview states that 2 devices are no longer available. The overview of evidence does not include any studies comparing ISKD with external fixators. Comparison of circular versus mono-lateral external fixators falls outside the scope of the guidance. NICE does not have a remit to recommend funding for a procedure.

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3	Consultee 6 British Limb Reconstruction Society (BLRS) President	**General**	The BRITISH LIMB RECONSTRUCTION SOCIETY (BLRS) is a Charitable Incorporated Organization and affiliated to the British Orthopaedic Association (BOA) as a subspeciality association. The aims of the BLRS are: • Advancing limb reconstruction services in the NHS through research, audit, training, and education. • Promoting limb reconstruction techniques to all Orthopaedic and Plastic Surgical trainees, Limb Reconstruction Surgeons (LRSs) and Allied Health Professionals (AHPs) in the United Kingdom. • Raising awareness of new techniques in the treatment of patients of all ages with complex limb problems including children with congenital limb deformities and deficiencies, bone infections, limb shortening and deformities, non-healing fractures etc.	Thank you for your comments and sharing briefly about the aims of BLRS.
4	Consultee 6 British Limb Reconstruction Society (BLRS)	**General**	The BLRS has over 150 surgeon members and our members provide limb reconstruction treatments across the NHS in England, Wales, Scotland, and Northern Ireland. They use various techniques to lengthen a limb including intramedullary (IM) lengthening devices. Over 90% of such procedures in UK are carried out by our members. They have presented and published papers on Intramedullary Lengthening Devices including a landmark paper on a retrieval study (Hothi, Bergiers et al. 2021). They have also brought this to the attention of MHRA prompting them to issue field notice and withdraw two of the most popular devices from use in 2020 until further investigations were completed.	Thank you for your comments. The paper by Hothi 2021 found in our update search is included in the appendix in the overview. Evidence on STRYDE nails published recently has been added to the overview.

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			We understand that NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure. However, we were surprised to note that BLRS, a society that provides such service, was not asked to be part of this important process. Furthermore, the request to provide comments on NICE's provisional recommendations was sent to the BOA and with a very short deadline. The time pressure is unhelpful and will likely result in an incomplete survey of the of members of the BLRS, the organisation most closely involved in these procedures. However, we immediately sent the relevant link to our members not only to provide feedback directly to NICE but also to the BLRS on two specific areas as follows: I. *At 1.3 Healthcare organisations should: Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.* II. *At 3.4 bullet point 4 - this procedure is only for use in people who have limb length discrepancy and not for overall height gain*. I am pleased to say that many of our members have been able to respond. I summarise the following paragraphs, and I am confident that this will appear in individual feedback. References: Hothi, H., S. Bergiers, J. Henckel, A. D. Iliadis, W. D. Goodier, J. Wright, J. Skinner, P. Calder and A. J. Hart (2021). "Analysis of retrieved STRYDE nails." Bone & Joint Open 2(8): 599-610.	When IPAC considered the evidence, the committee took advice from a professional expert. BLRS, BOA, and BSCOS were the 3 professional societies that NICE consulted for this procedure. Through your comments we now understand that our email alert to consultation and request to provide comments on provisional recommendations was not received by BLRS. We have verified and noted that this was sent to the past president of BLRS. Our programme team will seek to update contact info for the BLRS to a generic email, so this does not happen in the future. We apologize for the inconvenience and short deadline but appreciate all the efforts taken by BLRS to provide feedback on this draft guidance. We thank all the members who have also provided individual feedback.

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5	Consultee 3 NHS professional	**1**	Agree that robust mechanisms for clinical governance, consent and audit or research should be in place at hospitals that perform these procedures. Hospitals/surgeons providing this treatment should also establish a multidisciplinary team to assess, discuss and support patient pathway.	Thank you for your comments. IPAC considered and added a recommendation in section 1 of the guidance about multidisciplinary team (MDT) involvement in providing this treatment.
6	Consultee 3 NHS professional	**1.2**	Agree	Thank you for your comments.
7	Consultee 3 NHS professional	**1.3**	This effectively means that the healthcare organisations or wider NHS should have a registry of these procedures similar to the National Joint Registry (NJR). Currently there is no such mechanisms or arrangements in place because lack of funding to support and run it. Perhaps industry can contribute towards setting up such a registry but the ownership of data should be with healthcare organisation and not the industry to avoid misuse of data.	Thank you for your comments. There is no registry available that NICE could recommend for this procedure. IPAC considered your views and amended 1.7 to state that further research could be registry data. A committee comment about the importance of a registry was added to section 3.7.
8	Consultee 4 NHS professional	**1.3**	agree at a local level with annual presentations to rest of department. National database previously attempted and had an epic and costly fail for different reasons.	Thank you for your comments. See response above
9	Consultee 6 President, BLRS	**1.3**	Draft recommendation 1.3 – how health care organizations can ensure collection of data on outcomes. Respondents agreed that data collection is essential for patient safety, quality control, and research. However, there is concern about how this can be achieved. A National Registry of IM lengtheners is by far the preferred and the best way to achieve it. Many examples of Registries exist internationally and with proven benefit. The BLRS has previously tried to establish a Registry but failed because of the cost and	Thank you for your comments. See response above. IPAC considered and added a recommendation in section 1 of the guidance about multidisciplinary team (MDT) involvement in providing this treatment.

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			legal implications of so doing. The BLRS will be very keen to support a registry but cannot fund it. The BLRS strongly advises that the NICE recommendations should include the minimum support system for the service, including dedicated clinical nurse specialists, physiotherapists, and mental health support. We have demonstrated that one third of patients undergoing limb reconstruction techniques will have active mental health difficulties requiring intervention(Rayner, Simpson et al. 2016). References: Rayner, L., A. Simpson, F. Matcham, S. Shetty, O. Lahoti, G. Groom and M. Hotopf (2016). "Mental disorder in limb reconstruction: Prevalence, associations and impact on work disability." Journal of psychosomatic research 89: 53-60.	
10	Consultee 3 NHS professional	**1.4**	Agree	Thank you for your comments.
11	Consultee 5 NHS professional	**1.4**	I would value some guidance from NICE or others on point 1.4 as a fair amount of this work is still being done by non-specialist surgeons and centres who then have increased complications and reduce the availability of the technique for other patients.	Thank you for your comments. The guidance states that *'this technically challenging procedure should only be done in specialist centres by surgeons with training and specific experience in limb lengthening techniques'*.
12	Consultee 4 NHS professional	**1.4**	Absolutely. Lots of surgeons can do femoral nails but only surgeons who are familiar with distraction osteogenesis and lengthening should do this.	Thank you for your comments. The guidance states that *'this technically challenging procedure should only be done in specialist centres by surgeons with training and specific experience in limb lengthening techniques'*.

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13	Consultee 5 NHS professional	**1.5**	Agree - This works very well and one IM lengthening device is already under investigation by MHRA.	Thank you for your comments.
14	Consultee 3 NHS professional	**1.6**	Agree. A registry will help this research.	Thank you for your comments. There is no registry available that NICE could recommend for this procedure. IPAC considered your views and amended 1.7 to state that further research could be registry data. A committee comment about the importance of registry was added to section 3.7.
15	Consultee 5 NHS professional	**2.1**	There are also potential effects on hip, knee and back disorders in patients with significantly large enough discrepancies.	Thank you for your comments. IPAC considered your comments and slightly amended 2.1 to state that unequal leg length can have an effect on other joints.
16	Consultee 4 NHS professional	**2.1**	Not sure this statement is true. I have lengthened hundreds of patients and I would be surprised if congenital causes are more rare than acquired. Hemihypertrophy (primary long leg) is also not that rare and this group is very well suited to the Precice.	Thank you for your comments. See response above.
17	Consultee 3 NHS professional	**2.2**	It might be worth highlighting the 'threshold' for offering leg lengthening procedure in straight (non deformed) limbs - majority of surgeons offer a surgical procedure if the difference is above 2 cms for example. Less than 2 cm difference without any deformity of the affected limb can be safely managed with shoe elevation.	Thank you for your comments. IPAC considered your comment but did not add the threshold for offering leg lengthening procedures. However, the text in 2.2 has been amended to highlight the key problems with external frames.
18	Consultee 3	**2.2**	This comment gives the impression that the IM lengthening is free of pain, hip and knee subluxation,	Thank you for your comments.

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	NHS professional		risk of infection. Obvious difference between the two procedures is the external frame and pin site issues (infection is generally decreasing since the introduction of hydroxyappetite coated pins) - that are common in the femoral lengthening frames and not so much in tibial lengthening. This is the main reason for switching to an intramedullary nail for the femur mainly and to some extent for the tibia. It is worth highlighting the risks properly - the main advantage of IM lengthener is that there is no external frame and pins that need care. Pain, stiffness of adjacent joints, inadequate/poor bone healing and need for further surgery is equally a risk with IM lengtheners. It is not 'OFTEN' that the bone is augmented by either an internal plate fixation or an intramedullary nail after an external fixation.	IPAC considered your comments and amended 2.2 to highlight the key problems with external frames and removed the word 'often' in the last sentence.
19	Consultee 5 NHS professional	**2.2**	This should make it clear that this works after an osteotomy is made. Also the vast majority do not, or should not need secondary stabilisation with a plate or IM Nail if done correctly unless there is an underlying bone pathology.	Thank you for your comments. IPAC considered your comment and amended 2.2 to state that it is done after an osteotomy and removed the word 'often' in the last sentence.
20	Consultee 4 NHS professional	**2.2**	Hip and knee dislocation is just as possible with a nail as it is with a frame if you are not careful."	Thank you for your comments. IPAC considered your comments and amended 2.2 to highlight the key problems with external frames and removed the text about hip and knee sublaxation.
21	Consultee 3 NHS professional	**2.3**	This is incorrect - IM distraction systems are NOT USED IN MANAGING FRACTURES. They are sometimes used in fracture nonunion cases and in bone defects due to a fracture - so called transport nails/plates. Main use of intramedullary lengtheners is in lengthening a fully formed bone.	Thank you for your comments. IPAC considered your comment and amended 2.3 (removed text that it is used for managing fractures).

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22	Consultee 5 NHS professional	**2.3**	This is totally inaccurate- IM Distraction systems are used to correct limb length discrepancy. They CAN be used in trauma but are not primarily used in managing fractures.	Thank you for your comments. IPAC considered your comment and amended 2.3 (removed text that it is used for managing fractures).
23	Consultee 1 NHS professional	**2.3**	I have not encountered intra medullary distraction systems being used for managing fractures. I have used them for managing ununited femoral fractures but this work is being prepared for publication and I will not rely upon it until it has been peer-reviewed.	Thank you for your comments. IPAC considered your comment and amended 2.3 (removed text that it is used for managing fractures).
24	Consultee 3 NHS professional	**2.4**	Agree	Thank you for your comments.
25	Consultee 1 NHS professional	**2.4**	These devices are generally used for distraction, not compression. They do not generally allow bony alignment at the osteotomy site. Alignment must be achieved as or before the nail is inserted.	Thank you for your comments. IPAC considered your comment and slightly amended 2.4 (removed text about compression and bony alignment).
26	Consultee 3 NHS professional	**2.5**	Agree	Thank you for your comments.
27	Consultee 5 NHS professional	**2.5**	The only two IM Lengthening devices on the market now use Non Invasive remote lengthening - one using an Electromagnetic driver and one using an RF antenna to a motor. The mechanical device mentioned has been withdrawn from the market due to safety concerns,	Thank you for your comments. IPAC considered your comment and amended 2.5 (removed the last 2 sentences about how they work).
28	Consultee 3 NHS professional	**2.6**	Agree	Thank you for your comments.
29	Consultee 1 NHS professional	**2.6**	It is certainly true that the device is usually removed but this section reads to me as though the recommendation is that the device may be removed	Thank you for your comments.

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			"when there is radiological evidence of adequate bone consolidation". This form of words may be misleading. The normal guidance for removal of intra medullary nails is approximately two years from insertion. The same guidance should apply to the removal of intra medullary distractors as there is significant risk of deformity or refracture associated with premature metalwork removal.	IPAC considered your comment and amended text in 2.6 (about weight bearing and removal of device).
30	Consultee 3 NHS professional	**3**	I have looked at the evidence base and more recent important papers that deal with the adverse events with one very popular IM lengthening system are not included and they are 1. Frommer A, Roedl R, Gosheger G, Hasselmann J, Fuest C, Toporowski G, et al. Focal osteolysis and corrosion at the junction of Precice Stryde intramedullary lengthening device. Bone & Joint Research. 2021;10(7):425-36. 2. Panagiotopoulou VC, Davda K, Hothi HS, Henckel J, Cerquiglini A, Goodier WD, et al. A retrieval analysis of the Precice intramedullary limb lengthening system. Bone & Joint Research. 2018;7(7):476-84. 3. Rölfing JD, Kold S, Nygaard T, Mikuzis M, Brix M, Faergemann C, et al. Pain, osteolysis, and periosteal reaction are associated with the STRYDE limb lengthening nail: a nationwide cross-sectional study. Acta Orthopaedica. 2021;92(4):479-84.	Thank you for your comments. 2 studies (Panagiotopoulou 2018, Frommer 2021) found in update searches are included in the appendix in the overview. 1 study (Rolfing 2021) found in update searches is included in the summary of evidence section in the overview.
31	Consultee 3 NHS professional	**3.4**	Limb lengthening for stature correction/overall height gain is a controversial issue and needs clarification. I have come across patients who are psychologically severely affected because of constitutional short stature (and not syndromic) and it leaves clinician in a 'moral' dilemma. These procedures are not only expensive but also have serious risks as highlighted elsewhere in this document. Some guidance on	Thank you for your comments. IPAC considered and added a committee comment in section 3.6 about the use of this procedure for people with short stature. IPAC considered and also added a recommendation in section 1 of the guidance

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			whether NICE would allow the use of such procedures for stature correction in exceptional cases - subject to multidisciplinary discussion including psychiatrist's input, would be welcome.	about multidisciplinary team (MDT) involvement in providing this treatment.
32	Consultee 6 President, BLRS	**3.4**	Draft recommendation 3.4 bullet point 4, NICE guidance restricts the use of this device to people who have leg length discrepancy. Although this patient population forms a major indication for IM lengthening, it omits a small but significant minority of patients who are psychologically and functionally severely affected by short stature. The Society feels that there is a genuine need to support such patients and NICE recommendations should include a pathway to assess and offer this procedure to such patients. The risk of not doing so will drive this group of patients to seek private treatment in UK at enormous cost and our members have seen some disastrous outcomes requiring lengthy and complex treatment on the NHS. Some patients have gone abroad to have such treatment and ended up in the NHS after returning with either incomplete treatment or with complications. The BLRS will assist in drafting a protocol. Use of IM distraction devices in children is another controversial area that is not adequately covered in this consultation. The specific issues are indications, ideal age, inclusion, and exclusion criteria for the use of IM distraction of lower limbs in children. The BLRS and BSCOS (British Society for Children's Orthopaedic Surgery) will be able to assist.	Thank you for your comments. IPAC considered and added a committee comment in section 3.6 about the use of this procedure for people with short stature. IPAC considered and added a recommendation in section 1 of the guidance about multidisciplinary team (MDT) involvement in providing this treatment. Bullet point in 3.4 which restricts the use of this procedure for certain people (overall height gain) has been removed. The systematic review by Young (2017) included 3 studies with children who had correction of lower or upper limb deformities with Precice IM limb lengthening system. The guidance covers lower limb lengthening in adults and children and all the evidence for children has been considered in this overview. Studies not included in the summary of evidence in the overview are listed in the appendix. BSCOS (British Society for Children's Orthopaedic Surgery) is one of the professional societies that IP team has consulted on this draft guidance. Unfortunately, we had no response from them.
33	Consultee 1 NHS professional	**3.4**	I am broadly in agreement with the committee comments except that there is a small minority of patients for whom there are pressing psychological	Thank you for your comments.

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			needs for seeking some height gain. There should be, in my opinion, a pathway for these patients to have some hope of NHS treatment. At present, they are obliged to seek private treatment at very large expense. Our unit already has a very close association with the Institute of psychiatry. All our patients are screened through the IMPARTS and those are exhibiting psychological or psychiatric symptoms are referred for early intervention. This system could readily be adapted for that very small group patients for whom height gain is extremely important. I have yet to undertake a limb lengthening procedure for height gain but, from time to time I encounter patients who have good justification for seeking it. At present they are vulnerable to unscrupulous (and I use the word advisedly) private practitioners. I would like to see them offered the protection of proper screening and advice.	IPAC considered and amended bullet point 4 in section 3.4. IPAC considered and added a recommendation in section 1 of the guidance about multidisciplinary team (MDT) involvement in providing this treatment.
34	Consultee 2 NHS professional	**3.4**	While the device is used for discrepancy in the majority of patients, I would suggest that there is a small group in whom height gain may be appropriate. Significant short stature (e.g. achondroplasia, although other causes exist) with clear functional limitations might be a reasonable consideration. There would have to be a "target height" in order to overcome the specific limitation. I wouldn't suggest this for purely cosmetic reasons.	Thank you for your comments. IPAC considered and added a committee comment in section 3.6 about the use of this procedure for people with short stature. IPAC considered and added a recommendation in section 1 of the guidance about multidisciplinary team (MDT) involvement in providing this treatment.
35	Consultee 4 NHS professional	**3.4**	I think it is a bit harsh to ban for overall height gain - this type of procedure if carried out carefully and appropriately after a proper psychological evaulation	Thank you for your comments. IPAC considered and amended bullet point 4 in section 3.4.

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			can be massively life-changing for selected patients of shorty stature.	IPAC considered and added a recommendation in section 1 of the guidance about multidisciplinary team (MDT) involvement in providing this treatment.

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