NHS England and NHS Improvement: Equality and Health Inequalities Impact Assessment (EHIA)

A completed copy of this form must be provided to the decision-makers in relation to your proposal. The decision-makers must consider the results of this assessment when they make their decision about your proposal.

1. Name of the proposal (policy, proposition, programme, proposal or initiative): Direct Skeletal Fixation for transfemoral limb loss [URN 2206]

2. Brief summary of the proposal in a few sentences

This clinical commissioning policy outlines the commissioning criteria for the use of direct skeletal fixation, a type of osseointegration. This intervention is for patients with transfemoral amputation (TFA) or congenital limb deficiency, who are unable to tolerate the first-line device which is a conventional socket prosthesis. This treatment is a two-step procedure and aims to promote active participation, inclusion, and enablement.

The policy was developed through conducting an externally conducted evidence review and by a Policy Working Group (PWG) consisting of orthopaedic surgeons, rehabilitation and prosthetic experts, a public health specialist and specialist commissioner for NHS England. This policy recommends a process of assessment and evaluation in which the user's amputation and functional need have been considered, after which this surgery may be available for patients who meet specific criteria.

3. Main potential positive or adverse impact of the proposal for protected characteristic groups summarised

Please briefly summarise the main potential impact (positive or negative) on people with the nine protected characteristics (as listed below). Please state **N/A if your proposal will not impact adversely or positively on the protected characteristic groups listed below. Please note that these groups may also experience health inequalities.**

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Age: older people; middle years; early years; children and young people.	This intervention is contraindicated in children due to a lack of skeletal maturity, because insertion of the implant into the femur when the bone is not fully mature can cause disruption of the growth plate. Among patients with TFA due to trauma, the average age is under 50 years, and these patients are disproportionately affected by conditions such as cardiovascular disease caused by reduced mobility if they are unable to use conventional sockets.	Patient selection should be carried out by a multidisciplinary team (MDT), including a surgeon experienced in amputation and bone and soft tissue reconstruction as well as rehabilitation specialists, with expertise in prosthetics and implant design. The policy requires patients to undergo a full assessment before proceeding to surgery. This will allow patients, their families, and the MDT to determine the benefits, risks and challenges this procedure may hold. Patients should be assessed at least annually by MDT including clinical examination, physiotherapy assessment, radiographic assessment, and assessment of activity level. This policy, if agreed and published, will be reviewed at a future specified date to consider the results of longer-term outcomes from ongoing clinical trials to ensure the commissioning criteria reflect the most up to date evidence base.

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
Disability: physical, sensory and learning impairment; mental health condition; long-term conditions.	Patients with TFA or congenital limb loss who are unable to use a conventional socket may be unable to ambulate without crutches and may be wheelchair bound. This intervention can allow these patients to ambulate and thus has potential to significantly decrease physical disabilities. Depending on the cause of TFA or congenital loss, some individuals with this condition may have other complex or long-term health conditions including more widespread limb loss or other physical, sensory, or learning needs. Many people who've had an amputation report emotion such as grief and bereavement, and amputations as a result of trauma are associated with an increased risk of developing post-traumatic stress disorder (PTSD).	Friction between the residual limb and socket can cause pain and skin breakdown, and for the patients who experience these complications the current alternative is the use of mobility aids such as crutches or a wheelchair. This can lead to, or make worse, pre-existing conditions. Direct skeletal fixation (DSF), also known as osseointegration, replaces the need for an amputee to wear a socket upon which normally a prosthesis would be attached.
Gender Reassignment and/or people who identify as Transgender	There should be no direct negative or positive impact on this group as it has not been identified as a high-risk group.	Not Applicable
Marriage & Civil Partnership: people married or in a civil partnership.	There should be no direct negative or positive impact on this group as it has not been identified as a high-risk group.	Not Applicable
Pregnancy and Maternity: women before and after childbirth and who are breastfeeding.	The functional requirements of individuals who are pregnant, breastfeeding or postpartum may	MDT and rehabilitation specialists identify patients' suitability for DSF and it is recommended that the MDT work with the patient to consider their unique

Protected characteristic groups	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	change, requiring a reassessment of the prosthetic choice. Surgical risk may also be impacted by pregnancy status.	functional needs and clinical and anatomical factors.
Race and ethnicity[1]	There should be no direct negative or positive impact on this group as it has not been identified as a high-risk group.	Not applicable
Religion and belief: people with different religions/faiths or beliefs, or none.	There should be no direct negative or positive impact on this group as it has not been identified as a high-risk group.	Not applicable
Sex: men; women	In the majority of included studies, over half of the population were male. A contributing factor may be that trauma is a key cause for amputation.	The policy is inclusive of all individuals irrespective of gender, if they meet the inclusion criteria.
Sexual orientation: Lesbian; Gay; Bisexual; Heterosexual.	There should be no direct negative or positive impact on this group as it has not been identified as a high-risk group.	Not applicable

4. Main potential positive or adverse impact for people who experience health inequalities summarised

[1] Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity includes people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

Please briefly summarise the main potential impact (positive or negative) on people at particular risk of health inequalities (as listed below). Please state **N/A if your proposal will not impact on patients who experience health inequalities.**

Groups who face health inequalities[2]	**Summary explanation of the main potential positive or adverse impact of your proposal**	**Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact**
Looked after children and young people	There should be no impact upon this group as the intervention is contraindicated in children due to a lack of skeletal maturity.	Not applicable
Carers of patients: unpaid, family members.	Carers may be indirectly affected by this policy. It could positively reduce the burden on carers as individuals may be able to complete a greater number of tasks independently including activities of daily living. By improving an individual's active participation, the intervention can reduce the assistance required by those who support patients with work, family and personal tasks. The rehabilitation process requires an extensive series of appointments, which may require ongoing carer support to facilitate these sessions.	The policy recommends that the suitability of DSF as an intervention be assessed by the MDT team. This includes considering the support and care mechanisms a patient would require undergoing the intervention. If this policy is adopted, a commissioning plan will set out the pathway of provision which will include access at appropriately staffed centres.
Homeless people. People on the street; staying temporarily with friends /family; in hostels or B&Bs.	This group may be less likely to enter the patient pathway, due to access issues (e.g., if not registered with a General Practitioner).	The policy will enable access for anyone who meets the inclusion criteria to benefit from the prosthetic intervention. Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local

[2] Please note many groups who share protected characteristics have also been identified as facing health inequalities.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	The lack of a permanent base for which follow-up and/or rehabilitation appointments could be co-ordinated may be challenging in this cohort of patients. If identified, those who are homeless could be at risk of adverse outcomes, due to lack of access to services, incomplete follow-up as well as environmental conditions which may exposure individuals to infection, which is a serious risk highlighted in the literature due to the transcutaneous nature of implant.	Authority, charities) to mitigate risk for homeless patients.
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	All patients who met the inclusion criteria would be considered for treatment. This group is not identified at high risk.	Not applicable
People with addictions and/or substance misuse issues	All patients who met the inclusion criteria would be considered for treatment. This group is not identified at high risk.	Not applicable
People or families on a low income	Currently there is inequity in access because some patients with lower limb loss who cannot tolerate sockets are opting for DSF privately. This may not be a viable option for patients and families on low incomes.	The policy will increase the number of individuals who can access DSF and enable access for anyone who meets the inclusion criteria to benefit from the prosthetic intervention.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
People with poor literacy or health Literacy: (e.g. poor understanding of health services poor language skills).	This group can be negatively impacted in terms of access if poor literacy or health literacy impedes their ability to be aware of different treatment options. Language skills also affects amputees' ability to understand and follow the prosthetic instructions and report any issues if they arise.	Clinicians will need to ensure that patients are well informed when discussing and consenting for this procedure. Communication with those with poorer language skills or literacy can be through various mediums for example by adapting verbal communication style, using written shared decision-making tools, and accessing Easy Read materials. Access to translation services is also important. The provision of a prosthetic involves face-to-face assessment and verbal instruction, this can assist those with poor health or literacy skills.
People living in deprived areas		A national commissioning policy attempts to ensure there is equal access to treatment regardless of location, it will reduce variation in practice.
People living in remote, rural and island locations		A national commissioning policy attempts to ensure there is equal access to treatment regardless of location, it will reduce variation in practice.
Refugees, asylum seekers or those experiencing modern slavery	This group may be less likely to enter the patient pathway, due to access issues (e.g., if not registered with a General Practitioner). The lack of a permanent base for which follow-up and/or rehabilitation appointments could be co-ordinated may be challenging in this cohort of patients. This group could be further impacted if poor literacy or health literacy impedes their ability to be aware of different	The policy will enable access for anyone who meets the inclusion criteria to benefit from the prosthetic intervention. Commissioned providers should work with the patient and other relevant agencies (e.g. GP, Local Authority, charities) to mitigate risk for refugees and asylum seekers.

Groups who face health inequalities[2]	Summary explanation of the main potential positive or adverse impact of your proposal	Main recommendation from your proposal to reduce any key identified adverse impact or to increase the identified positive impact
	treatment options. Language skills may also negatively impact patients' ability to engage with appointments, assessments, rehabilitation processes and report any issues if they arise.	
Other groups experiencing health inequalities (please describe)	Military veterans and military personnel may be affected by traumatic amputations	Commissioned providers should work with the patient and other relevant agencies, in this case, agencies who look after military veterans and military personnel.

5. Engagement and consultation

a. Have any key engagement or consultative activities been undertaken that considered how to address equalities issues or reduce health inequalities? Please place an x in the appropriate box below.

Yes X	No	Do Not Know

b. If yes, please briefly list up the top 3 most important engagement or consultation activities undertaken, the main findings and when the engagement and consultative activities were undertaken.

Name of engagement and consultative activities undertaken		Summary note of the engagement or consultative activity undertaken	Month/Year
1	Stakeholder testing	There was a 2-week stakeholder engagement period with key stakeholders as per NHS England's standard methods.	**27th March 2023-14th April 2023**
2	Public Consultation	Not formally required.	

6. What key sources of evidence have informed your impact assessment and are there key gaps in the evidence?

Evidence Type	Key sources of available evidence	Key gaps in evidence
Published evidence	An external review of available clinical evidence was undertaken to inform this policy.	There was no evidence identified for cost effectiveness. The evidence review did not find evidence for subgroups of patients who may benefit more than others. The PWG acknowledge that further evidence may be difficult to generate given small patient numbers.
Consultation and involvement findings		n/a
Research	As above.	n/a
Participant or expert knowledge For example, expertise within the team or expertise drawn on external to your team	A PWG including rehabilitation specialists, orthopaedic surgeons and patients was assembled and contributed to this policy and impact assessment.	n/a

7. Is your assessment that your proposal will support compliance with the Public Sector Equality Duty? Please add an x to the relevant box below.

	Tackling discrimination	Advancing equality of opportunity	Fostering good relations
The proposal will support?		x	
The proposal may support?	x		
Uncertain whether the proposal will support?			x

8. Is your assessment that your proposal will support reducing health inequalities faced by patients? Please add an x to the relevant box below.

	Reducing inequalities in access to health care	Reducing inequalities in health outcomes

The proposal will support?		x
The proposal may support?		
Uncertain if the proposal will support?		

9. Outstanding key issues/questions that may require further consultation, research or additional evidence. Please list your top 3 in order of priority or state N/A

Key issue or question to be answered		Type of consultation, research or other evidence that would address the issue and/or answer the question
1		
2		
3		

10. Summary assessment of this EHIA findings

This assessment should summarise whether the findings are that this proposal will or will not make a contribution to advancing equality of opportunity and/or reducing health inequalities, if no impact is identified please summarise why below. The use of DSF in a small subsection of the amputee population (which in some cases overlaps with the veteran population) would allow patients to increase their ambulation and independence. The procedure negates the requirement for conventional sockets. This would reduce dependence, improve access to the workplace and improve employment opportunities, reduce isolation and improve mental health. The increased physical activity would help reduce obesity, BP, cholesterol, vascular and coronary artery disease. It would also reduce the risk of diabetes and metabolic syndrome. The use of DSF would also help with stimulating bone formation and reduce risk of osteoporosis.

11. Contact details re this EHIA

Team/Unit name:	Trauma Programme of Care
Division name:	Specialised commissioning
Directorate name:	CFO
Date EHIA agreed:	29/11/22
Date EHIA published if appropriate:	