Clinical Policy Engagement & Consultation Panel Minutes

Thursday 28 September 2023, 14.00-15.00
via Microsoft Teams

Present:

Name	Role
Steve Clark	Joint Partnerships and Involvement Manager, NHS Devon
Thandiwe Hara*	Non-executive director for citizen and community involvement, NHS Devon
Carol McCormack-Hole*	Lay Member from the Patient Engagement Forum
Rebecca Owen	Clinical Effectiveness Governance Manager, NHS Devon
Chris Roome	Head of Clinical Effectiveness, NHS Devon
Mark Taylor*	Lay Public Member, Clinical Policy Recommendation Committee

* Denotes voting members

1. Welcome and introductions

The group were welcomed and those attending to deputise today were introduced.

It was noted that Steve Clark was attending to deputise for Nicola Bonas on behalf of the Communications, Involvement and Inclusion team.

Apologies:

Name	Role
Nicola Bonas	Associate director of communications, involvement and inclusion, NHS Devon
Mac Merrett*	Lay Public Member, Clinical Policy Recommendation Committee
Martyn Nicoll	Patient Experience Manager, NHS Devon

2. Declarations of Interests

All those attending had previously completed a declaration of interests which has been recorded on the panel's register of interests.

No further interests pertinent to the items for discussion on the meeting agenda were declared.

3. Minutes of the meeting held on Thursday 20 July 2023 and matters/ actions arising

The panel considered the minutes from the meeting held on Thursday 20 July 2023 and agreed them to be an accurate record. There are no outstanding actions or matters arising to note.

4. Discussion and recommendation on the Clinical Policy Recommendation Committee (CPRC) decisions from 6 September 2023

Breast Implant Removal and Replacement

An overview of the Clinical Policy Recommendation Committee recommendation and the context within which it had arisen was noted by the panel.

Breast implants have a finite lifespan, and most will change in shape over time. In some cases, complications can develop for which removal of the implant is clinically indicated.

NHS Devon has an existing commissioning policy for breast implant removal and replacement which details the clinical indications for which implant removal is routinely commissioned in Devon. This long standing policy has been in place since 2012.

Review of this policy has been prompted by the publication of list 3 of the Evidence Based Interventions (EBI) guidance by the Academy of Medical Royal Colleges. This includes recommendations for the removal and replacement of breast implants which differ from the existing NHS Devon commissioning position.

The panel considered the public interest themes in relation to this policy:

1. **Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?**

   It was noted that review of NHS Devon's existing policy for breast implant removal and replacement has been prompted by the Academy of Medical Royal Colleges Evidence Based Interventions (EBI) guidance, which includes recommendations for the removal and replacement of breast implants.

   The Clinical Policy Recommendation Committee has subsequently recommended a revised policy which adopts the EBI recommendations, with the exception of the proposed definition for severe capsular contracture. Following consultation with local plastic surgery specialists it is proposed that the existing criteria in respect of capsular contracture are retained, i.e. to clarify that this is only commissioned when accompanied with associated pain, rather than for solely cosmetic issues.

3. **Have the effects of the policy on individual patients and carers been considered?**

   It was discussed that the NHS has a duty of care to patients where there is a clinical indication for removal of breast implants, irrespective of the reasons for the original surgery and whether this was NHS or privately funded.

However it is clarified in the policy that the NHS will only fund removal and also replacement of implants where the original procedure was undertaken by the NHS. In patients whose original procedure was undertaken privately and would not have been routinely provided under NHS criteria, only the removal is funded.

The revised policy was supported by local specialists following consultation and engagement. It adopts the EBI recommendations but retains the existing criteria in respect of capsular contracture to support implant removal being undertaken when there is associated pain, but not solely for cosmetic reasons.

It was noted that there is no longer a need to specifically include removal of Poly Implant Prothèse (PIP) implants within the policy and this is not included in EBI guidelines. This reflects that things have moved on since the existing policy position in terms of the evidence of the safety of these implants. The Medicines and Healthcare Products Regulatory Agency (MHRA) have since concluded that removal of intact PIP implants is no longer routinely needed as there is no evidence that they pose a greater safety risk than other implants.

The panel discussed situations where mental health issues are contributing to a patient's concerns regarding their appearance. It was clarified that it is standard NHS practice that if it is not a medical issue then the patient should be treated psychologically, not cosmetically. The policy does not specifically apply to psychological aspects; however patients would be eligible for support and NHS treatment to address mental health issues.

4. Have the wider consequences on society been considered?

It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

There is not expected to be an overall increase in the numbers of procedures performed in Devon or an impact on capacity from the revised policy. There could potentially be a possible reduction due to the explicit statement regarding associated pain, however this is already established clinical practice locally.

The panel raised some concerns about the potential increasing future costs to the NHS resulting from its duty of care to support patients where there is a medical need and cosmetic surgery becoming normalised, particularly as breast implants have a finite lifespan and will therefore always fail at some point.

Although the NHS will only fund removal, not replacement, of implants where the original procedure was undertaken privately it was questioned whether the NHS has any ability to recoup costs from private providers. There was concern about the increasing pressures on an already challenged NHS in terms of supporting patients to address medical issues following private cosmetic treatment. It was suggested that this concern and the question relating to cost recovery from the private sector could be raised with the finance team.

ACTION: Chris Roome to share the panel's discussion and question regarding cost recovery from the private sector with the finance team.

6. **Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?**

   The panel were not aware of any particular public concern in respect of breast implant removal and replacement.

   Updated safety reports from the MHRA have clarified that removal of intact PIP implants is no longer routinely needed as there is no evidence that they pose a greater safety risk than other implants.

7. **What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?**

   nhs.uk gives information on breast implants but does not give specific information on removal and replacement on the NHS. However it is advised that breast implants do not last a lifetime, and it is likely that they will need to be replaced at some point.

   Some women may need further surgery after about 10 years, either because of problems with the implants or because their breasts have changed around the implants.

   Breast implants can sometimes cause problems, including:

   - thick, obvious scarring
   - the breast feeling hard because scar tissue has shrunk around the implant (capsular contracture)
   - a ruptured implant – this may cause small tender lumps (siliconomas), which are only noticeable on breast scans; the implant will need to be removed
   - creases or folds in the implant
   - the implant rotating within the breast, resulting in an abnormal shape
   - rippling of the implant
   - nerve problems in the nipples
   - not being able to breastfeed or producing slightly less breast milk than you would without implants

   nhs.uk also notes that a type of breast implant, called PIP (Poly Implant Prothèses) implants, were withdrawn from the UK in 2010 after it was found they had been fraudulently manufactured with unapproved silicone gel, and were far more prone to splitting (rupturing) than other breast implants.

   Research has not found any evidence to suggest that PIP implants pose a serious health risk, but they can cause unpleasant symptoms if they rupture, and you may be anxious about leaving them in. If you have PIP implants, you should discuss with a surgeon whether they should be taken out. The implants do not necessarily need to be removed, but they should be taken out if they rupture or you are worried about this happening.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

Circumcision

An overview of the Clinical Policy Recommendation Committee recommendation and the context within which it had arisen was noted by the panel.

NHS Devon has an existing commissioning policy for circumcision which details the medical conditions for which circumcision is routinely commissioned in Devon. This policy has been in place since 2013.

Review of this policy has been prompted by the publication of list 3 of the Evidence Based Interventions (EBI) guidance by the Academy of Medical Royal Colleges. This includes recommendations which differ in some respects from the existing NHS Devon position, including recommendations for penile circumcision in patients under 16 years.

The panel considered the public interest themes in relation to this policy:

1. **Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?**

   It was noted that review of NHS Devon's existing policy for circumcision has been prompted by the Academy of Medical Royal Colleges Evidence Based Interventions (EBI) guidance, which includes recommendations on penile circumcision.

   The Clinical Policy Recommendation Committee has subsequently recommended a revised policy which recognises the EBI recommendations; however it includes revised local wording in some areas to provide greater clarity of the criteria whilst still reflecting the intention of the EBI recommendations.

3. **Have the effects of the policy on individual patients and carers been considered?**

   It was discussed that in forming the revised policy recommendation there had been consultation with local urology specialists, who are engaged with the Peninsula Urology Network. They suggested alternative wording in respect of some of the EBI recommendations to ensure clarity and reduce the risk of inappropriate local referral or surgical activity. This includes in respect of physiological phimosis to ensure a clear definition of persistent symptomatic cases, and a definitive criterion for circumcision to prevent UTI as the EBI wording was considered to be too vague.

   There is not anticipated to be a significant impact for patients as a result of the revised policy. The existing policy also already clarifies that circumcision is only undertaken based on medical need; not for cultural or religious reasons.

4. **Have the wider consequences on society been considered?**

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved and their parents/carers.

5. **Has the opportunity cost been considered?**

   It was discussed that the revised policy is not expected to result in an increase in circumcision activity. There are relatively lower numbers of circumcisions undertaken in Devon but there do not appear to be a significant number of requests

via the Individual Funding Request (IFR) Panel, suggesting this does not appear to be an issue.

6. **Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?**

   The panel were not aware of any particular public concern in respect of penile circumcision. It is already well-established that circumcision is only undertaken by the NHS based on medical need and not for cultural or religious reasons.

7. **What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?**

   nhs.uk notes that in boys it is rare for circumcision to be recommended for medical reasons because other less invasive and less risky treatments are usually available.

   It is normal for a baby boy's foreskin not to pull back (retract) for the first few years of life. Around the age of 3 – or later, in some cases – the foreskin should start to separate naturally from the head of the penis (glans). Full separation occurs in most boys by the age of 5 years. For some boys, the foreskin can take longer to separate, but this does not mean there is a problem, and it will usually just detach at a later stage.

   It is noted that the following conditions affect the penis and, in rare cases, may require a circumcision:

   - Tight foreskin (phimosis) – where the foreskin is too tight to be pulled back over the head of the penis. This can sometimes cause pain when the penis is erect and, in rare cases, passing urine may be difficult.
   - Recurrent infection (balanitis) – where the foreskin and head of the penis become inflamed and infected.
   - Paraphimosis – where the foreskin cannot be returned to its original position after being pulled back, causing the head of the penis to become swollen and painful. Immediate treatment is needed to avoid serious complications, such as restricted blood flow to the penis.
   - Balanitis xerotica obliterans – a condition that causes a tight foreskin and, in some cases, also affects the head of the penis, which can become scarred and inflamed.

In men, it is noted that circumcision is most commonly carried out when the foreskin is tight and won't retract, known as phimosis. But alternative treatments, such as topical steroids, are sometimes preferred.

Circumcision is sometimes considered a possible treatment option for:

- Tight foreskin (phimosis)
- Recurrent balanitis
- Paraphimosis
- Balanitis xerotica obliterans
- Cancer of the penis

In most cases, circumcision will only be recommended when other, less invasive, and less risky treatments have been tried and have not worked.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

5. Any other business

No other business was raised.

6. Next meeting date

It was advised that the next meeting will now be cancelled as the Clinical Policy Recommendation Committee meeting which was scheduled for November has been stood down.

The next panel meeting will therefore now be held on **Thursday 8 February 2024**.

Arrangements will be made to enable panel members to attend either face-to-face or to join via Microsoft Teams. These will be confirmed following the ICB's relocation from County Hall to their new office at Aperture House, Pynes Hill, Exeter in December 2023.

Summary of actions			
	Action	**Lead(s)**	**Status**
23/02	Share the panel's discussion and question regarding cost recovery from the private sector with the finance team.	Chris Roome	Pending