Clinical Policy Engagement & Consultation Panel Minutes

Thursday 25 May 2023, 14.00-15.30
A203, County Hall, Exeter and via Microsoft Teams

Present:

Name	Role
Steven 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
Mac Merrett*	Lay Public Member, Clinical Policy Recommendation Committee
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

Observers:

Name	Role
Matt Howard	Clinical Evidence Manager, NHS Devon

1. Welcome and introductions

The group were welcomed and those attending to deputise or observe 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 and Matt Howard was attending as an observer, as he will potentially be deputising for Chris Roome on behalf of the Clinical Effectiveness team at the next meeting.

Apologies:

Name	Role
Nicola Bonas	Associate director of communications, involvement and inclusion, NHS Devon
Martyn Nicoll	Patient Experience Manager, NHS Devon

2. Declarations of Interests

Those deputising today completed a declaration of interests prior to the meeting which will be 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 8 December 2022 and matters/ actions arising

The panel considered the minutes from the meeting held on Thursday 8 December 2022 and agreed them to be an accurate record. The action log was updated as follows:

Summary of actions			
	Action	**Lead(s)**	**Status**
22/07	Liaise with the primary care commissioning team with regard to difficulties in patient access to ear irrigation in primary care.	Nicola Bonas	Chris Roome reported that the primary care commissioning team and the Local Medical Committee (LMC) are currently looking at the service specification as part of the pre-contract negotiation. It was noted that a lot of the perceived issues are from primary hearing aid providers, with particular considerations around managing demand. Action closed.

4. Discussion and recommendation on the Clinical Policy Recommendation Committee (CPRC) decisions from 26 April 2023

High Intensity Focussed Ultrasound (HIFU) for recurrent prostate cancer

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

High Intensity Focussed Ultrasound (HIFU) is a thermal ablation technique. When used in the management of prostate cancer, probes are inserted into the prostate which emit a beam of ultrasound energy that is focussed to reach a high intensity in the targeted area. Absorption of this energy creates an increase in temperature, destroying the tissue.

NHS Devon has a commissioning policy for HIFU for prostate cancer currently in place, under which it is not routinely commissioned in Devon.

Review of this position, which has been in place since 2011, has been prompted by National Institute for Health and Care Excellence (NICE) guidance and becoming aware of the divergence of local specialist opinion on the use of HIFU.

NICE clinical guideline NG131 states that HIFU should only be used for localised and locally advanced prostate cancer as part of controlled clinical trials comparing its use with established interventions. However NICE have published Interventional Procedures Guidance (IPGs) which have conflicting recommendations. Engagement with local specialists also revealed that oncologists at University Hospitals Plymouth have been referring patients with localised prostate cancer recurrence to an out of area provider for HIFU treatment and wish to continue to do so.

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 the existing NHS Devon policy for HIFU for prostate cancer has been reviewed following consideration of the NICE guidelines on this procedure and in light of feedback from specialists at University Hospitals Plymouth who wish to offer this treatment to patients with localised prostate cancer recurrence through referral to an out of area provider.

   Following consideration, the Clinical Policy Recommendation Committee has proposed an updated policy which re-confirms the existing commissioning position that HIFU for recurrent prostate cancer is not accepted for routine commissioning in Devon. The Committee noted that evidence of effectiveness and adverse events for HIFU in patients with prostate cancer recurrence is extremely limited.

   The panel discussed the use of treatments without evidence, how these may be offered and what this means for patients. It was clarified that there is not a total absence of evidence; however there is a lack of comparative evidence of the standard required to support a broader population level decision on the use of this treatment in Devon. In terms of the evidence considered, the clinical policy development and review process is not limited to NHS or national evidence but looks at all internationally published literature on the treatment when conducting an evidence review.

   It was noted that HIFU is a long established technique, however the European Association of Urologists only recommend its use within the context of a clinical trial.

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

   It was discussed that the position not to routinely commission this treatment in Devon means that it would only be available to patients on an exceptional basis via the Individual Funding Request (IFR) process. Approval would be on the basis that the patient has clinical features which make them significantly different to and likely to gain more clinical benefit than might normally be expected from other patients with the same condition. Each case would be looked at on its individual merits.

   Alternative treatment options include salvage radical prostatectomy, salvage radiotherapy, salvage cryotherapy, or hormone therapy.

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?**

   It was discussed that the number of patients potentially be eligible for treatment with this intervention is small. HIFU and cryotherapy, which is another treatment option that was considered by the Clinical Policy Recommendation Committee at the same time, are competing interventions for the same cohort of patients, estimated to be a maximum of 12 per year.

   The panel reflected on whether there is likely to be an increase in IFR applications submitted from specialists at University Hospitals Plymouth given that they have been referring a small number of patients out of area for this treatment, despite the existing commissioning position. It was considered that numbers are still likely to be small and applications are unlikely to be submitted by specialists from Royal Devon University Hospitals as they indicated during consultation that they would not use this treatment. It was noted that Torbay and South Devon were also included in the consultation process; however the trust does not undertake this level of treatment.

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 treatment options for prostate cancer. Alternative treatment options include salvage radical prostatectomy, salvage radiotherapy, salvage cryotherapy, or hormone therapy.

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

   nhs.uk notes that treatment for prostate cancer will depend on your individual circumstances. For many people with prostate cancer, no treatment will be necessary. When treatment is necessary, the aim is to cure or control the disease, so it affects everyday life as little as possible and does not shorten life expectancy. Sometimes, if the cancer has already spread, the aim is not to cure it but to prolong life and delay symptoms.

   It states that HIFU is sometimes used to treat localised prostate cancer that has not spread beyond the prostate. HIFU treatment is still going through clinical trials for prostate cancer. In some cases, doctors can carry out HIFU treatment outside of clinical trials. However HIFU is not widely available, and its long-term effectiveness has not yet been conclusively proven.

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

Cryotherapy for recurrent prostate cancer

An overview of the Clinical Policy Recommendation Committee recommendation and the context within which it had arisen was noted by the panel. Cryotherapy and HIFU were both considered at the same as they represent competing treatment interventions for the same cohort of patients with recurrent prostate cancer.

Cryotherapy is a form of thermal ablation using electrodes to freeze cancer cells. Cryoprobes are inserted into the prostate through which argon gas is circulated, generating very low temperatures which freeze and destroy the surrounding tissue.

NHS Devon has an existing commissioning policy for cryotherapy for localised recurrent prostate cancer which states that it may be offered as an option where the consultant, patient and multidisciplinary team consider that this might better serve the patients interests than other options. The treatment must be provided from a specialist centre that will enter the patient into research or audit of this treatment with data collated at a regional or national level and has the appropriate governance procedures in place in line with NICE guidance to ensure patients are fully informed of the alternatives and the risks associated with the procedure.

Review of this position, which has been in place since 2011, has been prompted by an update to the NICE clinical guideline and consultation with providers which revealed differing opinions, and subsequent provision of cryotherapy, across Devon.

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 the existing NHS Devon policy for cryotherapy for localised recurrent prostate cancer has been reviewed following consideration of the updated NICE clinical guideline in this area and consultation with local specialists which revealed differing opinions, and the provision of cryotherapy, across Devon.

   Following consideration, the Clinical Policy Recommendation Committee has proposed an updated policy which states that cryotherapy for recurrent prostate cancer is not accepted for routine commissioning in Devon. The Committee noted that evidence of effectiveness and adverse events for cryotherapy in patients with prostate cancer recurrence is extremely limited. The European Association of Urologists only recommend its use within the context of a clinical trial.

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

   It was discussed that, unlike HIFU, the policy recommendation for cryotherapy represents a change from an existing positive policy position. However the committee had considered that the justification for both treatment options was the same and there was no reason to distinguish between these. Cryotherapy and HIFU are competing interventions for the same small cohort of patients. However in reality a greater proportion of these patients have received treatment with HIFU rather than cryotherapy due to the preferences of the specialist treating clinician.

   It was queried whether the outcomes of the clinical trial, for which patients are currently being recruited, are likely to have a bearing on the organisation's decision

on the availability of cryotherapy as a treatment option for patients in Devon. It was explained that this trial is non-comparative and as such there are doubts about how the findings will significantly change the situation. The relative importance of the different possible outcome measures was also recognised.

Alternative treatment options include salvage radical prostatectomy, salvage radiotherapy, salvage high intensity focussed ultrasound, or hormone therapy.

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?**

   It was discussed that the number of patients potentially eligible for treatment with this intervention is small. Cryotherapy and HIFU are competing interventions for the same cohort of patients, estimated to be a maximum of 12 per year.

   As with HIFU, the panel reflected on whether there is likely to be an increase in IFR applications submitted from specialists who were previously referring patients for this treatment. It was considered that numbers are still likely to be small, particularly as only one provider in Devon is currently offering referral for this treatment to a small number of patients.

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 treatment options for prostate cancer. Alternative treatment options include salvage radical prostatectomy, salvage radiotherapy, salvage high intensity focussed ultrasound, or hormone therapy.

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

   nhs.uk notes that treatment for prostate cancer will depend on your individual circumstances. For many people with prostate cancer, no treatment will be necessary. When treatment is necessary, the aim is to cure or control the disease, so it affects everyday life as little as possible and does not shorten life expectancy. Sometimes, if the cancer has already spread, the aim is not to cure it but to prolong life and delay symptoms.

   It states that cryotherapy is a method of killing cancer cells by freezing them. It's sometimes used to treat localised prostate cancer that has not spread beyond the prostate gland. Cryotherapy is still undergoing clinical trials for prostate cancer. In some cases, doctors can carry out cryotherapy treatment outside of clinical trials. However it is not widely available, and its long-term effectiveness has not yet been conclusively proven.

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

Focal hyperhidrosis

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

Hyperhidrosis refers to sweating in excess of normal body temperature regulation. The most common presentation of hyperhidrosis is focal (localised) and primary, i.e. not caused by an underlying condition.

NHS Devon has an existing policy for focal hyperhidrosis which is resembles the treatment pathway at the time it was published in 2013. Over time much of the treatment of hyperhidrosis has transitioned from specialist settings to primary care, prompting a review of the policy which is no longer considered reflective of current clinical practice.

Drug treatments for focal hyperhidrosis have been considered by the Devon Formulary Interface Group, with guidance and advice in the Devon Formulary to support their use without requiring referral to a specialist in a secondary care setting. The remaining aspects of treatment requiring inclusion within a revised commissioning policy represent the end of the pathway, i.e. treatments for patients with severe hyperhidrosis.

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 the existing NHS Devon policy for focal hyperhidrosis has been reviewed as this is no longer considered reflective of current clinical practice. Much of the treatment of hyperhidrosis has transitioned to primary care, with treatments offered in specialist settings reserved for those with severe hyperhidrosis.

   Following consideration, the Clinical Policy Recommendation Committee has recommended a revised policy which now focuses on the use of botulinum toxin A (botox) for the management of focal hyperhidrosis. Local specialists have proposed a slightly higher threshold for treatment, with botox only provided to those patients with severe hyperhidrosis, in line with the product license.

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

   It was discussed that much of the treatment of hyperhidrosis has moved to primary care, with most patients not needing referral to a specialist in a hospital setting.

   It was clarified that there are a number of treatments along the pathway for patients with hyperhidrosis, including lifestyle adjustments, self-care strategies and drug treatments. Referral to a specialist would only be required for patients with severe hyperhidrosis for whom these have not proved effective. Local specialists consider that those patients who do not meet the criteria for treatment with botox would have a disease severity that would appropriately respond to other treatments.

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?**

The proposed policy includes revised criteria for the treatment of hyperhidrosis with botox which ensure that this is only provided to those with severe hyperhidrosis, in line with the product license. Local specialists consider that patients who do not meet the criteria would have a disease severity that was appropriately responding to other treatments. Extensive advice on primary care management will now be included in the Devon Formulary.

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 the treatment of hyperhidrosis.

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

nhs.uk states that excessive sweating is common and can affect the whole body or just certain areas. Sometimes it gets better with age but there are things you can do and treatments that can help. You can buy things without a prescription, such as stronger antiperspirants instead of deodorant, armpit or sweat shields to protect your clothing, foot powders for sweaty feet and soap substitutes that are gentler on your skin.

In terms of treating severe excessive sweating, it advises that if there is no obvious cause, and nothing seems to be helping, then you may be referred to a specialist (dermatologist). They may recommend other treatments that you can try, such as taking tablets that reduce sweating, treating the areas with a weak electric current passed through water or on a wet pad (iontophoresis), having botox injections for sweating under the armpits (this may not be available on the NHS) and surgery – for example, removal of the sweat glands.

If your sweating is caused by another condition, any treatment you may need will depend on what's causing it.

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

5. Annual Report 2022-23

The panel received the annual report for 2022-23, which gives an account of the activity and governance of the panel in 2022-2023, from the period NHS Devon ICB was established on 1 July 2022.

The panel has continued, following the transition to the ICB, to support the organisation in determining the need for any further engagement or formal public consultation on recommendations made by the Clinical Policy Recommendation Committee. The wider public interest issues are considered to determine the need for any further engagement or formal public consultation. This process occurs prior to a final decision being taken by the ICB on any clinical policy recommendations.

The panel welcomed Thandi Hara and Martyn Nicoll as new members in July 2022.

Two panel meetings were held during the shorter than usual reporting period; however considering 10 clinical policy recommendations across a range of topics.

Some specific outputs arising from these discussions included:

a) When the Panel considered the proposed update to the Assisted Conception policy, the subjective nature of a 'stable' relationship was discussed, along with the appropriateness of a clinician making a moral judgement on this to determine eligibility to access assisted reproduction. It was a concern that the definition was open to interpretation, and therefore potential challenge.

   The ICB was asked to consider further engagement work on this, within the context of other non-clinical factors relating to the social nature of relationships, which are a growing area and are broader than clinical factors for infertility. The ICB took a decision to approve the policy amendment, noting that fertility specialists indicated that this was workable from their perspective and was consistent with the majority of other ICB areas. However the wider issues relating to non-clinical and societal factors were flagged with the communications team to scope and consider how future engagement and/or consultation might be undertaken in this area.

b) Consideration of the updated policy for Continuous Glucose Monitoring highlighted the need for the previously produced clinical policy patient support information to be reviewed for ongoing relevance and updated as needed to support the publication and communication of any changes to commissioning policy.

ACTION: Annual Report to be reported onwards in the ICB for information and assurance.

There was discussion of the level of approach taken by the panel, and it was queried whether there was any reflection on its recommendations and outputs, i.e. any feedback, aspects which proved to have not been in line with expectations, etc.

It was commented that the clinical effectiveness team was not aware of any negative response to panel outputs. However there had been instances where clinical policy patient support information was positively received, reinforcing the recommendations of the panel. For example, feedback was received from clinicians that the supporting information outlining the differing glucose monitoring technologies had been a helpful resource when speaking with patients.

It was also discussed that the level of scrutiny of the public interest issues by the panel, as an integral step in the process for clinical policy development, supports the robustness of the overall process. This means that potentially controversial issues should have been flagged up and considered at a much earlier point in the process.

There are also measures in place to gauge the impact of a policy, for example increased contacts with the patient experience team or applications to the IFR panel.

Rebecca Owen and the Clinical Effectiveness team were thanked for their ongoing support to the panel members and in facilitating the smooth running of the group. In particular, the members were appreciative of the quality of the meeting papers which are felt to be easy to read and enable them to gain a good understanding of often complex topics.

6. Any other business

No other business was raised.

7. Next meeting date

The next meeting will be held on Thursday 20 July 2023 from 14.00 at County Hall, Exeter for those wishing to join face-to-face and also via Microsoft Teams.

Summary of actions			
	Action	**Lead(s)**	**Status**
23/01	Annual Report to be reported onwards in the ICB for information and assurance.	Rebecca Owen	Pending