Clinical Policy Engagement & Consultation Panel Minutes

Thursday 8 December 2022, 14.00-15.30
Via Microsoft Teams

Present:

Name	Role
Nicola Bonas	Associate director of communications, involvement and inclusion, 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
Grace McMahon	Clinical Effectiveness Support Officer, NHS Devon
Amy Rice	Clinical Effectiveness Pharmacist – Commissioning Projects Lead, NHS Devon

1. Welcome and introductions

The group were welcomed, including the observers from the Clinical Effectiveness team who were joining the panel meeting today.

Apologies:

Name	Role
Martyn Nicoll	Patient Experience Manager, NHS Devon

2. Declarations of Interests

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

3. Minutes of the meeting held on Monday 13 October 2022 and matters/actions arising

The panel considered the minutes from the meeting held on Monday 13 October 2022 and agreed them to be an accurate record. The action log was updated as follows:

Summary of actions			
	Action	**Lead(s)**	**Status**
22/03	Share the panel's recommendation that the ICB is asked to consider further engagement work around the requirement for a 'stable relationship', and to consider how other non-clinical factors in relation to the social nature of relationship will be addressed where they sit outside the clinical policy criteria.	Chris Roome/ Rebecca Owen	At ratification of the policy the broader issues re non-clinical factors were acknowledged and recognised. The policy amendment was approved without further engagement on the definition of a stable relationship because fertility specialists implementing this indicated that it is workable from their perspective, the policy position is in line with the majority of other ICB areas and the IFR process exists for patients who feel their relationship has been inappropriately judged. However the wider issues connected with non-clinical and societal factors were considered important for further work up of how future engagement and/or consultation might be undertaken. The communications team were asked to give some thought to this. Nicola Bonas will take this forward with some initial scoping and intelligence gathering, before clarifying the focus, scope and appropriate route for any future engagement activity in this area.
22/04	If, after due consideration of the complexities raised by the panel discussion, the ICB decide that further engagement would be beneficial before policy ratification the clinical effectiveness team should contact the local fertility centres. This would be to make them aware of the potential delay while this issue is considered further, and to seek clarification on what they perceive would be the consequences/impact of not having the proposed relationship criterion wording.	Chris Roome/ Rebecca Owen	
22/05	Review and update previously produced clinical policy patient support information on 'Glucose monitoring technology to help patients manage their diabetes' and 'Easy Read about Diabetes and FreeStyle Libre Sensors' to support the publication and communication of any changes to commissioning policy.	Chris Roome/ Rebecca Owen	The existing support information has been reviewed for ongoing relevance in light of the updated continuous glucose monitoring policy. As the eligibility criteria are now much wider and more straightforward it was felt that these leaflets are no longer required. Action complete.

22/06	Annual Report to be reported onwards in the ICB for information and assurance.	Rebecca Owen	Action complete.

4. Discussion and recommendation on the Clinical Policy Recommendation Committee (CPRC) decisions from 16 November 2022

Guanfacine for the management of attention deficit hyperactivity disorder (ADHD) in children and adolescents

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

ADHD is a behavioural syndrome characterised by the core symptoms of hyperactivity, impulsivity, and inattention. NHS Devon currently has a commissioning policy in place, published in 2016, which does not accept the routine commissioning of the drug guanfacine in Devon for the management of ADHD in children and adolescents.

This position has been reviewed following a request from local specialists to reconsider its use in light of updated National Institute for Health and Care Excellence (NICE) recommendations on the management of ADHD (NG87) since the original decision.

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 on guanfacine for the management of ADHD in children and adolescents has been reviewed following a request from local specialists to reconsider its routine use in Devon. This was in the context of an updated non-mandatory NICE guideline on the management of ADHD (NG87) which makes recommendations about the place of guanfacine in therapy for children and adolescents.

Following consideration, the Clinical Policy Recommendation Committee has proposed that the use of guanfacine is now accepted in Devon for the management of ADHD in children and adolescents aged 6 to 17 years where previous treatment with stimulants and previous treatment with atomoxetine, is ineffective, or not tolerated, or these treatments are not suitable. The committee recommended that guanfacine should only be used after previous treatment with atomoxetine to reflect the substantial cost difference between the two, with guanfacine considerably more expensive and considered to represent poor value for money in comparison to atomoxetine.

The period of time since the original policy decision was taken, and how the need for review of policies is identified and prioritised, was queried. It was discussed that this is responsive to a number of factors, including new evidence, national guidance, a changing context and requests from local specialists. In this instance it was noted that there is no new trial evidence and there remain uncertainties over cost effectiveness. However the context has changed with the updated NICE guideline and there has been some local use within a small cohort of patients which has been held within the provider trust.

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

   It was acknowledged that the proposed updated policy would allow for the routine use of guanfacine as an additional treatment option in Devon for the management of ADHD in children and adolescents where previous treatment with stimulants and atomoxetine has failed or is unsuitable. Guanfacine is anticipated to be used in a small number of patients in Devon, with atomoxetine and guanfacine representing only a minority of overall prescribing in ADHD.

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 noted that the proposed policy acknowledges the NICE guidance and makes guanfacine available in Devon as a treatment option for ADHD in children and adolescents; however its routine use is limited to instances where previous treatment with stimulants and atomoxetine has failed or is unsuitable.

   This decision was based on the significant cost of guanfacine compared to atomoxetine and that it is considered poor value for money in comparison. Its proposed place in therapy after other first line treatment options is anticipated to result in a low budget impact.

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 ADHD or the use of guanfacine as a treatment option in children and adolescents.

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

   nhs.uk notes that there are five types of medicine licensed for the treatment of ADHD; methylphenidate, lisdexamfetamine, dexamfetamine, atomoxetine and guanfacine. These medicines are not a permanent cure for ADHD but may help someone with the condition concentrate better, be less impulsive, feel calmer, and learn and practise new skills.

   It states that guanfacine acts on part of the brain to improve attention, and it also reduces blood pressure. It is usually taken as a tablet once a day, in the morning or evening, and may be offered to teenagers and children over the age of 5 if it is not possible to use methylphenidate or lisdexamfetamine. Guanfacine should not be offered to adults with ADHD.

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

Nefopam for the management of chronic pain

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

Nefopam is a non-opioid painkiller which is licensed in the UK for the relief of acute and chronic pain. It is an old drug which has been available for over 40 years; however it has never featured as a locally recommended treatment option in the Devon Formulary. Its routine use in Devon for the management of patients with chronic secondary pain has been considered following a request from local pain specialists.

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 routine use of nefopam for the management of chronic secondary pain had been considered following a request from local pain specialists.

   Following consideration, the Clinical Policy Recommendation Committee has proposed a policy which does not accept its routine use in Devon. The committee concluded that the evidence base to support the use of nefopam for chronic pain is extremely limited and of poor quality. NICE guidelines for the management of chronic primary pain and for chronic secondary pain conditions do not include any recommendations on the use of nefopam. Professional society guidelines either don't include nefopam or recommend against using it because of a lack of evidence.

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

   The proposed policy position clarifies that the routine use of nefopam is not accepted in Devon for patients with chronic pain. Although local clinicians requesting its use had suggested benefits for patients with chronic secondary pain with limited analgesic options, it was noted that the committee decision was based on the lack of evidence or professional guidelines to support its use. Adverse events following repeated use have not been evaluated in large scale or long-term studies. It was also noted that there was conflicting opinion among local specialists, with some actively discouraging its use as a treatment option for patients.

   The panel noted that nefopam is a non-opioid treatment and it was therefore discussed what the impact of not supporting its use would be for patients for whom opioid addiction was a concern. It was commented that, prior to consideration by the committee, nefopam has had a niche use in a small number of patients but it became apparent that there was concern from a local hospital that they were an outlier in terms of its use. With a policy in place, the Individual Funding Request (IFR) panel process would be the route for requests from clinicians for its use in individual patients to be assessed on an exceptional basis. It was clarified that this was felt to be an appropriate route given that the policy relates to the use of nefopam in chronic pain, not in acute pain (with patients experiencing the latter requiring more timely assessment and treatment to address their pain).

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 acknowledged that nefopam is not currently included within the Devon Formulary and the proposed policy position reinforces that its use is not accepted in Devon for the management of chronic pain.

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

   It was noted that chronic pain is common; however not all those experiencing chronic pain may need or wish for treatment. There was discussion about those for whom opioid addiction may be a concern. Devon Formulary guidance is that drugs for managing chronic pain should be prescribed in a step wise approach, increasing potency to sufficiently manage symptoms, and that this should be alongside the use of non-pharmacological interventions. A person's individual needs, preferences, priorities, and expectations of treatment should all be considered.

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

   nhs.uk gives support information on ways people can manage chronic pain and suggests an approach to reducing pain via a combination of exercise, staying at work, physical therapy and painkillers.

   Separate information is also given on nefopam, which is states is a painkiller available on prescription only. It treats moderate pain, for example after an operation or a serious injury, dental pain, joint pain and muscle pain, or pain from cancer. You can also take nefopam for other types of long-term pain when weaker painkillers no longer work.

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

Ear wax removal in secondary care

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

Impacted ear wax may result in impaired hearing and individuals may also complain of pain, and vertigo-like symptoms. Bothersome ear wax impactions are usually managed in primary care. However, in some circumstances, individuals may require management in secondary care.

Due to the way the referral system works some concerns had been raised of a poor patient experience. At present a referral for ear wax removal which does not meet the current local referral guideline can be returned to the referrer with advice, but if they request referral then it has to be sent on to secondary care. These referrals may then

be declined by secondary care as the patient is not deemed suitable for ear wax removal in secondary care. As a result, Devon Referral Support Services (DRSS) and specialists from ear, nose and throat (ENT) services had requested development of a commissioning policy for ear wax removal to support the local referral arrangements for ear wax removal in secondary care.

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 DRSS clinicians and specialists from secondary care had requested development of a commissioning policy for ear wax removal to support the local referral arrangements for ear wax removal in secondary care.

   Following consideration, the Clinical Policy Recommendation Committee has recommended a policy which clarifies the circumstances in which ear wax removal in secondary care is accepted in Devon. This aims to ensure that secondary care provision is targeted to those for whom it is clinically appropriate.

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

   It was discussed that the proposed policy aims to support the patient experience and ensure that referral for ear wax removal in secondary care is targeted to those with a clinical need for this expertise.

   How secondary care ear wax removal services are commissioned by the other ICBs in the NHS England Southwest region was considered during the development of the policy to aim to provide an equitable approach for patients.

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 estimate that up to 62 unnecessary ENT appointments could be avoided per year in Devon through introduction of the proposed policy was noted by the panel, with a potential positive impact in terms of efficiencies within ENT services and DRSS referral processing times.

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

   Communications colleagues were aware that sometimes patients report difficulties in accessing ear irrigation in primary care which have led to enquiries to the ICB. The panel noted that the policy position confirms the clinical appropriateness of the setting of care for various clinical scenarios. Nicola Bonas will liaise with the primary care commissioning team with regard to difficulties in patient access.

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

   nhs.uk gives information on ear wax build-up. It states that earwax normally just falls out on its own. When it's blocking your ears, a pharmacist can help give advice and suggest treatments. They might recommend medicines to dissolve the earwax. The earwax should fall out on its own or dissolve after about a week.

   It advises to see a nurse at your GP practice if your symptoms have not cleared after 5 days and your ear is badly blocked, and you cannot hear anything (you can get an infection if it has not cleared). It is noted that not all GP practices remove earwax. Some can flush the wax out with water (ear irrigation) or suck the wax out (microsuction).

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point. However the panel noted that, resulting from enquiries received, the communications team would discuss with the primary care commissioning team difficulties in patient access to ear irrigation.

ACTION: Nicola Bonas to liaise with the primary care commissioning team with regard to difficulties in patient access to ear irrigation in primary care.

Surgical interventions for chronic rhinosinusitis

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

Chronic rhinosinusitis is defined as inflammation (swelling) of the nasal sinuses that lasts longer than 12 weeks. First line treatment is with medical therapy, which includes intranasal steroids and saline irrigation. Where first-line medical treatment has failed, patients can be referred for specialist assessment which includes diagnostic confirmation and (where indicated), surgical intervention.

Referral to specialists and surgical treatment of patients with chronic rhinosinusitis is one of the interventions included in the Evidence-Based Interventions (EBI) list 2 guidelines published by the Academy of Medical Royal Colleges, and a policy had previously been agreed to reflect these recommendations. However the policy has subsequently been reconsidered by the Clinical Policy Recommendations Committee following feedback from DRSS colleagues who raised concerns about the practical implementation of one of the policy criteria.

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 a policy had previously been agreed for surgical intervention for chronic rhinosinusitis to reflect the recommendations made in the EBI list 2 guidelines published by the Academy of Medical Royal Colleges. However some concerns had later been raised by DRSS colleagues with the wording of one of the criterion which would make practical implementation of the policy problematic.

Consequently, a decision was taken not to publish the policy; instead it has been reviewed by the Clinical Policy Recommendation Committee.

Following reconsideration, the Clinical Policy Recommendation Committee has recommended revised wording for the referral criteria, which have been agreed following consultation with GP Referral Facilitators and local specialists to address the identified issue. An additional amendment has been made to align the definition of chronic rhinosinusitis in the policy with guidance from relevant national bodies.

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

   It was acknowledged that the policy represents no change to the clinical criteria for individual patients. It is consistent with the clinical referral guideline already in place and will support referrals to be managed in a more robust way. This is anticipated to help ensure the referral of patients at the appropriate point in the pathway and support consistency for patients across Devon.

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 acknowledged that introduction of the proposed policy is not expected to significantly impact current rates of surgical activity. However a definitive policy position will allow the referral process to be managed in a more robust way than is possible by reliance on a clinical referral guideline alone.

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 sinusitis, although it was noted that it is a common condition.

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

   nhs.uk gives information on sinusitis, stating that it is a swelling of the sinuses, usually caused by an infection. It is common and usually clears up on its own within 2 to 3 weeks. Advice is given on how to check if you have sinusitis, how you can treat it yourself, how a pharmacist can help and treatment from a GP.

   It is stated that a GP may refer you to an ear, nose and throat (ENT) specialist if, for example, you still have sinusitis after 3 months of treatment, keep getting sinusitis or only have symptoms on 1 side of your face. They may also recommend surgery in some cases. Surgery to treat chronic sinusitis is called functional endoscopic sinus surgery (FESS) and is carried out under general anaesthetic. The surgeon can widen your sinuses by either removing some of the blocked tissue or inflating a tiny balloon in the blocked sinuses, then removing it. You should be able to have FESS within 18 weeks of your GP appointment.

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

Otigo for acute otitis media

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

Acute otitis media is a disease of the middle ear which is common in children under the age of 10. It is characterised by inflammation of the middle ear, with patients generally presenting with ear pain. A discharge from the ear, and a perforation of the ear drum may also be present. The condition may be caused by a bacterial or viral infection, meaning patients may also have a fever or display other symptoms of being systemically unwell. Most cases will be managed in primary care and the condition is generally viewed as self-limiting. As pain is a primary complaint of acute otitis media most patients will be managed using oral pain relief; some will also require antibiotics.

An update to the NICE guideline NG91 on antimicrobial prescribing for acute otitis media in March 2022 includes a new treatment recommendation to consider the provision of ear drops containing a local anaesthetic and an analgesic in patients with acute otitis media who have not been provided with an immediate prescription for antibiotics and who do not have a perforation of the ear drum.

Otigo is a prescription only medicine licenced for the local symptomatic treatment and relief of pain in middle ear diseases when a perforation of the ear drum is not present. It is currently the only ear drop containing a local anaesthetic and analgesic licenced for the treatment of acute otitis media in the UK.

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 consideration of the use of Otigo ear drops in Devon had been prompted by an update to the non-mandatory NICE guideline on antimicrobial prescribing for acute otitis media. The guideline includes a new treatment recommendation to consider the provision of ear drops containing a local anaesthetic and an analgesic in patients with acute otitis media who have not been provided with an immediate prescription for antibiotics and who do not have a perforation of the ear drum.

   Following consideration, the Clinical Policy Recommendation Committee has recommended a policy which does not accept the routine commissioning of Otigo ear drops in Devon for the treatment of acute otitis media. The committee concluded that the lack of evidence identified for the clinical effectiveness of Otigo, alongside a likely increase in costs for uncertain clinical benefit, means it is not clear if it represents a suitable use of NHS resources in Devon. Feedback from local ENT and microbiology specialists also demonstrated a lack of support for its routine use in Devon for acute otitis media.

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

   The panel acknowledged that Otigo is not currently included as a treatment option in the Devon Formulary and there was judged insufficient evidence of benefit to support its inclusion for the costs incurred. It was noted that acute otitis media is generally a self-limiting condition managed using oral pain relief, with some patients also requiring antibiotics.

   Local specialists had shown a lack of support for the use of Otigo, and it was discussed that there is limited clinical trial evidence examining its effect for acute otitis media, with no data forthcoming from the manufacturer of the product to support local assessment of its use. There was also uncertainty that its use would lead to a reduction in antibiotic prescribing and the associated costs of this.

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 acknowledged that the committee concluded that the clinical and cost effectiveness of Otigo for the treatment of acute otitis media is uncertain. Local budget impact assessments estimated that its use is likely to increase NHS costs. Therefore, without clear evidence of a clinical benefit it is not considered good value for the use of local NHS funds.

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

   The panel were aware that acute otitis media is common; however they were not aware of any particular public concern in respect of its treatment.

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

   nhs.uk states that ear infections are very common, particularly in children. You do not always need to see a GP for an ear infection as they often get better on their own within 3 days. Most ear infections clear up within 3 days, although sometimes symptoms can last up to a week.

   It advises on steps that can be taken to help relieve any pain and discomfort from an ear infection, including painkillers, placing a warm or cold flannel on the ear and removing any discharge by wiping with cotton wool. It states to speak to a pharmacist if you think you have an outer ear infection; they can recommend acidic eardrops to help stop bacteria or fungus spreading. It also states when to see a GP.

   Antibiotics are not usually offered because infections inside the ear often clear up on their own and antibiotics make little difference to symptoms, including pain. Antibiotics might be prescribed if an ear infection does not start to get better after 3 days, you or your child has any fluid coming out of the ear or you or your child has an illness that means there's a risk of complications, such as cystic fibrosis. They

may also be prescribed if your child is less than 2 years old and has an infection in both ears. If antibiotics are not prescribed, eardrops containing a painkiller and an anaesthetic might be prescribed.

For outer ear infections, the GP might prescribe antibiotic eardrops – to treat a bacterial infection, steroid eardrops – to bring down swelling, antifungal eardrops – to treat a fungal infection or antibiotic tablets – if your bacterial infection is severe. Eardrops may not work if they're not used correctly.

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

The next meeting will be held on Thursday 2 March 2023 from 14.00 at County Hall and/or via Microsoft Teams – details to be confirmed.

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	Pending