

Clinical Policy Engagement & Consultation Panel

MINUTES

Tuesday 10 December 2019, 14.00-15.30

Torridge Room, Annexe, County Hall, Exeter

Present:

Nicola Bonas	Deputy Head of Communications
Rebecca Heayn	Clinical Effectiveness Governance Manager
Carol McCormack-Hole*	Lay Member from the Patient Engagement Forum
Chris Roome	Head of Clinical Effectiveness
Mark Taylor*	Lay Public Member, Clinical Policy Committee

* Denotes voting members

1. Welcome and Introductions

Nicola Bonas, Deputy Head of Communications was welcomed to the meeting and introductions were made for the benefit of the group. Nicola advised that she would be attending the panel in future in place of Nick Pearson.

Apologies were noted from Charlotte Burrows, Governing Body Lay Member for patient and public involvement, Mac Merrett, Lay Public Member, Clinical Policy Committee and Jon Taylor, Strategy Manager.

It was also noted that Jenny McNeill, Associate Director of Planning Development had now left the group following her recent retirement.

2. Declaration of Interests

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

3. Minutes from the meeting 22 August 2019

The panel considered the minutes from the meeting held on 22 August 2019 and agreed them to be an accurate record.

The action log was updated as follows:

Action no.	Description and update
19/07	Follow up on the pledge made in the NHS Long Term Plan that all pregnant women with type 1 diabetes will be offered continuous glucose monitoring by 2020/21 to query how this will be enacted. Chris Roome advised that he had contacted NHS England to query how their pledge in respect of continuous glucose monitoring for pregnant women with type 1 diabetes would be implemented. Although no direct response to the query had been received, NHS England had subsequently published a letter on 21 October which advised they are currently working with Local Health Economies to scope and take forward this commitment. Delivery will begin from April 2020 and further information would be provided shortly.
19/08	Production of an explanatory leaflet about technology available for patients encountering different types of problems with the management of their diabetes and the routes of access to these. This will accompany publication of the policy. Chris Roome advised that a leaflet had been prepared and published alongside the CCG's policies for continuous glucose monitoring and FreeStyle Libre to help with understanding of the differences between these technologies and their availability on the local NHS. Positive feedback had been received from a GP colleague and this had already proved useful in responding to an MP enquiry received by the CCG. Rebecca Heayn agreed to share this with the group for information. Action complete.

4. Discussion and recommendation on the Clinical Policy Committee decisions from 24 November 2019

Referral for the surgical management of heavy menstrual bleeding

It was noted that this was a further existing policy area affected by the NHS England statutory guidance issued to CCGs in November 2018 to introduce and implement commissioning policies for selected interventions. NHS England issued criteria which should be met before hysterectomy for heavy menstrual bleeding is undertaken. This had prompted review of the existing CCG policy for referral for the surgical management of heavy menstrual bleeding. Local gynaecology specialists had been asked for their input in terms of assessing the clinical, service and financial impacts of the differences between the NHS England guidance and the existing CCG policy. As a result, a revised commissioning policy has been recommended by the Clinical Policy Committee. This proposes revisions to remove a criterion regarding patients with a uterus greater than 12cm as it is no longer recommended by the National Institute for Health and Care Excellence (NICE). Previously ambiguous wording regarding the referral of patients with significant fibroids has also been clarified.

The panel considered the public interest themes in relation to these revised policies:

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

It was acknowledged that the current CCG policy has been reviewed with regard to statutory guidance published by NHS England in November 2018, and a revised CCG policy has been proposed as a result.

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

It was noted that the proposed revisions to the policy do not represent a significant change to the existing position. Consultation with local gynaecology specialists revealed that the wording in the NHSE guidance was ambiguous and open to differing interpretation. The proposed policy makes it clear that hysterectomy should only be considered for heavy menstrual bleeding after other treatment options have been tried, and the woman wishes for amenorrhoea (no periods), and she requests it (having been fully informed), and she no longer wishes to retain her uterus and fertility. This position is consistent with the existing policy and is supported by gynaecology specialists as current practice.

It was discussed that some patients may hold the view that they wish to have a hysterectomy without having tried other treatments first. It was considered that informed discussions between the patient and their clinician should include the relevant clinical criteria, alternative treatments and their respective consequences.

4. Have the wider consequences on society been considered?

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

5. Has the opportunity cost been considered?

It was discussed that adoption of the changes proposed was not expected to significantly affect the number of patients undergoing a hysterectomy. NHS England has set a target for a reduction in activity data and their data show 759 hysterectomy procedures were carried out in Devon in 2017-18. However local data show a considerable number of these procedures were not solely carried out for heavy menstrual bleeding but for other primary diagnoses; only 60 related to patients with a primary diagnosis suggesting heavy menstrual bleeding.

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 specific public concern in respect of heavy menstrual bleeding or hysterectomy.

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

nhs.uk states that various treatment options are available for heavy periods. A hysterectomy will stop any future periods but should only be considered after other options have been tried or discussed. A hysterectomy is only used to treat heavy periods after a thorough discussion with a specialist about the benefits and disadvantages of the procedure.

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

The referral and specialist management of haemorrhoids

This was another existing policy area affected by the NHS England statutory guidance issued to CCGs in November 2018 to introduce and implement commissioning policies for selected interventions. NHS England issued criteria which should be met before haemorrhoid surgery is undertaken. This had prompted review of the existing CCG policy for referral and specialist management of haemorrhoids. Local colorectal specialists had been asked for their input in terms of assessing the clinical, service and financial impacts of the differences between the NHS England guidance and the

existing CCG policy. As a result, a revised commissioning policy has been recommended by the Clinical Policy Committee which now includes pain (significant discomfort) as a relevant criterion, in addition to or separate from bleeding. However it is recommended that the existing policy position is maintained in respect of the surgical treatment of grade 1 haemorrhoids.

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

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

It was acknowledged that the current CCG policy has been reviewed with regard to statutory guidance published by NHS England in November 2018, and a revised CCG policy has been proposed as a result.

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

It was noted that haemorrhoids are graded from 1 to 4 depending on the degree of prolapse. Many symptomatic episodes of haemorrhoids settle with conservative management techniques, which include dietary and lifestyle modification, bulk forming laxative and analgesia/topical preparations for relief of symptoms. Where this fails, there are a number of non-surgical treatments (rubber band ligation, sclerotherapy or infra-red coagulation) which may be considered before surgical treatment.

It was acknowledged that the addition of pain to the policy criteria may be beneficial for some patients. Although patients usually present with mixed symptoms and there are likely to be only a small number of people undergoing haemorrhoid surgery where there is pain alone, the addition of this to the policy would ensure that patients experiencing pain alone suspected to be from their haemorrhoids are referred for specialist assessment. It was discussed that this would ensure equity of access with patients referred for investigation of anal pain without reference to haemorrhoids.

It was noted that the Clinical Policy Committee has recommended retaining the existing policy position in respect of grade 1 haemorrhoids (small swellings on the inside lining of the anal canal which cannot be seen or felt from outside the opening of the anus). This allows for their non-surgical treatment following failure of conservative management, but not surgery. This represents no change 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?

It was noted that NHS England data show that 119 haemorrhoid procedures were carried out in Devon in the last 12 months. NHS England has set a target annual activity for haemorrhoid surgery of 121 procedures. The revised policy is not anticipated to significantly alter current clinical practice or activity levels for surgery.

The recommendation to retain the existing policy position in respect of grade 1 haemorrhoids avoids an increase in the rates of surgical intervention that would be expected if surgical interventions were extended to grade 1 haemorrhoids. The Clinical Policy Committee considered that this was not a priority for the use of healthcare funds in Devon.

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 specific public concern in respect of haemorrhoids.

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

nhs.uk gives information and advice on how people can treat or prevent their piles (haemorrhoids), and notes that a pharmacist can suggest creams to ease the pain, itching and swelling, treatment to help constipation, and cold packs to ease discomfort. It advises to see a GP if there is no improvement after 7 days of treatment at home and the person keeps getting piles. The GP may prescribe stronger medicines for haemorrhoids or constipation.

If there is no improvement after home treatments, it states that hospital treatment may be needed. Common hospital treatments without surgery include rubber band ligation, sclerotherapy, electrotherapy and infrared coagulation. If these treatments do not work, surgery may be needed to remove the piles. Surgical treatments include haemorrhoidectomy, stapled haemorrhoidopexy and haemorrhoidal artery ligation.

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

Referral for varicose veins

This was another existing policy area affected by the NHS England statutory guidance issued to CCGs in November 2018 to introduce and implement commissioning policies for selected interventions. NHS England issued criteria which should be met before varicose veins interventions are undertaken. This had prompted review of the existing CCG policy for referral for varicose veins. Local vascular specialists had been asked for their input in terms of assessing the clinical, service and financial impacts of the differences between the NHS England guidance and the existing CCG policy.

It was noted that the NHS England guidance is in line with NICE clinical guideline 168 on the management of varicose veins. The NICE guideline was considered in 2014 and the CCGs took a decision at that time not to align with NICE in respect of referral for all patients with symptomatic varicose veins due to the substantial increase in activity and cost that this would entail. The Clinical Policy Committee has recommended that, given this position, this would still be considered a low priority for investment in Devon and the existing policy position should be maintained.

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 acknowledged that the current CCG policy has been reviewed with regard to statutory guidance published by NHS England in November 2018; the result of this was that the Clinical Policy Committee has recommended maintaining the existing policy position in Devon.

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

It was discussed that the policy only allows for referral for varicose veins where these are accompanied by skin changes, i.e. not routinely for patients with symptomatic varicose veins without complications. No change to the existing policy position is proposed in respect of this.

It was queried what the longer term outcomes would be for patients by not operating on symptomatic varicose veins without complications. It was explained that there are no good data that characterise progression from this stage of varicose veins to

complicated veins and ulceration. Although varicose veins are common, NICE identified the need for further research into aspects such as factors affecting progression from milder disease to more serious consequences, and the optimal treatment at the various stages of disease.

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 noted that local specialists were supportive of the NHS England and NICE criteria which were deemed to be clinically appropriate, and they stated they would like to see all patients with varicose veins. However varied impacts were reported in terms of local providers' service capacity for them to see all patients with symptomatic varicose veins. The Clinical Policy Committee acknowledged that varicose vein interventions are a cost effective intervention; however there would be a budgetary impact of extending the existing policy and, on balance, it was not thought to be a good use of resources to operate on symptomatic but not complicated varicose veins.

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

It was acknowledged that the CCG's policy represents no change from the existing position for patients; however it does not align with NHS England and NICE guidance. The panel considered this, but also that they were not aware of any specific public concern or issues relating to varicose veins. It was felt that this could be due to a number of factors, including a well-established local policy position, that some patients may opt to receive private treatment for milder varicose veins, and potentially improvements in prevention.

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

nhs.uk states that varicose veins do not always need treatment. If they are not causing discomfort, a person may not need to have treatment. It advises that treatment of varicose veins is usually necessary to ease symptoms (if the varicose veins are causing pain or discomfort), to treat complications (such as leg ulcers, swelling or skin discolouration) and for cosmetic reasons (but this is rarely available on the NHS).

If treatment is necessary, a doctor may first recommend up to 6 months of self-care at home. This may involve using compression stockings, exercising regularly, avoiding standing up for long periods, and elevating the affected area when resting.

If varicose veins need further treatment or they are causing complications, the type of treatment will depend on a person's general health and the size, position and severity of the veins. A vascular specialist will be able to advice on the most suitable form of treatment for the patient.

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

Loteprednol (Lotemax®) for the treatment of steroid responsive inflammatory eye conditions

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. Loteprednol eye drops are licenced in the UK for the treatment of post-operative inflammation following ocular surgery.

The use of loteprednol steroid eye drops for the more general treatment of inflammatory eye conditions had been considered by the Clinical Policy Committee following an application from a local ophthalmologist.

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 request received was for the use of loteprednol eye drops to be supported in Devon for the treatment of steroid responsive inflammatory eye conditions. After consideration, the Clinical Policy Committee has recommended the routine commissioning of loteprednol eye drops in Devon for the treatment of steroid responsive inflammatory eye conditions in patients who have a known clinically significant rise in intraocular pressure with other steroid eye drops, i.e. for second line use.

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

It was discussed that it is common for patients with inflammatory eye conditions (such as uveitis and vernal keratoconjunctivitis) to require long term or frequent courses of eye drops. Prolonged use of steroid eye drops can raise intraocular pressure in some patients, which if left untreated can be sight threatening.

It was noted that although loteprednol has not been shown to be more effective than other steroid eye drops, in patients who have experienced a rise in intraocular pressure with other eye drops, it offers an alternative treatment which may result in a lower rise in intraocular pressure in some patients. This would enable them to continue treatment with steroid eye drops and avoid the use of other additional treatments for ocular hypertension.

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 noted that loteprednol is recommended for second line use in patients who have experienced a rise in intraocular pressure with other eye drops. Consultation with specialists confirmed that this is in line with the practice of the majority of local ophthalmologists and the regional uveitis centre in Bristol. Although loteprednol has not been shown to be more effective than other steroid eye drops, the Clinical Policy Committee had considered that supporting its use second line would offer a pragmatic alternative for patients. It may result in a lower rise in intraocular pressure in some patients, allowing continued treatment without the need for multiple additional treatments to control intraocular pressure. Its use in this way is anticipated not to have a significant resource impact as patient numbers are low.

The wording of the exceptionality statement of the proposed policy was queried as this differs from the commonly used statement referring to application for individual patients via the Individual Funding Panel (IFR). It was discussed that application via IFR was considered disproportionate in this instance due to the numbers of patients

anticipated to be treated, the clear place in therapy for its use and the small acquisition cost of loteprednol eye drops.

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 specific public concern in respect of inflammatory eye conditions and the use of steroid eye drops to treat them. It was acknowledged that loteprednol is not licenced in the UK for the treatment of steroid responsive eye conditions; however following discussion it was considered that this is not an unusual position and it does not raise any particular concerns. Loteprednol is an established treatment, it is licensed for this indication in the US, and the proposed policy makes it clear that patients will need to be made aware its unlicensed nature for this indication before being treated.

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

nhs.uk does not provide any information specifically relating to loteprednol or to vernal keratoconjunctivitis. However information is given on uveitis. It is stated that treatment for uveitis depends on what is causing it and which area of the eye is affected. Medication is the main treatment, but in rare cases, surgery may be recommended to treat particularly severe uveitis.

Most cases of uveitis can be treated with steroid medication and a medicine called prednisolone is usually used. Corticosteroid eye drops are usually the first treatment used for uveitis that affects the front of the eye (anterior uveitis) and is not caused by an infection. It is advised that in some people, steroid eye drops can increase pressure in the eye. The ophthalmologist will check for this and advise you if this happens.

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 is due to be held on Thursday 30 January 2020 from 2.00pm in the Otter Room, County Hall, Exeter or via teleconference.

ACTION LOG

Action no.	Meeting date	Action description	Lead(s)
19/07	22/08/2019	Follow up on the pledge made in the NHS Long Term Plan that all pregnant women with type 1 diabetes will be offered continuous glucose monitoring by 2020/21 to query how this will be enacted. Update 10/12/2019: Chris Roome contacted NHS England to query how their pledge would be implemented. Although no direct response had been received, NHS England published a letter on 21 October which advised they are currently working with Local Health Economies to scope and take forward this commitment. Delivery will begin from April 2020 and further information would be provided shortly.	Chris Roome