NHS
Devon
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel

MINUTES

Thursday 22 August 2019, 14.00-15.30

Otter Room, County Hall, Exeter and via teleconference

Present:

Charlotte Burrows*	Governing Body Lay Member for patient and public involvement
Rebecca Heayn	Clinical Effectiveness Governance Manager
Carol McCormack-Hole*	Lay Member from the Patient Engagement Forum
Mac Merrett*	Lay Public Member, Clinical Policy Committee
Chris Roome	Head of Clinical Effectiveness
Keri Ross	Communications Manager
Jon Taylor	Strategy Manager
Mark Taylor*	Lay Public Member, Clinical Policy Committee

* Denotes voting members

1. Welcome and Introductions

It was noted that Keri Ross was attending on behalf of Nick Pearson and she was welcomed to the meeting. Introductions were made for the benefit of the group.

Apologies were noted from Jenny McNeill, Associate Director of Planning Development and Nick Pearson, Head of Communications and Engagement.

2. Declaration of Interests

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

3. Minutes from the meeting 9 July 2019

The panel considered the minutes from the meeting held on 9 July 2019 and agreed them to be an accurate record.

The action log was updated as follows:

Action no.	Description and update
19/06	DRSS to be advised of the need for clinical referral guidance to be updated in respect of carpal tunnel syndrome and for appropriate referral messages to be reiterated with communication of the revised policy.

	Rebecca Heayn contacted DRSS regarding this following the completion of the CCG governance and approval processes for this policy. DRSS are currently reviewing the clinical referral guidance. A 'go live' date for the policy will then be agreed, with communication/publication in line with this. Action complete.

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

Myringotomy

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 insertion of grommets for children with glue ear is undertaken. This had prompted review of the existing CCG policies for myringotomy. There are two policies currently in place, one applies to children under 12 years and the other to adults and children over 12 years. Local 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 policies. As a result, revised commissioning policies had been recommended by the Clinical Policy Committee. These propose the addition of a specific criterion for children under 12 years who cannot undergo standard hearing assessment, and a good practice point to ensure glue ear has not resolved once a date for surgery has been agreed.

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 policies had been reviewed with regard to statutory guidance published by NHS England in November 2018, and revised CCG policies had been proposed as a result.

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

   It was discussed that it was proposed to retain the existing CCG age cut off at 12 years for the policies. NHS England does not define an age for "children" and activity data quoted by them is based on patients aged 1-17 years. However following consultation with local specialists it was agreed that retaining the current age cut off at 12 years is logical from a clinical perspective and is consistent with the NICE Clinical Guideline on which both the CCG and NHS England documents are based.

   The addition of a criterion in respect of children who cannot undergo standard hearing assessment was noted to provide specific clarification within the policy; however it was not anticipated that this would change overall surgical activity levels as local specialists indicated that these patients would already be treated.

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 the adoption of the changes proposed was not expected to significantly affect activity levels and that local specialists noted there was very little difference in practice between the current policies and the NHS England guidance. Given this, the ambitious NHS England target for a reduction in activity in Devon for

grommets for glue ear is not likely to be met. The Clinical Policy Committee noted that activity in Devon had already decreased significantly since the introduction of the existing policies (51% decrease in activity between 2016/17 and 2018/19).

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 myringotomy/grommets.

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

   nhs.uk states that glue ear is much more common in children. It is not always treated, and the GP will usually wait to see if symptoms get better on their own. This is because there is no effective medicine for glue ear, and it often clears up on its own within 3 months. A child may be referred to a specialist in hospital if glue ear symptoms are affecting their learning and development, they already had severe hearing loss before glue ear, or they have been diagnosed with Down's syndrome or a cleft lip and palate as glue ear is less likely to get better by itself.

   It is stated that the two main treatments are temporary hearing aids or grommets; the specialist in hospital will help patients decide on the best treatment option. Grommets are small temporary tubes that are placed in the ear during surgery. They help to drain fluid away and keep the eardrum open. The grommet should fall out naturally within 6 to 12 months as the ear gets better.

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

Tonsillectomy

It was noted that 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 a surgical procedure to remove the tonsils, as a treatment for recurrent sore throats, is undertaken. This had prompted review of the existing CCG policy for tonsillectomy. Local 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 had been recommended by the Clinical Policy Committee. This proposes the addition of a number of medical conditions to the policy for which NHS England states tonsillectomy may be beneficial at a lower threshold.

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 had been reviewed with regard to statutory guidance published by NHS England in November 2018, and a revised CCG policy had been proposed as a result.

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

   It was noted that the addition of a number of medical conditions to the policy for which NHS England states tonsillectomy may be beneficial at a lower threshold provides clarity. It was also discussed that, on the recommendation of the Clinical Policy Committee, the policy clarifies that there should be appropriate review by the

relevant specialist for these conditions before surgery is undertaken. For example, where it is proposed that tonsillectomy is carried out for a patient with renal disease resulting from acute bacterial tonsillitis, the renal specialist should be included in the assessment of whether this is undertaken.

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 has set a challenging target for reduction in activity for tonsillectomy which local specialists indicated was not likely to be met since both the NHS England guidance and the current CCG policy contain almost identical criteria; both are based on the recommendations in SIGN Clinical Guideline 117.

   Addition of the specific medical conditions for which tonsillectomy may be undertaken at a lower threshold provides clarity but is not expected to reduce surgical activity. There is a possibility that there could be an increase as a result of the change, but due to the very small number of patients to which this is anticipated to apply, it is not expected to be a significant increase.

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 tonsillitis or tonsillectomy.

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

   nhs.uk states that tonsillitis is a common childhood illness, but teenagers and adults can get it too. It usually goes away on its own after a few days. Tonsillitis can feel like a bad cold or flu. The tonsils at the back of the throat will be red and swollen.

   It is made clear that it is very rare that someone needs to have their tonsils taken out. This is usually only the case if they have severe tonsillitis that keeps coming back.

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

Glycopyrronium bromide oral solution for the treatment of severe sialorrhoea in children and adolescents aged 3 years and older

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. The use of licensed glycopyrronium bromide oral solution for the treatment of sialorrhoea (severe drooling) in children and adolescents had been considered by the Clinical Policy Committee following an application from a local paediatric specialist. Currently patients requiring treatment use unlicensed specials preparations of glycopyrronium bromide. However two solutions are now licensed for use. Glycopyrronium bromide is an antimuscarinic (anticholinergic) medicine that reduces salivary secretions. NICE clinical guideline NG62 recommends considering the use of anticholinergic medication to reduce the severity and frequency of drooling in children and young people with cerebral palsy.

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 licensed glycopyrronium bromide oral solution to be accepted as a treatment option for severe sialorrhoea in children and adolescents aged 3 years and older with chronic neurological disorders. After consideration, the Clinical Policy Committee has recommended the routine commissioning of licensed glycopyrronium bromide in Devon for this patient group.

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

   It was discussed that currently patients requiring treatment use unlicensed specials preparations of glycopyrronium bromide. However one product cannot be readily substituted for another as there are differences in the dose delivered to the patient. It is therefore difficult to maintain a stable dose when different products are used. Acceptance of licensed glycopyrronium bromide in Devon will give consistency for patients and support better maintenance of a stable dose, reducing the potential for under or over dosing and potentially the likelihood of experiencing side effects.

   It was commented that it was positive that committee discussions had included social as well as clinical factors, specifically that this patient group may experience increased wetness, odour and social embarrassment as a result of their drooling. It was felt that the impact of these social factors could be significant and should not be underestimated.

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 unlicensed specials preparations of glycopyrronium bromide currently dispensed in Devon are either the same price or more costly that the licensed products. Prescribing licensed glycopyrronium instead at the average dose estimated by the manufacturer has the potential for cost savings, as well as giving consistency for patients in receiving a single product which supports delivery of a stable dose.

   It was raised that hyoscine patches are a considerably cheaper alternative treatment than glycopyrronium bromide and questioned whether the use of these should be promoted as a preferred treatment option. It was discussed that although hyoscine patches are less costly, a higher drop-out rate has been observed with their use, suggesting that the side effects are more troubling than with glycopyrronium bromide. Moreover, they are unlicensed for this indication, which makes it difficult to promote them over a licensed treatment option. General Medical Council (GMC) guidance states that in general unlicensed medicines should only be prescribed where this is no suitably licensed medicine that will meet the patient's need. Where a clinician intends to prescribe unlicensed medicines and there are suitably licensed alternatives available, they should explain this to the patient along with their reasons for doing so.

   It was acknowledged that work would be undertaken via the Devon Formulary groups, who support the implementation of policy decisions into local treatment guidance, to clarify the available treatment options and help ensure that the cost differences between these are understood by specialists when discussing options with an individual patient.

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 severe drooling; however it was felt to be positive that the social as well as clinical factors had been considered during committee discussions.

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 in relation to sialorrhoea (severe drooling) in children and adolescents.

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

Continuous glucose monitoring in diabetes

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. Continuous glucose monitors (CGM) measure interstitial glucose levels using a sensor which has a small filament sitting under the skin. Measurements are generally taken every 5 minutes and are transmitted to a receiver. CGM devices are used as an alternative to self-monitoring blood glucose or intermittent glucose monitors such as the FreeStyle Libre.

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 CCG currently has a policy in place for the use of FreeStyle Libre for patients who meet certain criteria. However the Libre was deemed unsuitable for patients with impaired awareness of hypoglycaemia as it does not have an alarm to notify patients when their glucose levels are low. Patients with impaired awareness of hypoglycaemia often do not perceive hypoglycaemic symptoms and therefore may not scan the Libre sensor at the appropriate time to be aware of low or lowering glucose levels.

   Furthermore, it was identified that there is currently inequity in the provision of CGM across Devon, with one provider able to make it available to patients under provider managed criteria due to historical arrangements, but other providers needing to apply to the CCG's Individual Funding Request Panel. There was therefore an identified need to consider the circumstances in which the use of CGM would be supported in Devon and to provide clarity of this for patients and clinicians.

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

   The Clinical Policy Committee has recommended a 6 month trial of CGM for patients with type 1 diabetes with either an impaired awareness of hypoglycaemia, or hypoglycaemia unawareness, plus recent episodes of severe hyperglycaemia; or who are incapable of self-management of their diabetes and have an inability to recognise or communicate about symptoms of hypoglycaemia. Discussion of the appropriate treatment options, initiation of the device and all subsequent clinical reviews would be undertaken by the secondary care diabetes specialist. As with FreeStyle Libre, continuation of the device beyond 6 months would be subject to the patient meeting specified continuation criteria.

It was noted that CGMs can be programmed to alert the patient, and their parent or carer, with an alarm if their glucose levels fall below a pre-specified level which can enable prompt action to be taken to address their glucose levels and reduce the number of severe hypoglycaemic episodes experienced.

It was commented that a CGM device would be positive for patients with type 1 diabetes and dementia or learning disabilities, and their carers. It was also positive for pre-school age children who were anticipated to be the largest group most likely to be unable to recognise or communicate about symptoms of hypoglycaemia.

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 CGM is very expensive compared to conventional methods of blood glucose testing. Under the criteria proposed by the policy a small number of patients are anticipated to be eligible for a CGM. It was explained that for the majority of patients a CGM is only likely to give marginal benefit, as most patients do not experience a problem with self-testing. Its use in Devon has been supported in the groups specified in the policy to target resources to those most likely to derive significant benefit.

   It was discussed that most diagnoses of type 1 diabetes are in childhood. As children get older they are likely to develop better awareness of their symptoms and be able to communicate these, which would prompt review with their diabetes specialist of what form of diabetes monitoring would be most appropriate for them.

   It was queried how long the CGM technology would last. It was explained that sensors have a limited life which varies by device. However the Clinical Policy Committee financial considerations had reflected the replacement rate, offset by the cost of self-monitored blood glucose testing and a portion of the healthcare costs associated with experiencing a hypoglycaemic event.

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

   Type 1 diabetes is a well-recognised condition and it was acknowledged that there was patient interest in technologies which could support them with their glucose monitoring. The CCG had received a significant number of queries in relation to the FreeStyle Libre and had also received enquiries regarding the availability of CGM.

   It was highlighted that the NHS Long Term Plan pledges that all pregnant women with type 1 diabetes will be offered continuous glucose monitoring by 2020/21, and it was queried how the proposed policy sits in the context of this. It was discussed that to date no national guidance has been issued in respect of the provision of CGM for pregnant women; however pregnant women with type 1 diabetes are automatically eligible for a FreeStyle Libre in Devon. However this would be followed up to ascertain the intention behind the pledge and to query how this will be enacted, e.g. if guidance or criteria for reimbursement will be issued to CCGs in the same way as with FreeStyle Libre. If so, this may result in review of the policy at a later stage.

   Action: 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.

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

   nhs.uk states that patients can check their sugar levels at any time with a continuous glucose monitor (CGM). It lets them see patterns in their levels and sends an alert if their sugar (glucose) is too high or low. Interstitial fluid sugar readings are a few minutes behind blood sugar levels, which means patients will still need to do finger-prick checks every now and then. To get the best out of a CGM, patients will need to look at the information with their team.

   It is advised that patients can buy a CGM themselves. In terms of getting a CGM on the NHS, it is stated that flash glucose monitoring should be available on the NHS to anyone who meets certain criteria.

   Concern was expressed that there is commonly confusion of the difference between FreeStyle Libre (frequently referred to as flash glucose monitoring) and CGM. The information given by nhs.uk does not help to clarify this; the advice about getting a CGM on the NHS actually refers to FreeStyle Libre. It was noted that the clinical effectiveness team had fed this back to nhs.uk, along with concerns that this was misleading for patients. It had been suggested that the explanation of the difference between the two given by diabetes.uk might be more helpful - *"CGM monitors your sugar levels continuously and sends data to your display device (a hand held monitor or pump). So you can set alerts for high, low or rate of change. With flash glucose monitoring, you only get your reading and trends when you scan your sensor".*

   Given the confusion between the different types of technology, it was considered important to try to clarify this when the policy for CGM is published on the CCG website, alongside the existing policy for FreeStyle Libre. Furthermore, it was discussed and agreed that it would be helpful to produce 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.

After considering all the patient interest factors the panel recommended that an explanatory leaflet be produced about technology available for patients encountering different types of problems with the management of their diabetes and the routes of access to these. This would be produced to accompany publication of the policy.

Action: 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.

5. Any Other Business

No other business was raised.

6. Next meeting date

The next meeting is due to be held on Tuesday 10 December 2019 from 2.00pm in the Torridge 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.	Chris Roome
19/08	22/08/2019	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/ Rebecca Heayn