

Clinical Policy Committee

MINUTES

Wednesday 24th July 2019

Clinton Room, County Hall, Exeter

Present:

Dr Jo Roberts (Chair)	Chair	NHS Devon CCG
Dr Andrew Craig	Voting Member	NHS Devon CCG
Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Tracey Foss	Chief Pharmacist	RD&E NHS FT
Dr Lucy Harris	Voting Member	NHS Devon CCG
Barbara Jones	Head of Contracting	NHS Devon CCG
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NHS Devon CCG
Dr Alison Round	Voting Member	NHS Devon CCG
Dr Peter Rowe	Consultant Nephrologist	University Hospitals
	Hon Associate Professor in Medicine	Plymouth NHS Trust
Mark Taylor	Lay Public Member	
Dr Emily Youngman	Consultant in Public Health Medicine	Devon County Council
Sarah Zaroni	Associate Director of Nursing	NHS Devon CCG

Guests:

Matt Howard	Clinical Evidence Manager	NHS Devon CCG
David McGregor	Consultant Paediatrician	Royal Devon & Exeter NHS FT
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Graham Simpole	Joint Formulary Support Pharmacist	NHS Devon CCG
Becky Smith	Consultant Physician	University Hospitals Plymouth
		NHS Trust
Neil Walker	Consultant Physician	Royal Devon & Exeter NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NHS Devon CCG

1. Welcome and announcements

Attendees were welcomed to the meeting and introductions were made. Jo Roberts reported that this was his final CPC meeting as he was stepping down as Chair of the Committee.

Apologies

Dr Glen Allaway	Voting Member	NHS Devon CCG
Paul Foster	Clinical Director of Pharmacy and Prescribing	T&SD NHS FT
Dr Andrew Harrison	Voting Member	NHS Devon CCG
Dr Paul Melling	Voting Member	NHS Devon CCG
Simon Polak	Associate Chief Nursing Officer	NHS Devon CCG
Dr Ben Waterfall	Voting Member	NHS Devon CCG

Confirmation of voting members and Declarations of interest

The 7 voting members present were identified.

Dr Glen Allaway had delegated voting to Richard Croker
Dr Andrew Harrison had delegated voting to Dr Tawfique Daneshmend
Dr Paul Melling had delegated voting to Dr Peter Rowe
Dr Ben Waterfall had delegated voting to Chris Roome
Paul Foster was represented by Tracey Foss
Simon Polak was represented by Sarah Zaroni

Declarations of Interest

Declarations of Interest were collected and reported. The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item. All Declarations of Interest are reported in the minutes.

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea in children and adolescents aged 3 years and older with chronic neurological disorders Alternative treatments: Hyoscine hydrobromide tablets or transdermal patches Glycopyrronium bromide tablets or unlicensed oral solutions Trihexyphenidyl hydrochloride oral solution or tablets	Proveca Limited, Colonis Pharma Various Various Various
Myringotomy/grommets in adults and children	Would benefit from private provision of myringotomy/grommets or alternative treatments for otitis media
Tonsillectomy	Would benefit from private provision of adeno/tonsillectomy

Continuous glucose monitoring for patients with type 1 diabetes Alternative treatments: Blood glucose monitoring devices	Dexcom, Medtronic, Roche Diabetes Care/ Senseonics Inc, Abbott, various others Various
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Name of Attendee	Role	Declaration
Dr Neil Walker	Consultant Physician	Previously invited to Dexcom Launch meeting in October 2016.
Dr David McGregor	Consultant Paediatrician	Received a bursary of £600.00 from Pfizer to attend BSPED (British Society for Paediatric Endocrinology and Diabetes) in 2017

Notification of Any Other Business

Members were asked if there were any items of AOB for consideration.

2. Minutes of the meeting held on 22nd May 2019 and matters/actions arising

The minutes of the meeting held on 22nd May 2019 were approved.

Summary of actions		
	Action	Lead
19/01	<i>Surgical treatment options for lower urinary tract symptoms caused by benign prostatic hyperplasia.</i> <i>Committee recommendations to be submitted to the CCGs to inform senior level commissioning discussions for services for this condition.</i> Formal approval through the CCG governance processes is awaited. These decisions have been published. Action complete.	
19/05	Semaglutide (Ozempic®) for the treatment of type 2 diabetes: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. Formal approval through the CCG governance processes is awaited. This policy has been published. Action complete.	
19/06	Review of FreeStyle Libre for interstitial glucose monitoring in diabetes: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	

	Formal approval through the CCG governance processes is awaited. This policy has been published. Action complete.	
19/07	Review: Policy for the referral and specialist management of meibomian cysts (chalazia): Clinical scenario for suspected abscess to be reflected in the CRG to support urgent referrals of appropriate patients. It is expected that this has been completed. Confirmation to be sought. Confirmation has been received. Action complete.	
19/08	Review: Policy for the referral and specialist management of meibomian cysts (chalazia): Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. Formal approval through the CCG governance processes is awaited. This policy has been published. Action complete.	
19/09	Review: Policy for Breast Reduction: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. Formal approval through the CCG governance processes is awaited. This policy has been published. Action complete.	
19/10	<i>Hydroxychloroquine monitoring schedule - recommendations to be incorporated into the development of a commissioning specification for monitoring patients for hydroxychloroquine retinopathy.</i> <i>This has been communicated to specialists, commissioners and contractors. Discussions are ongoing with the Local Medical Committee. DRSS are receiving referrals.</i> CPC recommendations have been communicated to the CCG lead commissioner for ophthalmology to incorporate into the commissioning service plans. DRSS working with LMC on a referral specification. Action complete	
19/11	<i>Review: Policy for Dupuytren's contracture treatment – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</i> This policy is awaiting CCG sign-off.	Rebecca Heayn

19/12	<i>Review: Policy for surgery for carpal tunnel syndrome – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</i> This policy is awaiting CCG sign-off.	Rebecca Heayn
19/13	<i>Review: Policy for surgery for ganglion cyst – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</i> This policy is awaiting CCG sign-off.	Rebecca Heayn
19/14	Clinical Policy Committee Annual Report 2018-19 – Report to be submitted to the CCGs governing body to be received and ratified. Action complete.	
19/15	Once Ratified CPC annual report to be published and made publicly available via the CCG website. Action complete.	
19/16	Clinical Policy Engagement and Consultation Panel Annual Report 2018 – 19 to be submitted to the CCGs governing body for acceptance and assurance. Action complete.	

3. Glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders

An application for the inclusion of glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders has been received from Dr Eleanor Thomas, Consultant Paediatrician, Community Child Health, Royal Devon and Exeter NHS Foundation Trust. Dr Thomas has indicated that glycopyrronium bromide oral solution would provide a licenced option for the systematic treatment of severe sialorrhoea in this patient group. Graham Simpole, Joint Formulary Support Pharmacist, NHS Devon CCG presented an evidence assessment. No specialists were able to attend the meeting.

Glycopyrronium bromide is a competitive antagonist of muscarinic receptors in the autonomic nervous system acting to reduce secretions including salivation. There are currently two glycopyrronium bromide oral solutions that are licensed for the treatment of severe chronic pathological drooling (sialorrhoea) in children and adolescents aged 3 years and older with chronic neurological disorders: Sialanar® oral solution (containing glycopyrronium bromide 400mcg/1ml) and an unbranded generic manufactured by Colonis Pharma (glycopyrronium bromide 200mcg/1ml). The dosing schedule for both products is based on the weight of the patient, with the dose being titrated upwards every 5-7 days. Oral glycopyrronium has low and highly variable oral bioavailability. The two licensed formulations are not bioequivalent and there are no data supporting bioequivalence of unlicensed versions.

A systematic literature search identified three short-term Randomised Controlled Trial (RCT) studies. Two of these compared glycopyrronium to placebo, whilst the other compared glycopyrronium to hyoscine. The primary endpoints in the placebo-controlled studies were based

on the improvement in the modified Teacher's Drooling Scale. In one the primary outcome was the "responder rate" based on the change in the severity and frequency of drooling, whilst in the other the primary outcome was the actual improvement in drooling. In the active comparator study the primary outcome was the Drooling Impact Scale score at 4 weeks. The primary endpoints across all three RCT studies support the claim of efficacy of glycopyrronium, demonstrating superiority to placebo and failing to find a significant difference against transdermal hyoscine. Adverse events are common, resulting in up to 20% of patients discontinuing treatment, although in the active-comparator study more patients discontinued treatment whilst taking hyoscine than glycopyrronium.

Sialanar® costs £3.20 per mg, and the Colonis Pharmaceuticals product costs £3.03 per mg. Whilst it initially appears that the generic product has a lower cost per unit dose, Sialanar® has been shown to have a greater bioavailability. Consequently, the doses required are 20% less than those of the Colonis Pharma product. Assuming that prescribing is undertaken in accordance with the manufacturer's dosing tables then, at any given weight and dose level combination, Sialanar® is cheaper than the Colonis pharmaceuticals generic product. At the manufacturers estimated average dose, Sialanar® would cost approx. £5,600 per patient each year and the Colonis Pharma product would cost approx. £6,600. Unlicensed specials preparations of glycopyrronium bromide oral liquid, currently dispensed in Devon are either the same price or more expensive. For comparison hyoscine 1.5mg transdermal patches would cost £783 per annum per patient.

The initial product choice is based on individual clinical circumstances including parental preference. The respective proportion of patients receiving either glycopyrronium or hyoscine is likely to remain unchanged

The applicant has estimated that up to 63 patients in Devon would be initiated on licensed glycopyrronium oral solution, based upon the cerebral palsy population.

A cost comparison of the different glycopyrronium products suggests that Sialanar® would be the most cost-effective option. Prescribing this brand at the average manufacturers estimated dose instead of other glycopyrronium formulations would potentially save up to £129,000.

The committee discussed issues pertinent to this application, including:

- Bio-equivalency and the use of tablets in clinical practice.
- The number of adult patients. Local data identified 70 patients over three months, however the indication for which treatment was given is unclear.
- Health problems associated with sialorrhoea and the possibility of introducing criteria for treatment. However it was felt that this may create problems and was likely to lack a robust evidence base.
- Specialists had reported that discussions take place with parents about the choice of product. Discussions include the potential side effects.
- Sialanar® may be cost neutral or cost saving.

The committee voted unanimously in favour of recommending the routine commissioning of Glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea in children and adolescents aged 3 years and older with chronic neurological disorders.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

4. Review: Policies for myringotomy

NHS England issued statutory guidance to CCGs in November 2018 to introduce and implement commissioning policies for selected interventions. The guidance details specific criteria which

should be met before insertion of grommets for children with glue ear is undertaken. Devon CCG already has two relevant policies in place regarding the insertion of grommets for glue ear in children and adolescents. These are:

- Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years.
- Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older.

Both these policies were produced in consultation with local specialists, agreed by CPC, and published in October 2016. These policies are now being reviewed having regard to the guidance issued by NHS England.

Matt Howard, Clinical Evidence Manager, NHS Devon CCG presented a paper.

The NHS England guidance states that “Glue ear is a very common childhood problem, and in most cases it clears up without treatment within a few weeks. Common symptoms can include earache and a reduction in hearing. Often, when the hearing loss is affecting both ears it can cause language, educational and behavioural problems”.

NHS England has set challenging goals for a reduction in local activity for this intervention and expects activity levels for insertion of grommets for glue ear in children to be reduced to the 25th percentile of the age-sex standardised rate for all CCGs in England.

To meet this requirement, NHS England is expecting a reduction in the number of grommet insertions for Otitis Media with Effusion (OME) in children of:

- 65% for the former NEW Devon CCG area (150 fewer procedures per year, from 232 in 2017/18) and
- 63% for the former South Devon and Torbay CCG area (42 fewer procedures per year, from 67 in 2017/18).

The NHS England guidance and the current Devon CCG’s policy are broadly similar, since both documents were based on NICE Clinical Guideline CG60: “*Otitis media with effusion in under 12s: surgery*”. There are however three notable differences.

The NHS England document contains an additional criterion:

- “Healthcare professionals should consider surgical intervention in children who cannot undergo standard assessment of hearing thresholds where there is clinical and tympanographic evidence of persistent glue ear and where the impact of the hearing loss on a child’s developmental, social or educational status is judged to be significant”.

The NHS England document also contains the following good practice point:

- “It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry as a minimum”.

Whilst the CCG policies are age specific, with a cut off at 12 years of age (in line with the NICE Clinical Guideline), the NHS England document does not define an age for “children”. Activity data quoted by NHS England are based on patients aged between 1 and 17 years.

Local specialists were contacted to seek their views on the clinical implications, the impact on services, and the impact on local activity levels, of adding the additional criterion and good practice point to the Devon CCG policy. Consideration was also given to amending the age limit for the two policies to “under 18 years” and “adults (18 years and older)”. They noted that there was very little difference in practice between the current Devon policies, and the NHS England guidance; and that adoption of the additional criterion from the NHS England document is unlikely to significantly affect activity levels. Comments received also highlighted retaining the current

age cut off of 12 years (rather than 18 years) was consistent with the NICE Clinical Guideline on which these documents were based, and it was therefore proposed that this is not changed.

It was proposed that the following changes are made to the two Devon policies:

For myringotomy with or without ventilation tubes in adults and children aged 12 years and older:

- Addition of a good practice point to ensure glue ear has not resolved once a date of surgery has been agreed.

For the policy “Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years”, two changes were proposed:

- Addition of a criterion allowing consideration of surgical intervention in children who cannot undergo standard assessment of hearing thresholds
- Addition of a good practice point to ensure glue ear has not resolved once a date of surgery has been agreed.

Making these changes to the two Devon policies recognises the national guidance issued by NHS England but is not expected to significantly increase or reduce surgical activity. Details of activity levels were tabled at the meeting. It was noted that Devon-wide activity had already decreased by 51% between 2016/17 (when the current policy was introduced) and 2018/19.

The committee discussed issues pertinent to the review of the policies for myringotomy:

- It was noted that the additional criterion is only for children who cannot undergo standard assessment.
- It was noted that the proposals were already occurring in practice and that the updated policy was for clarity.

The committee voted unanimously in favour of recommending acceptance of the proposed amendments to the CCG’s policies for myringotomy.

ACTION: Policy recommendations and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

5. Review: Policy for tonsillectomy

NHS England issued statutory guidance to CCGs in November 2018 to introduce and implement commissioning policies for selected interventions. This guidance includes recommendations for “tonsillectomy for recurrent tonsillitis” and details specific criteria which should be met before surgical procedures to remove the tonsils as a treatment for recurrent sore throats in adults and children are undertaken. Devon CCG already has a policy in place for tonsillectomy. This policy was produced in consultation with local specialists, agreed by CPC, and published in October 2016.

Matt Howard, Clinical Evidence Manager, NHS Devon CCG presented a paper.

The NHS England guidance states that recurring sore throats are a very common condition that presents a large burden on healthcare; they can also impact on a person’s ability to work or attend school. However, not all sore throats are due to tonsillitis and they can be caused by other infections of the throat. In these cases, removing the tonsils will not improve symptoms. NHS England also notes that their guidance should not be applied to other conditions where tonsillectomy should continue to be funded, these include obstructive sleep apnoea/sleep disordered breathing in children, suspected cancer, recurrent quinsy and emergency presentations. NHS England also include a list of conditions in which tonsillectomy should be considered at a lower threshold. Treatment of malignancy and emergency presentations requiring tonsillectomy are out of scope of the current Devon policy. The current Devon CCG

policy indicates that tonsillectomy is routinely commissioned in adults and children for Quinsy; and includes separate, specific commissioning criteria for tonsillectomy for obstructive sleep apnoea syndrome in children under 16. Since the NHS England guidance does not apply to these conditions, any existing Devon policy statements in respect of these conditions have not been reviewed.

NHS England has set goals for a reduction in local activity for this intervention. NHS England expects activity levels for tonsillectomy for recurrent tonsillitis to be reduced to the 25th percentile of all CCGs in England; this represents a reduction in the number of tonsillectomies for recurrent tonsillitis of 7% for the former NEW Devon CCG area (28 fewer procedures per year, from 419 in 2017/18), and 12.5% for the former South Devon and Torbay CCG area (16 fewer procedures per year, from 128 in 2017/18).

The NHS England guidance and the current Devon CCG policy contain almost identical criteria for tonsillectomy for recurrent acute sore throat due to tonsillitis, since they were both based on the recommendations in SIGN Clinical Guideline 117: "Management of sore throat and indications for tonsillectomy". The NHS England guidance also states that there are a number of medical conditions where episodes of tonsillitis can be damaging to health or tonsillectomy is required as part of the on-going management. These conditions were not specifically considered by CPC in 2016.

Local specialists were contacted to seek their views on the clinical implications, the impact on services, and the impact on local activity levels, of adding the additional conditions to the Devon CCG policy. They consider the routine commissioning of tonsillectomy for these conditions to be clinically appropriate, and that this would not significantly affect local activity levels, and particularly not result in the reduction expected by NHS England. Responses from ENT consultants suggested that currently applications would be made to the Individual Funding Request (IFR) panel for exceptional funding of patients with those conditions, however in the 12 months prior to 24th June 2019 the IFR panel had received no such applications for funding.

Feedback from GP referral facilitators indicated that the inclusion of the additional conditions with a lower threshold may slightly increase referrals, but it is not known by how much. Including these conditions in the Devon CCG provides clarity but is not expected to reduce surgical activity.

There is the possibility that activity could increase as a result of this change. Although it has not been possible to reasonably quantify this, it is not expected to be a significant increase.

The committee discussed issues pertinent to the review of the policy for tonsillectomy, including:

- The robustness of the evidence used by NHS England and how the level of reduction set is decided. Some members of the committee suggested that the CCG challenge the NHS England guidance on offering tonsillectomy in certain conditions at a lower threshold expressing concern regarding the remit of the committee to endorse a position for which there is little evidence.
- The possible consequences of not adopting the NHS England guidance and the need have a clear and defensible rationale for not doing so.
- Despite misgivings about the robustness of the evidence for some conditions it was acknowledged that the NHS England guidance had been drawn up in collaboration with the Academy of Medical Royal Colleges, NICE and NHS clinical commissioners and included a period of public consultation.
- If the NHS England guidance were to be adopted there is unlikely to be a reduction in the number of patients treated or change current practice.
- Details of activity levels were tabled at the meeting.

The committee were asked to decide between three options:

- Keep the current CCG policy.

- Accept the NHS England guidance.
- Accept the proposed CCG policy and add clarification that patients should be reviewed by appropriate non-surgical specialists.

The committee voted unanimously in favour of recommending acceptance of the proposed amendments to the CCG's policy for tonsillectomy with the addition of clarification that there should be appropriate review of the indication for surgery by a non-surgical specialist before the surgery is undertaken.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication

6. Continuous glucose monitoring for patients with type 1 diabetes

Continuous glucose monitors (CGMs), 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 (SMBG), or intermittent glucose monitors such as the FreeStyle Libre. The Libre is routinely commissioned in Devon in a number of patient groups, but it 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.

Naomi Scott, Healthcare Evidence Reviewer presented a paper. Dr Becky Smith, Consultant Paediatrician, University Hospitals Plymouth NHS Trust, Dr Neil Walker, Consultant Physician and Dr David McGregor, Consultant Paediatrician, Royal Devon and Exeter NHS Foundation Trust attended the meeting for the discussion.

The paper reviewed evidence of the efficacy of standalone CGM devices in two groups of patients with type 1 diabetes. Firstly, those who have an impaired awareness of hypoglycaemia or have hypoglycaemic unawareness, and have had recent severe hypoglycaemic episodes.

The HypoDe trial provides the most relevant clinical evidence of the efficacy of CGM in patients with an impaired awareness of hypoglycaemia. In the trial patients randomised to receive CGM had a 72% reduction in the occurrence of hypoglycaemic events in comparison to those in the SMBG group. The CGM group had 64% fewer severe hypoglycaemic episodes requiring any third-party assistance and 74% fewer severe hypoglycaemic episodes requiring third party assistance but not requiring medical intervention than the SMBG group. No significant differences were found in hypoglycaemia unawareness, hypoglycaemia fear, diabetes distress, HbA1c or quality of life.

No cost-effectiveness publications were identified which assessed the use of CGM in patients with impaired awareness of hypoglycaemia from a UK NHS perspective. Estimations of cost-effectiveness suggested values that were within the ranges previously used by NICE and All Wales when considering other interventions for type 1 diabetes. The annual cost of CGM per patient ranges from £2,670 to £3,470. This can be partially offset against a reduced need for SMBG testing and medical interventions for hypoglycaemic episodes.

There is considerable uncertainty regarding the number of adults in Devon who will fulfil this criterion. Estimates from a variety of sources range from 15 to 324 patients. Assuming all patients are given the cheapest CGM device and maximal savings are made against SMBG testing and medical interventions the budget impact of this ranges from £19,000 to £410,000 depending on the number of patients.

The second patient group considered were those who are incapable of self-management of their diabetes and have an inability to recognise, or communicate about, symptoms of hypoglycaemia. It is expected that patients will be reviewed at regular intervals so that patients who develop the ability to self-manage their diabetes and hypoglycaemia are stepped down from CGM therapy.

A search to identify evidence of CGM in patients who have an inability to recognise symptoms of hypoglycaemia identified one pilot study which suggests that CGM can be used in young children with high parental satisfaction, but that compliance may be an issue and that it does not exclude the possibility of severe hypoglycaemia occurring.

No cost-effectiveness publications were identified which assessed the use of CGM in this patient group. Local specialists estimate that there are 34 patients in Devon who would meet this criteria, commissioning CGM in these patients has a potential financial impact between £62,000 and £106,000 depending on the CGM device and the testing strips used. The annual incidence of new patients is not known.

The committee discussed issues pertinent to continuous glucose monitoring for patients with type 1 diabetes including:

- Specialists attending stated that hypoglycaemia was a significant fear for patients and the parents of children with type 1 diabetes. Specialists stated after repeated hypoglycaemic episodes over time the body adjusts and the warning signs of hypoglycaemia are not apparent to the patient. Help from others is then required to avoid the condition of the patient becoming life threatening.
- The routine commissioning of CGM was being sought for two patient groups; those who have an impaired awareness of hypoglycaemia or have hypoglycaemia unawareness, and have had recent severe hypoglycaemic episodes; and those who are incapable of self-management of their diabetes and have an inability to recognise, or communicate about, symptoms of hypoglycaemia. The second group are mainly paediatric patients, there is no requirement for these patients to have had a severe hypoglycaemic episode. Specialist opinion stated that this would 'be a step too far for parents'.
- Hypoglycaemia is difficult to predict in pre-school age children, as they may not be able to communicate their symptoms. Learning and concentration can be affected for up to two hours following the hypoglycaemic episode. The implications and the impact of severe hypoglycaemia on brain development is unknown.
- The number of patients that will fulfil the proposed criteria is subject to uncertainty. Specialists considered that estimates in the lower range of that presented were more likely to reflect actual usage and therefore costs, that is between 15-17 patients in the adult population and around 34 in paediatrics.
- Specialists indicated that CGM is superior to the FreeStyle Libre device. The FreeStyle Libre Device gives only a single beep or buzz if the patient goes out of range. It is more to get people to test themselves rather than alert them to the fact that they are becoming hyperglycaemic. CGM has a constant alarm until the patient responds.
- The HypoDE trial did not show a reduction in severe hypoglycaemia, however this was a less severely affected patient group to that being considered. It was suggested that there must be agreement that patients will be reviewed after six months, if no benefit is shown CGM will be stopped. Specialist opinion was that patients generally do benefit. It was agreed that continuation criteria be worked up outside of the meeting by the CCG clinical effectiveness team in liaison with the specialists.
- Specialists present stated that patients who were unsuccessful with CGM may require a transplant. Currently they feel there is a perverse situation whereby it is easier for patients to get a transplant than a monitor.
- It was suggested that reference to 'parents' in the policy be amended to state 'parents and carers'.

The committee were asked to make recommendations on the CGM devices in patients with type 1 diabetes who:

- Have an impaired awareness of hypoglycaemia OR have hypoglycaemia unawareness (defined using the GOLD or Clarke hypoglycaemia unawareness scales) PLUS recent episodes of severe hypoglycaemia (have experienced two or more severe hypoglycaemic episodes within 12 months where they have been unable to take oral treatments).

The committee voted unanimously in favour of recommending CGM devices for this patient group.

- Are incapable of self-management of their diabetes and have an inability to recognise, or communicate about, symptoms of hypoglycaemia.

The committee voted unanimously in favour of recommending CGM devices for this patient group.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication

The committee thanked the specialists for attending the meeting and Naomi Scott for her work in producing the meeting papers.

7. Update from Clinical Policy Engagement and Consultation Panel

The committee received an update from the Clinical Policy Engagement and Consultation Panel meeting which took place on Tuesday 9th July.

Charlotte Burrows and Carol McCormick-Hole had been welcomed as new members of the panel.

The panel had agreed one action related to the review of the policy for Surgery for carpal tunnel syndrome. This was that 'DRSS be advised of the need for clinical referral guidance to be updated in respect of carpal tunnel syndrome and for appropriate referral messages reiterated with communication of this policy'.

8. Any other business

Jo Roberts was thanked for the leadership he had provided to the committee since its inception in 2013 and the committee wished him well.

Summary of actions		
	Action	Lead
19/11	<i>Review: Policy for Dupuytren's contracture treatment – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</i> This policy is awaiting CCG sign-off.	Rebecca Heayn
19/12	<i>Review: Policy for surgery for carpal tunnel syndrome – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</i> This policy is awaiting CCG sign-off.	Rebecca Heayn
19/13	<i>Review: Policy for surgery for ganglion cyst – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</i> This policy is awaiting CCG sign-off.	Rebecca Heayn
19/17	Glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/18	Review: Policies for myringotomy - Policy recommendations and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/19	Review: Policy for tonsillectomy - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/20	Continuous glucose monitoring for patients with type 1 diabetes - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn