Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee (CPC)
Minutes

Wednesday 20th July 2016, 9.30 am to 12.30

Committee Suite, County Hall, Exeter

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker*	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Miles Earl	Contract Accountant	NEW Devon CCG
Paul Foster	Chief Pharmacist	Torbay & South Devon NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Mark Kealy	Consultant in Public Health	Devon County Council
Tracey Kerslake	Contracts Manager	South Devon and Torbay CCG
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Glenn Matfin	Consultant in Diabetes and Endocrinology	Plymouth Hospitals Trust
Dr Phil Melluish*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Chris Roome*	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Beverley Parker	Head of Planned Care	South Devon and Torbay CCG
Louise Crathorne	Clinical Evidence Scientist	NEW Devon CCG
Ioannis Dimitropoulos**	Consultant in Diabetes, Endocrinology & General Internal Medicine	Plymouth Hospitals NHS Trust
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
James Rainsbury	Consultant ENT Manager	Plymouth Hospitals NHS Trust
Carol Webb	Joint Formularies Technician	NEW Devon CCG

In attendance:

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

* Denotes voting members
** Denotes joined the meeting by teleconference

1. Welcome and announcements

Apologies

Jono Broad	Lay Member	
Dr Andrew Gunatilleke	Secondary Care Clinician	Torbay & South Devon NHS FT
Dr Peter Leman	GP Clinical Commissioner	NEW Devon CCG
Dr Ben Waterfall	GP Clinical Commissioner	NEW Devon CCG
Dr Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG

Dr Peter Leman had deputised voting to Chris Roome.

Dr Ben Waterfall had deputised voting to Richard Croker.

Confirmation of voting members and Declarations of Interest

The seven voting members present were identified.

Declarations of Interest forms were collected. The Chair reviewed the Declarations of Interest forms. It was noted that Dr Glenn Matfin had been an investigator for dulaglutide pen and was an author on a paper in 2013/2014. It was agreed appropriate that he could remain in the meeting but should not take part in the discussion for that agenda item.

All Declarations of Interest are reported in the minutes.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Dulaglutide for the treatment of type 2 diabetes (Trulicity®)	**Eli Lilly and Company Limited**
Alternative treatments: **Exenatide standard-release** (Byetta®) **Exenatide modified-release** (Bydureon®) **Liraglutide** (Victoza® and non-proprietary) **Lixisenatide** (Lyxumia®)	 **AstraZeneca UK Limited** **AstraZeneca UK Limited** **Novo Nordisk Ltd**; various manufacturers **Sanofi**
Myringotomy with or without ventilation tubes (grommets) in adults and children Alternative treatments: **Hearing aids**	Would benefit from private provision of myringotomy/grommets, adenoidectomy or alternative treatments for otitis media, Ménière's disease, sudden sensorineural hearing loss, etc.
Tonsillectomy Alternative treatments: **Continuous positive airway pressure (CPAP)**	Would benefit from private provision of adeno/tonsillectomy; manufacturers of CPAP devices

NAME OF ATTENDEE	ROLE	
Louise Crathorne	Clinical Evidence Scientist	*Work as a paid advisor to above pharmaceutical/manufacturing company/companies.* Previously provided advice on systemic review methodology; EG for HTA marketing materials. (Value dossiers). *Hospitality received where the drug(s) device(s) intervention(s) under consideration where discussed by a representative of a drug/manufacturing company/companies.* Presented on methods and company sponsored seminars where buffet lunch was provided. No projects undertaken related to any of the topics listed on agenda for July CPC.

Matt Howard	Clinical Evidence Manager	*Hospitality received where the drug(s) device(s) intervention(s) under consideration where discussed by a representative of a drug/manufacturing company/companies* In previous post, attended various CPD events where hospitality/refreshments etc may have been sponsored by various manufacturers.
Dr Glen Maftin	Consultant in Diabetes and Endocrinology	Had been an investigator for dulaglutide pen and was an author on a paper in 2013/2014.
Dr Ali Round	GP Clinical Commissioner	*Any other family or business interests (including personal or family medical conditions) which could be seen as influencing view of the drug(s)/intervention treatment under consideration.* Spouse has hearing impairment

Notification of Any other Business

Members were asked if they had any items of AOB to discuss.

2. Minutes of the meeting held on 20th April 2016 and matters/actions arising

The minutes of the meeting held on 20th April were approved.

Summary of actions		
	Action	**Lead**
16/02	*Policy recommendation and QEIA for Tadalafil (Cialis®) 5mg tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males to be prepared and subsequently processed to final CCG approval and communication* The policy recommendation and QEIA have been submitted to the CCGs' executive groups of both South Devon and Torbay CCG and NEW Devon CCG for approval at their meetings in April and May respectively. The policy has been published. Action complete.	
16/03	Insulin Degludec 100units/ml (Tresiba®) for use in patients with type 1 diabetes. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. The policy has been published. Action complete.	

16/04	Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. The policy has been published. Action complete.	
16/05	Clinical Policy Committee annual report to be submitted to the appropriate bodies of the Clinical Commissioning Groups to be received and ratified. Action complete	
16/06	Ratified annual report to be published and made publically available via the CCG website. Action complete	

3. Dulaglutide (Trulicity®) for the treatment of type 2 diabetes

A formulary application has been received for Trulicity for use in the treatment of type 2 diabetes. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented an evidence review. Dr Ioannis Dimitropoulos, Consultant in Diabetes, Endocrinology and General Internal Medicine, Plymouth Hospitals NHS Trust joined the meeting by teleconference for the discussion of this item.

Trulicity contains dulaglutide, a recently licensed long-acting GLP-1RA that is administered once weekly via a ready-to-use fixed dose pen. Dulaglutide is licensed at two doses. These are 0.75mg once weekly as monotherapy when diet and exercise alone have not proved successful, and for patients in whom metformin is not tolerated or contraindicated, (or as initiation dose for add-on therapy in frail patients) and 1.5mg once weekly as an add-on therapy in combination with other glucose-lowering agents, including insulin, when these, together with diet and exercise have failed to provide glycaemic control.

The application was made for the licensed indications, but to be used as described in NICE clinical guideline CG87 on type 2 diabetes. NICE guideline NG28 on the management of Type 2 diabetes in adults, has subsequently been published. This supersedes and replaces NICE CG87. NG28 places GLP-1RAs as an alternative to insulin therapy, only after the failure, intolerance or contraindication to standard triple therapy of metformin and two other antidiabetic medicines. Dulaglutide is therefore being assessed in line with NG28; only as part of triple therapy with metformin and a sulfonylurea.

Dulaglutide is the fourth drug in this class to receive a UK licence, the other three GLP-1RAs; exenatide, liraglutide, and lixisenatide; are all included in the Devon joint formularies. Two NICE technology appraisals (TAs) relating to Exenatide and Liraglutide have been replaced by NG28 and as such are no longer mandatory.

A literature search was carried out. Efficacy data comes from an extensive programme of randomised controlled trials (RCTs) evaluating efficacy in a range of different combinations, against different comparators. Three of these trials are relevant to the proposed place in therapy of dulaglutide consistent with UK guidelines; however there are some limitations in the precise combinations studied. The trials were designed to demonstrate non-inferiority, or superiority, of dulaglutide versus placebo or comparator with respect to change in HbA1c from baseline to the end of the trial period. In this regard, dulaglutide has been shown to be superior to twice daily exenatide when used in triple therapy regimes with metformin and pioglitazone, superior to insulin glargine when used in triple therapy regimes with metformin and a sulphonylurea and non-inferior to the higher strength of liraglutide in dual therapy with metformin.

In terms of drug acquisition costs, dulaglutide costs more than twice daily exenatide and lixisenatide, about the same as liraglutide 1.2mg and weekly exenatide; and is cheaper than liraglutide 1.8mg. In addition to drug costs the small cost of needles should be considered. The analyses take these into account. Cost-effectiveness analyses found that dulaglutide produces more quality adjusted life years (QALYs) at lower cost than the comparators in a base case analysis. This assumes a treatment duration of 2 years on GLP-1RA after which time insulin is started. The differences in costs and QALYS are small. Where a longer duration of treatment is assumed, dulaglutide becomes more costly but accrues more QALYs resulting in incremental cost ratios (ICERs) that would generally be considered cost-effective. With some comparators being more costly, and some being cheaper than dulaglutide, there is potential for increased or reduced expenditure on this drug class. The manufacturer's budget impact model predicts a small cost saving of around £20,000 per year for NEW Devon and £6,000 for South Devon and Torbay CCG. Because of the low use of the cheapest drug in class in both CCGs, the potential for increased expenditure is low. However, the use of dulaglutide instead of lixisenatide in place of the other two agents would generate less cost reduction.

The committee discussed a number of issues pertinent to this recommendation:

- Local specialist opinion is that dulaglutide provides additional benefits for some patients over other treatments.
- Dulaglutide
  - may be easier for patients to use than the alternative once weekly treatment;
  - is licenced for use with insulin whereas the alternative once weekly GLP-1RA (Bydureon) is not, although the alternative may be prescribed off licence for use with insulin if the patient is fully informed and consents;
- Trials have shown dulaglutide is non-inferior or superior to other relevant treatments for reduction of HbA1c.
- Models suggest patients treated with dulaglutide may have a small decrease in cardiovascular and all outcome mortality compared to lixisenatide.

The committee voted unanimously in favour of recommending Dulaglutide (Trulicity®) for the treatment of type 2 diabetes.

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

4. Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years

As part of work being undertaken to align commissioning policies across Devon consideration has been given to myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media.

In 2007, NHS Devon produced treatment guidance for Myringotomy and grommets as a procedure of limited clinical effectiveness. Torbay Care Trust produced a policy for Myringotomy and grommets in children and adults in April 2011.

2014/15 data from the Royal College of Surgeons Procedures Explorer Tool indicate that directly standardised activity rates (DSR) per 100,000 population for childhood hearing loss for both NEW Devon CCG and South Devon and Torbay (SD&T) CCG were more than three standard deviations higher than the national mean. This indicates that DSR were much higher than would be expected by chance. NEW Devon CCG had the highest DSR in England (98% higher than the national mean), South Devon and Torbay ranked 18th highest in England (53% higher than national mean). Ear, Nose and Throat (ENT) consultants across Devon were contacted to seek their comments on a proposed Devon-wide policy for myringotomy with or without grommets. The consultation process for the policy included GP Clinical Leads and GP Referral Facilitators working for the Devon Referral Support Services (DRSS). During consultation it became apparent that separate policies would be more suitable; these are **(a)** one for children under 12 years; and **(b)** one for adults and children aged 12 years and older. A proposed policy for adults and children aged 12 years and older is considered as item 5 of the minutes.

Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years

Matt Howard, Clinical Evidence Manager, NEW Devon CCG, presented a draft policy. Mr James Rainsbury, Consultant ENT Surgeon, Plymouth Hospital NHS Trust participated in the discussion of this item.

The proposed policy is in line with NICE clinical guideline CG60 (2008); local specialists are in agreement with the content therein with the exception of the NICE recommendation in respect of adjuvant adenoidectomy. NICE CG60 states that "*Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms*." Local specialists indicated that the evidence base had moved on since the publication of the NICE guideline, and that adjuvant adenoidectomy provided additional benefits over grommets alone. When discussing research recommendations, NICE CG60 identified a need for good quality RCTs documenting the adjuvant effect of adenoidectomy, and made some specific recommendations regarding the design of such trials.

The TARGET trial (2012) directly addresses some of these recommendations. This trial found a statistically significant improvement in hearing at 3 to 6 months compared to watchful waiting for both grommets; and grommets plus adenoidectomy; there was no statistically significant difference between surgical groups. At 12 months and beyond, adenoidectomy plus grommets produced a continued benefit to hearing levels whereas there was no significant difference between grommets and watchful waiting. The data suggest an additional benefit to hearing over months 12 to 24 of 4.2 decibels (dB) in favour of adjuvant adenoidectomy. TARGET also reported a significantly reduced rate of revision surgery in patients who underwent grommets plus adenoidectomy compared to those who received grommets only; 9% vs 30%. Meta-analyses of grommet reinsertion rates from up to 72,000 children from five RCTs and five retrospective studies also reported reduced reinsertion rates (absolute risk reduction between 13.7% and 15.5% depending on analysis). These analyses did not include data from the TARGET trial, despite it having been published at the time. The Clinical Effectiveness team contacted the corresponding author to see if TARGET had been excluded for a specific reason; the author indicated that TARGET was missed in error, it should have been included in their analyses, and would have strengthened their conclusions.

To examine this, the Clinical Effectiveness team extracted data from the five RCTs included in the analysis plus TARGET and produced a meta-analysis of mean reinsertion rates from pooled data from 1,139 children from six RCTs. This showed a stronger result in favour of adjuvant adenoidectomy; a widening of the difference between point estimates and a narrowing of the confidence intervals. The absolute risk reduction was 15.9%. The beneficial effect of adenoidectomy on reinsertion rates is expected to be seen beyond one year; if any trials which do not report data beyond one year are excluded the best estimate is a difference of 16.4%, with confidence intervals from fractionally above zero to 32.7%. Trials included have not been individually critically appraised by the Clinical Effectiveness team. Clinical heterogeneity, variation in study methodology and endpoint reporting, and differences in study duration are likely to result in these wide confidence intervals.

An analysis of pooled data from 10 RCTs investigating failure of treatment reported significant benefits for adjuvant adenoidectomy plus grommets over grommets alone: **(a)** a significantly reduced failure rate at 12 months **(b)** a significant reduction in additional surgery rates from 6 to 24 months, **(c)** a higher proportion of children with a hearing benefit in excess of 10 dB.

NICE CG60 contains an economic analysis which found that grommets plus adjuvant adenoidectomy was not cost effective at a willingness to pay threshold of £20,000 per QALY, compared to grommets alone in the base case analysis; but was considered so under certain plausible scenarios in sensitivity analysis. The additional efficacy data, published following NICE, report greater differences in reinsertion rates than NICE assumed and an improvement in hearing levels which NICE did not assume. The impact of these research findings provides an even stronger economic case than the most cost effective of the scenarios assumed by NICE. Grommets plus adjuvant adenoidectomy are less costly and more effective than a policy of ventilation tube insertion alone, and would therefore be considered cost effective. If the directly standardised rates as per RCS procedures explorer tool for the two CCGs in Devon were in line

with the national mean, this would represent approximately 290 fewer procedures for NEW Devon CCG; and 48 fewer for South Devon and Torbay CCG. The resulting reduction in activity would release almost £196,000 for investment in other treatments or services across Devon (approx. £168,000 in NEW Devon CCG and approx. £28,000 in South Devon and Torbay CCG). However, local specialists have stated that they are currently providing a service for this patient group in line with NICE CG60, and therefore in line with the proposed policy. It is unclear therefore whether a policy in line with NICE CG60 is likely to result in a reduction in activity. Data from RCTs suggest adjuvant adenoidectomy reduces grommet reinsertion rates and has the potential to reduce activity, but at an increased expense overall.

It was not possible to identify validated grommet re-insertion rates for NEW Devon, and South Devon and Torbay CCGs; so an analysis was conducted to estimate the budget impact of routinely commissioning adjuvant adenoidectomy under a number of broad assumptions. For NEW Devon CCG, for an annual cohort of 376 children; the analysis suggested a reduction in grommet re-insertions, but the additional cost of adjuvant adenoidectomy resulted in a net increase in annual expenditure of approximately £116,773 in the first year and approx. £89,163 per year from year two onwards. For South Devon and Torbay CCG, for an annual cohort of 86 children; the analysis suggested a net increase in annual expenditure of approximately £26,733 in the first year and approx. £20,442 per year from year two onwards. It is not known how rates are affected beyond two years; and this simple calculation does not include the costs associated with current adenoidectomy activity; re-presentation at GP; or repeated audiology appointments associated with reinsertion; as such is likely to be an overestimation.

Any reduction in risk of re-insertion produces benefits for the individual patient, as well as releasing capacity in ENT services across Devon.

The committee discussed a number of issues pertinent to this policy recommendation:

- Benefits - the QALY gains in the NICE guideline considered hearing level changes only however, specialists cite additional benefits to children. The child's hearing level is assessed against adult hearing but a young child should have better hearing than an adult and this is regarded as "normal" for development. A committee member questioned the robustness of the evidence for these softer developmental outcomes, particularly in children with hearing level <20dBHL. Specialist opinion indicated that not providing grommets to children would be a massive disservice to them. Children with reduced hearing may have delayed speech and be held back at school. There are also upper respiratory tract benefits with fewer infections after adenoidectomy. Alternatives would be in-ear hearing aids or a headband worn aid.
- Risks – all interventions have potential for harm and have costs associated with them. Fitting grommets can result in scarring that may have a longer term impact. It was suggested that treated children may have better hearing for a few years compared to adults but worse hearing when they are older due to side effects of the treatment. Specialist opinion indicated that it is difficult to know whether scarring is a side effect of the intervention or results from glue ear. Grommets are low risk compared to doing nothing.
- Cost - across Devon the upper estimate of the cost of adjuvant adenoidectomy would be approximately £140,000 in the first year and £110,000 thereafter. This assumes that all children have an adenoidectomy in the future and does not include the offset costs of fewer GP appointments or other interventions; it is therefore likely to be an overestimate.
- Not all patients having grommets would undergo adenoidectomy. This is usually undertaken if patients require a second treatment with grommets or for those with respiratory infections. It is good practice to remove the adenoids in a patient with recurrent glue ear.
- When writing the draft policy the Clinical Effectiveness team reviewed the policies in place at other CCGs. Generally those policies state that they commission in line with NICE guidance or reproduce the NICE wording.
- Some concern was expressed that local rates of grommet insertion are twice the national rate. Local specialist opinion was that the data are not correct and that an audit was needed to understand the true picture.

The committee were asked to make two decisions as follows:

The committee voted 6 to 1 in favour of recommending the commissioning policy for Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years.

The committee voted 4 to 3 in favour of the routine commissioning of adenoidectomy.

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

5. Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older

Matt Howard, Clinical Evidence Manager, NEW Devon CCG, presented a draft policy. James Rainsbury, Consultant ENT Surgeon, Plymouth Hospital NHS Trust participated in the discussion of this item.

In adults, myringotomy with or without grommets is a procedure used for a number of indications, including use to improve drainage in hearing loss due to otitis media with effusion (OME), the most common indication for the procedure across both adults and children.

There is an absence of RCTs assessing the efficacy of grommets versus watchful waiting or alternative treatments in adults with OME. Observational data in the form of prospective case series demonstrate improvements in hearing in adult patients with OME, which is broadly consistent with evidence in children under 12 years with OME. Follow up is short and limited. One report showed a mean hearing gain in excess of 10 dB in nearly 60% of patients following grommet insertion. Another reported a mean improvement in hearing of 13.3 dB following grommet insertion. Hearing gains in excess of 5 dB were reported in over 75% of ears following insertion of grommet in a third series. RCT data support myringotomy for intratympanic administration of medicines for vertigo or as salvage therapy for sudden sensorineural hearing loss. Cochrane reviews report a statistically significant reduction in vertigo following intratympanic gentamicin versus placebo; and for intratympanic dexamethasone versus placebo. Meta-analysis was not possible due to heterogeneity. Meta-analysis of RCT data demonstrated a significant reduction in hearing thresholds – that is a greater improvement in hearing – in patients with sudden sensorineural hearing loss who received intratympanic steroids as salvage therapy following failed systemic steroid treatment versus no further treatment. This is supported by meta-analyses of data from additional RCTs and lower quality studies which reported statistically significant benefit of IT steroids as salvage therapy.

There is an absence of cost-effectiveness studies of myringotomy with or without ventilation tubes in adults for any indication; published utility values or quality of life outcome changes that could be used to generate utility value changes associated with myringotomy with or without ventilation tubes in adults for any indication could not be identified. A health economic model developed by NICE indicated that insertion of ventilation tubes was considered a cost-effective treatment option in children under 12 years with OME. However, it is not known whether the results of the model are applicable to adults and children aged over 12 years with OME. Current annual expenditure on myringotomy with or without grommets for NEW Devon CCG is estimated to be approximately £93,000; and approximately £46,000 for South Devon and Torbay CCG. Benchmarking data are not available for regional or national comparison of standardised activity rates of myringotomy with/without grommets in adults and children aged over 16 years. The proposed policy is broadly in line with the stated practice of local specialists; whilst data sources do not allow validation of this, it is anticipated that there will not be a significant impact on activity rates or costs on the introduction of this policy. The proposed policy ensures consistency across Devon and is broadly in line with the NHS England Interim Commissioning Policy for grommets; and the policies of other CCGs in the region.

The committee discussed a number of issues pertinent to this policy recommendation:

- Some children grow up with glue ear; their symptoms may fluctuate but will be there most of the time. Hearing aids have usually been tried.
- Some patients get glue ear as a result of flying or diving which does not subside with medication. For these patients the symptoms do not return following myringotomy.
- There are a few patients who experience symptoms due to malignancy at the base of the eustachian tube.

The committee voted unanimously in favour of recommending myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older.

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

6. Tonsillectomy

As part of the work being undertaken to align commissioning policies across Devon consideration has been given to tonsillectomy. NHS Plymouth produced a "procedures of limited clinical effectiveness" guidance document in 2010 which includes tonsillectomy; Torbay and Devon approved separate tonsillectomy commissioning policies in 2011. It is not expected that the proposed policy will have a significant impact on activity levels. Matt Howard, Clinical Evidence Manager, NEW Devon CCG, presented a draft policy. Mr James Rainsbury, Consultant ENT Surgeon, Plymouth Hospital NHS Trust participated in the discussion of this item.

Indications for Tonsillectomy include for recurrent tonsillitis, peritonsillar abscess, tonsillar hypertrophy causing sleep apnoea, and suspected malignancy. Peritonsillar abscess is a rare and potentially serious acute complication of tonsillitis requiring prompt intervention. The evidence for the benefits of tonsillectomy in recurrent tonsillitis and sleep apnoea was reviewed.

Between one and three percent of primary school children are estimated to suffer from obstructive sleep apnoea (OSA); a condition where the walls of the throat relax and narrow during sleep, interrupting normal breathing. In most patients with moderate or severe OSA, a continuous positive airway pressure (CPAP) device is considered first line treatment. CPAP is a small pump that delivers a continuous supply of compressed air through a mask that covers the nose; or nose and mouth; the compressed air prevents the throat from closing. Patients are likely to require life-long treatment, and poor compliance is common. Since hypertrophy of the tonsils and adenoid tissue is thought to be the commonest cause of OSA in children; tonsillectomy may be indicated.

The frequency of sore throat episodes and upper respiratory infections reduces with time whether or not tonsillectomy has been performed. There is moderate quality evidence from randomised controlled trials (RCTs) that for patients with chronic or recurrent acute tonsillitis, tonsillectomy offers small clinical benefits compared with non-surgical treatment. Compared with watchful waiting, tonsillectomy produces a reduction in sore throat episodes, days of sore throat associated school absence, and upper respiratory infections. In otherwise healthy children with mild to moderate obstructive sleep apnoea, there is moderate quality evidence from RCTs that adenotonsillectomy provides benefit in terms of quality of life, symptoms, and behaviour as reported by the child's caregiver. Resolution rates based on normalisation of sleep studies were 79% in the surgery group and 46% in the watchful waiting group. This is supported by meta-analyses of lower quality data. In the same patient group, high quality evidence indicates tonsillectomy provides no benefit over watchful waiting in terms of objective measures of attention or neurocognitive performance. A national prospective tonsillectomy audit in the UK reported the risk of haemorrhage following tonsillectomy to be in the region of three to four percent, the risk of return to theatre as a result was approximately one percent. Other, complications include pain, infection, and risks associated with general anaesthetic.

No published cost effectiveness analyses of tonsillectomy could be located. The current average cost per procedure is approximately £1,136. Limited pre- and post-operative data from a prospective case series of 41 patients undergoing tonsillectomy for a minimum of 5 episodes of recurrent tonsillitis allowed mapping of SF-36 quality of life scores to EQ-5D utility values. This suggests pre-operative utilities of 0.79 for patients awaiting operation and 0.92 for patients 1 year post-operatively; a difference of 0.13. Utility changes for a comparator group managed with watchful waiting could not be located. Using the utility values derived, the clinical effectiveness team conducted a number of simple threshold analyses to investigate the cost-effectiveness of tonsillectomy compared with watchful waiting. These data suggest tonsillectomy is likely to be considered cost effective at usual thresholds. Local activity data show 750 tonsillectomy procedures for all indications in the financial year 2014/15, in NEW

Devon CCG at a total cost of £851,849. For South Devon and Torbay CCG, in 2014/15, 239 procedures were recorded totalling £275,466.

The purpose of the proposed Devon-wide policy is to harmonise existing policies and ensure consistency going forward; it is not expected that the proposed policy will have a significant impact on activity levels if current practice is in line with the criteria stated in existing policies.

The committee discussed issues pertinent to this policy recommendation:

- The draft policy identifies a strong clinical history suggestive of sleep apnoea as a criterion for tonsillectomy. However polysomnography would provide a more objective diagnosis but access to this is very limited both locally and nationally. A small number of local children are investigated in Bristol.
- Local specialists are operating to working practice guidelines on the basis of the best evidence available. Working practice guidelines provide guidance on which children to investigate but do not identify children with sleep apnoea. Local specialist opinion indicated that polysomnography is useful, however it is expensive. Usually parents show a video of their child asleep to specialists to demonstrate night time symptoms.
- The trials available were carried out in children who have undergone polysomnography.

The committee voted unanimously in favour of recommending the commissioning policy for tonsillectomy.

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

7. Update on discussions of policy access criteria for Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm

At the Clinical Policy Committee meeting in September 2015 it had been agreed that Matt Howard, Clinical Evidence Manager, NEW Devon CCG would work with local consultants to agree access criteria for botulinum toxin A for the management of blepharospasm and for the management of hemifacial spasm which capture the functional limitations consistent with the position the CCGs adopt in relation to other conditions.

However, it had not been possible to meet with specialists from each local trust. Daniel Byles, Consultant Ophthalmologist at RD&E NHS FT agreed to meet with Matt on behalf of the consultants and feed back to them on the discussion. This meeting had taken place on 7th June 2016.

At the meeting the access criteria in policies for other conditions had been considered. Following the meeting a draft policy had been written and sent to Daniel Byles. A response is awaited.

8. Joint Formularies Annual Report 2015-16

Carol Webb, Joint Formularies Technician, NEW Devon CCG presented the Devon Formularies Interface Groups Annual Report 2015 - 2016. The aim of the report was to highlight the work undertaken by the North and East Devon Formulary Interface Group and the South and West Devon Formulary Interface Group for April 2015 to March 2016.

The aim of the Devon Formularies is to promote prescribing which is safe, clinically appropriate and cost-effective in both primary and secondary care, providing guidance on locally recommended drug choices. The Formularies are delivered through the Formulary Interface Groups (FIGs) which reflect natural healthcare communities. Representatives from both primary and secondary care sit on each FIG.

The report provides a comprehensive account of the work of the Devon FIGs:

- In the year, each FIG met 6 times.
- A bi-monthly virtual eFIG process has been introduced to be run in the months when FIG meetings do not take place.

- Developments include the inclusion of some biological (biosimilar) medicines into the formulary. The addition of a palliative care chapter to the North and East Devon formulary and the inclusion of stoma work in the South and West Devon formulary.
- The publication of new or revised national guidance has prompted review of a number of chapters and sections in both formularies.
- Forty-one NICE TAs and one HST have been added to the formularies.
- After approval by the Clinical Policy Committee and the CCGs the FIG consults with appropriate clinicians to position the drug entry within the formularies. Four such decisions took place.
- Nineteen new product applications were received.
- The FIGs approved the inclusion of 11 formulary preferred brands. The brands had been identified by the Medicines Optimisation teams and underwent a standardised assessment of key criteria.
- The Devon Formularies each have a website which is geographically tailored to reflect the decisions of the FIGs. These sites are available on a single app. The Devon Formulary App was launched in March 2015. It has been downloaded 2157 times to different mobile devices. The App was shortlisted as a finalist in the 2015 HSJ Award.
- At the end of September 2015 to mid-January 2016 a survey was conducted of all potential users of the formulary websites and app. 175 people completed the survey.

The committee discussed a number of issues pertinent to the annual report:

- It was noted that under the previous NHS organisations four formularies had existed. These had successfully been merged into two formularies. It was suggested that consideration be given to merging these into a pan Devon formulary.
- Merging the current formularies would provide operational benefits. The possibility of having one committee overseeing two formularies targeted to distinct geographical areas of Devon has been raised and could be explored again. There may be logistical issues with regard to meeting venues.
- It is important that people remain engaged in the formularies. No consultant from Plymouth Hospitals Trust had been present at a FIG meeting for six months. It was suggested that the four Drug and Therapeutic chairs could be regular attendees and that consultants could be asked to attend as required. It was noted that trust job plans determine consultants' time allocations. Trusts regard this as the norm and if a clinical list is cancelled another has to be set up making consultant attendance at formulary meetings increasingly difficult.
- The antimicrobial stewardship group at the RD&E have set up their own app. However a robust link with the Devon Formularies has been established.

9. Update from NICE Planning, Quality and Assurance Group (NPAG)

The committee received an update from the NPAG meeting that had taken place on 3rd May 2016.

The NPAG Annual Report has been submitted to the Quality Committees of both NEW Devon CCG and South Devon and Torbay CCG. Engagement with NPAG by a number of key areas in the each of the Devon CCGs has been limited. This has been noted and work is being undertaken to identify the future role and format of the group. The agendas have been reformatted and now include the area of work to which each item links. The agenda items discussed fit better with the commissioning control centres than with the Success Regime.

Much of the guidance considered at the meeting held on 3rd May is commissioned by NHS England and is non-controversial.

The group had considered five pieces of NICE Technology Appraisal guidance, four NICE Guidelines, one Clinical Guideline, two pieces of Diagnostic Guidance, one piece of Medical Technology Guidance and seven pieces of Interventional Procedures Guidance.

10. Clinical Policy Engagement & Consultation Panel Annual Report 2015-16

Rebecca Heayn, Clinical Governance Manager, NEW Devon CCG presented the Clinical Policy Engagement and Consultation Panel Annual Report 2015-16.

The Clinical Policy Engagement and Consultation Panel is a lay member led panel that routinely considers the wider public interest issues relating to a commissioning recommendation made by the Clinical Policy Committee. The panel determine the need for any further engagement or formal public consultation. Five meetings were convened in 2015/6 at which thirteen policy recommendations were considered. None of the recommendations raised any public interest concerns.

Clinical policy patient support information is developed to provide clarity for patients, the public and staff about why and how a decision has been taken. In year this has been produce for 4 policies:

- Benign skin and subcutaneous lesions – removal
- Cataract surgery
- Haemorrhoids (piles) – referral and specialist management
- Hernia – surgical repair

The Clinical Policy and Engagement & Consultation Panel Annual Report 2015-16 has been presented to the Patient and Public Engagement Committee, NEW Devon CCG and both the Engagement and the Commissioning and Finance Committee, South Devon and Torbay CCG.

All documentation is available on the CCG website with the Clinical Policy Committee information.

11. Update from Clinical Policy Engagement and Consultation Panel

The committee received the minutes of the Clinical Policy Engagement and Consultation Panel meeting which took place on Wednesday 11th May 2016.

It was reported that:

- Jenny Willmott has joined the group as the new Governing Body lay member Patient and Public Engagement Committee, NEW Devon CCG.
- The group had considered two policy recommendations from the Clinical Policy Committee meeting held on 20th April 2016 and agreed that no action was required.

12. Any other business

There was no other business to report.

Meeting closed at 12 noon

Summary of actions		
	Action	**Lead**
16/07	Policy recommendation and QEIA for Dulaglutide (Trulicity®) for the treatment of type 2 diabetes to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/08	Policy recommendation and QEIA for Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/09	Policy recommendation and QEIA for Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/10	Policy recommendation and QEIA for Tonsillectomy to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn