NHS
Devon
Clinical Commissioning Group

Clinical Policy Committee

MINUTES

Wednesday 20th November 2019

Committee Suite, County Hall, Exeter EX2 4QD

Present:

Dr Nick D'Arcy	Chair	NHS Devon CCG
Dr Glen Allaway	Voting Member	NHS Devon CCG
Dr Andrew Craig	Voting Member	NHS Devon CCG
Paul Foster	Clinical Director of Pharmacy and Prescribing	T&SD NHS FT
Dr Lucy Harris	Voting Member	NHS Devon CCG
Dr Andrew Harrison	Voting Member	NHS Devon CCG
Dr Claire Hooper	Voting Member	NHS Devon CCG
Barbara Jones	Head of Contracting	NHS Devon CCG
Dr Paul Melling	Voting Member	NHS Devon CCG
Chris Roome	Head of Clinical Effectiveness	NHS Devon CCG
Dr Alison Round	Voting Member	NHS Devon CCG
Tracey Polak	Assistant Director/Consultant of Public Health	Devon County Council
Mark Taylor	Lay Public Member	
Dr Ben Waterfall	Voting Member	NHS Devon CCG

Guests:

Mr Andrew Cowan	Consultant Vascular and Endovascular Surgeon	RD&E NHS FT
Mr Frances Dix	Consultant Vascular and Endovascular Surgeon	UHP NHS Trust
Alan Elstone	Vascular Specialist Nurse	UHP NHS Trust
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Mr Robert McCarthy	Consultant Vascular Surgeon	T&SD NHS FT
Mr Ben Peyton-Jones	Consultant Obstetrician and Gynaecologist	RD&E NHS FT
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Miss Tamsin Sleep	Consultant Ophthalmologist	T&SD NHD FT
Graham Simpole	Healthcare Evidence Reviewer	NHS Devon CCG
Darren Wright	Joint Formulary Technician	NHS Devon CCG

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

Apologies

Mac Merrett	Lay Public Member	
Simon Polak	Deputy Chief Nursing Officer	NHS Devon CCG
Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon CCG
Tawfique Daneshmend	Secondary Care Clinician	RD&E NHS FT

Confirmation of voting members and Declarations of interest

The 7 voting members present were identified. A further voting member, Dr Claire Hooper, joined the meeting at 9.55 am.

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
Surgical management of heavy menstrual bleeding	As a provider of private treatments for patients with heavy menstrual bleeding
Referral for varicose veins	As a provider of private treatments for patients with varicose veins
The referral and specialist management of haemorrhoids in adults	As a provider of private treatments for patients with haemorrhoids
Loteprednol etabonate 0.5% (Lotemax®) **for the treatment of steroid responsive inflammatory conditions of the eye**	Bausch & Lomb UK Ltd
Alternative treatments:	
Prednisolone acetate 1% eye drops (Pred Forte®)	Allergan Ltd
Fluorometholone 0.1% eye drops (FML Liquifilm®)	Allergan Ltd
Other corticosteroid eye drops	Various manufacturers

Name of Attendee	Role	Declaration
Mr Robert McCarthy	Consultant Vascular Surgeon	Private vascular practice Devon Vein Solutions LTD

Notification of Any Other Business

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

2. Minutes of the meeting held on 24th July 2019 and matters/ actions arising

The minutes of the meeting held on 24th July 2019 were approved.

Summary of actions		
	Action	**Lead**
19/11	*Review: Policy for Dupuytren's contracture treatment – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* This policy was published on 14th October 2019. Action complete.	
19/12	*Review: Policy for surgery for carpel tunnel syndrome – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* This policy was published on 14th October 2019. Action complete.	
19/13	*Review: Policy for surgery for ganglion cyst – policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* This policy was published on 14th October 2019. Action complete.	
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.* This policy was published on 10th October 2019. Action complete.	
19/18	*Review: Policies for myringotomy - Policy recommendations and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* These policies were published on 28th October 2019. Action complete.	
19/19	*Review: Policy for tonsillectomy - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* This policy was published on 28th October 2019. Action complete.	

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.* This policy was published on 10th October 2019. Action complete.	

3. Review: Referral Policy for surgical management of heavy menstrual bleeding

NHS England (NHSE) issued statutory guidance to CCGs in November 2018 to introduce and implement commissioning policies for selected interventions. NHSE has described hysterectomy for heavy menstrual bleeding (HMB) as a Category 2 intervention and has published specific criteria which should be met before surgery is undertaken. Alongside these recommendations NHSE has set a target of reducing the number of hysterectomies for HMB by 262 elective interventions from a baseline of 759 in 2017/18. However local data suggests a considerable number of these procedures were conducted on patients with primary diagnoses that indicate the treatment was not solely for HMB. This is in line with feedback from specialists during the consultation.

Naomi Scott, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper. Mr Ben Peyton-Jones, Consultant Obstetrician and Gynaecologist, RD&E attended the meeting for this discussion.

The current CCG policy routinely commissions referral for specialist advice and surgery when patients have significant fibroids, there is suspicion of structural or histological abnormalities, when uterine length is more than 12 cm or when appropriate pharmacotherapy has failed. NHSE guidance states that hysterectomy should not be used as a first line treatment solely for HMB and it should only be considered when other treatment options have failed or are contraindicated, there is a wish for amenorrhoea, the women requests it or the woman no longer wishes to retain her fertility.

During consultation with local specialists it became apparent that the wording used within the NHSE guidance is ambiguous and consequently there was inconsistent interpretation of whether the criteria were mutually exclusive or additive. Specialists indicated that an additive interpretation would not alter current practice, but that a mutually exclusive interpretation could have a huge impact on demand and safety.

In response to the consultation a revised CCG policy was proposed and considered to be acceptable by local specialists. The proposed policy includes a good practice statement to ensure that women offered hysterectomies are appropriately informed, it removes the criterion regarding patients with a uterus greater than 12cm, and alters the wording relating to submucosal fibroids.

The CPC were asked to recommend one of the following three options:

- To adopt the NHSE recommendations into local policy
- Retain the current policy position
- Adopt the proposed CCG policy

The committee considered issues pertinent to the review of the policy for surgical management of heavy menstrual bleeding.

- The consultant present stated that over a year 156 hysterectomy procedures had been undertaken at the RD&E, 13% of which were for HMB, only 3 of these patients had not tried other treatments prior to hysterectomy.
- It was noted that the CCG's current policy also requires patients to try other treatments prior to undergoing hysterectomy.
- It was noted that GPs should be the gatekeepers of referrals and that Devon Referral Support Services may be able to help.

The committee voted unanimously in favour of adopting the proposed CCG policy. Dr Claire Hooper was not in attendance for discussion and voting for this item.

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

4. Review: Referral Policy for varicose veins

The CCG currently has a referral policy for varicose veins. This policy resulted from a review of a former peninsula-wide policy, which was prompted by the publication of NICE clinical guideline 168. At this time the CPC recommended that commissioning in line with the NICE guidance would be clinically and cost effective. However the executive groups of the time decided that due to the substantial increase in activity and costs that this would entail the local policy would not align with NICE. Referral for all patients with symptomatic varicose veins was considered to be a low priority for investment. Varicose vein interventions were included in NHS England's Evidence Based Interventions programme as a Category 2 intervention. The NHS England guidance is in line with NICE and thus varies from the current Devon policy by recommending referral for all patients with symptomatic varicose veins, whereas the current Devon policy does not. Alongside the clinical recommendations NHS England has given the CCG a target for reducing surgical activity for varicose veins by 122 interventions.

Naomi Scott, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper. Mr Robert McCarthy, Consultant Vascular Surgeon, Torbay and South Devon NHS Foundation Trust, Mr Andrew Cowan, Consultant Vascular and Endovascular Surgeon, Royal Devon and Exeter NHS Foundation Trust, Mr Francis Dix, Consultant Vascular and Endovascular Surgeon, and Alan Elstone, Vascular Nurse Specialist, University Hospitals Plymouth NHS Trust attended the meeting for this discussion.

The NHS England criteria are deemed to be clinically appropriate and specialists would like to see patients with symptomatic varicose veins. Adopting the NHS England recommendations would allow patients access to a clinically and cost-effective treatment. Based on current rates of surgical intervention, the adoption of NHS England recommendations could result in increasing activity between 123 and 154 procedures, at an increased cost of £131,000 to £164,000.

There are mixed capacity constraints across Devon, at least one provider would be challenged to meet the demand of increased activity but two providers have indicated the ability to cope with the increased demand.

The committee were asked to make a recommendation on whether the NHS England recommendations should be adopted into local commissioning policy knowing that this will increase activity, or whether the current local position should be maintained, with the knowledge that this restricts access to a clinically and cost-effective treatment.

The committee discussed issues pertinent to this policy recommendation:

- A specialist present noted that prior to implementation of the current CCG policy specialists were following the criteria now recommended by NICE. He felt that subsequent to the adoption of the CCG policy referrals reduced by 70%. However, specialists wish to follow

the new NHS England guidance which is in line with NICE but trusts would require additional funding for this.

- Some capacity exists to treat patients at University Hospitals Plymouth NHS Trust. Capacity in general was considered. The shortage of vascular input into the treatment of patients with diabetes was noted. A GP present suggested that spare capacity may be used to treat this patient group.
- Specialists present stated that the surgical treatment of varicose veins is a very effective treatment which may prevent ulceration of the skin and permanent skin change. There is low grade evidence that around 30% of patients with Stage 2 varicose veins will progress to Stage 3.
- Specialist opinion stated that it may be detrimental to patients to delay treatment until progression to Stage 3 disease and that permanent damage may be done. Treating patients at Stage 2 may result in fewer patients in their 60s and 70s with leg ulcers. However, it cannot prevent currently normal veins becoming varicose in the future and rates of recurrence after treatment range from 10-30%.
- It was acknowledged that some patients are living with painful veins. It was also acknowledged that GPs are under pressure to reduce referrals and that heavy legs and aching are symptoms common to other conditions. Following NICE and accepting referral of patients with Stage 2 varicose veins is likely to increase referrals by 20% - 25% and increase costs by between £130,000 to £160,000.
- In reaching the decision the committee need to take into account commissioning best value for money for the whole system.
- A specialist present suggested that there is a need to move away from a focus on varicose veins to treating patients more holistically. A discussion with a specialist can help and reassure patients.
- Specialists present indicated that modern non-surgical interventions are available.
- Consideration was given to use of compression stockings which may help. Some patients are happy with these but others do not like wearing them.

The committee were asked to make a recommendation on whether to accept referral of patients with grade 2 varicose veins in line with NHS England recommendations or to retain the existing CCG policy and accept referral of patients only when they progress to having stage 3 varicose veins.

The committee voted 7 to 1 in favour of retaining the current CCG policy.

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

5. Review: Policy for referral and specialist management of haemorrhoids in adults

NHS England (NHSE) issued statutory guidance to Clinical Commissioning Groups on 28th November 2018 to introduce and implement commissioning policies for selected interventions. This included haemorrhoid surgery which it described as a Category 2 intervention. Specific criteria were published which should be met before surgery is undertaken. NHS Devon Clinical Commissioning Group currently has a policy for the referral and specialist management of haemorrhoids in adults which has been in place since December 2015 and encompasses referral and non-surgical interventions, as well as haemorrhoid surgery.

Graham Simpole, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper.

The NHSE guidance relates specifically to haemorrhoid surgery and varies from the current Devon commissioning policy on surgical treatment in a number of areas:

- The current CCG policy allows the non-surgical treatment, for example by banding, of Grade 1 haemorrhoids that have failed conservative management but does not routinely allow surgery. The NHSE criteria would permit surgery in persistent Grade 1 haemorrhoids under certain conditions.
- For Grade 2 haemorrhoids the NHSE guidance is inconsistent although it is clear that it is only intended for persistent cases that have not improved with dietary changes or non-surgical intervention. The CCG policy is very clear and includes recurrent cases with persistent bleeding.
- For Grade 3 haemorrhoids the current CCG policy allows surgery in cases with persistent bleeding that have not responded to non-surgical treatment or which are too large for non-surgical measures. It does not consider pain. The NHSE criteria allow surgery if the haemorrhoids are recurrent, with persistent pain or bleeding and there is no requirement for prior non-surgical treatment.
- The CCG policy allows surgery in all cases of Grade 4 haemorrhoids, without further qualification. The NHSE criteria allow surgery in Grade 4 haemorrhoids if they are recurrent, with persistent pain or bleeding.

Consultation has taken place with local specialists who have indicated that adoption of NHSE policy would not greatly alter current clinical practice or activity levels, other than for Grade 1 haemorrhoids which might lead to higher rates of surgical intervention. It was therefore, proposed that treatment of Grade 1 haemorrhoids remains in line with the current CCG policy.

Pain is not considered in the CCG policy and the general consensus among the specialists is that pain or bleeding should be considered as per NHSE criteria. Devon Referral Support Services (DRSS) has indicated that there may be an increase in referrals if pain alone is included as one of the criteria for grades 2, 3 and 4 haemorrhoids. However, specialists have suggested that the amount of surgeries undertaken in cases where there is pain alone would make up a very small proportion of the total. 119 haemorrhoid cases presented for surgery in Devon, this is already below the numerical baseline target of 121 surgeries set by NHSE. Therefore, there is no expectation that Devon CCG will need to make any reductions to achieve the NHSE target.

Specialists have seen and are in support of the proposed policy.

The Clinical Policy Committee were asked to make a recommendation on whether the proposed policy, which combines elements of both the current CCG policy and the NHSE criteria, should be adopted into local commissioning policy or whether the current policy should be maintained.

The Committee considered issues pertinent to this policy recommendation:

- Due to yearly variation, there may be a slight increase in the number of surgical interventions regardless of whether the current CCG policy is retained, or the new proposed policy adopted.
- On reflection, it was considered that the impact on referrals may only be small, as a specific referral for a haemorrhoid procedure due to pain only is unusual. Furthermore, inclusion of pain in the wording may help with ensuring the equity of access for similar circumstances where the referral is made for investigation of anal pain without reference to haemorrhoids.

The Committee voted unanimously in favour of recommending acceptance of the proposed commissioning policy:

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

6. Loteprednol etabonate 0.5% (Lotemax®) for the treatment of steroid responsive inflammatory conditions of the eye

Loteprednol is a steroid eye drop which is currently listed on the Devon formulary as a red, (hospital only), drug for its UK licenced indication, the treatment of post-operative inflammation in adults following ocular surgery. An application for the routine commissioning of loteprednol for the treatment of steroid responsive inflammatory eye conditions has been received from Miss Tamsin Sleep, Consultant Ophthalmologist from Torbay and South Devon NHS Foundation Trust. The use of loteprednol in this manner is an unlicensed indication.

Naomi Scott presented a paper. Miss Sleep attended the meeting for the discussion of this item.

There are a range of inflammatory eye conditions in which the applicant has proposed the use of loteprednol. It is common for patients with these conditions to require long term or frequent courses of eye drops. The applicant suggests that loteprednol has a significantly lower rate of sight threatening side effects, in particular, increased intraocular pressure (IOP), than the formulary treatment options prednisolone and fluorometholone.

One trial found loteprednol to generally improve the signs and symptoms of Vernal keratoconjunctivitis significantly more than fluorometholone but comparably to prednisolone. No significant differences in IOP were observed between loteprednol and fluorometholone treated patients, but prednisolone treated patients had a statistically, but not clinically, significantly higher IOP.

Loteprednol was found to be superior to placebo in a poorly reported trial of the treatment of seasonal allergic conjunctivitis. In the treatment of giant papillary conjunctivitis, two studies significantly favoured loteprednol over placebo and one failed to meet its primary endpoint. A study involving patients with dry eye failed to meet its primary endpoint.

In the comparison of IOP, one study reported mean IOPs of loteprednol and placebo treated patients to be comparable. A further three studies found loteprednol treated patients had significantly higher IOP than placebo and a higher proportion exhibited a clinically significant IOP rise.

Two studies assessed the efficacy of loteprednol in comparison to prednisolone in the treatment of acute anterior uveitis. The first, a post hoc analysis, failed to meet its primary endpoint. The second found prednisolone to be superior to loteprednol for chamber cell number and anterior chamber flare; but did not find any significant differences in terms of pain and photophobia. IOP was higher in the prednisolone group but the US Food and Drug Administration (FDA) noted that this could be due to prednisolone being a more effective treatment of uveitis since uveitis is known to decrease IOP.

Collating the rates of clinically significant IOP increases of the reviewed studies showed that approximately 16% of loteprednol treated patients and 19% of prednisolone treated patients exhibited a clinically significant rise in IOP.

The FDA determined that the class warnings in relation to IOP should appear on loteprednol prescribing information since, despite the theoretical reasons for a decreased rate of IOP evaluations, a significant number of IOP rises were observed. In addition, the single study evaluating the IOP response of known steroid responders was significantly flawed.

Although there is a lack of evidence that suggests patients will be less likely to have an IOP increase when using loteprednol, there is a pragmatic choice that needs to be made for a patient with a known clinically significant rise in IOP during treatment with current formulary options. The routine commissioning of loteprednol in patients with a history of raised IOP whilst using steroid eye drops gives a treatment option that may not require the additional use of ocular hypertension

treatment. The use of loteprednol in this manner is in line with guidelines from the regional uveitis centre in Bristol.

Loteprednol costs more than a fluorometholone and prednisolone. In Devon the prescribing of the 1,096 bottles of loteprednol in the last 12 months cost approximately £4,000 more than if patients were prescribed fluorometholone or prednisolone.

There is variation in the level of prescribing of loteprednol across Devon, with the highest level of prescribing in Torbay and South Devon. Based on current population figures, if prescribing in other localities was to match the level of prescribing in South Devon the prescribing of loteprednol would increase by 127% to 2,500 bottles per year. This would cost approximately £9,000 more than prescribing fluorometholone or prednisolone.

The committee discussed issues pertinent the routine commissioning of loteprednol 0.5% for the treatment of steroid responsive inflammatory conditions of the eye:

- Loteprednol is licenced in the UK for the treatment of post-operative inflammation of the eye. It is not licenced for other indications.
- Loteprednol is routinely used first line by a local specialist to treat paediatric patients who have juvenile idiopathic arthritis with optical inflammation or Vernal Keratoconjunctivitis.
- It was noted that Torbay and South Devon NHS Foundation Trust prescribes the most loteprednol in Devon.
- The specialist present indicated that she was responsible for all paediatric patients at Torbay and South Devon NHS Foundation Trust. This patient group required treatment on a long-term basis and have to attend hospital frequently for their prescription.
- The lack of a licence for paediatrics was considered. Loteprednol is not licensed in paediatric ophthalmology as trials have not been done, however, the specialist present indicated that clinical experience has shown it to work.
- The lack of robust evidence supporting less of an IOP rise with loteprednol was discussed. It was proposed that a second-line placement would offer the potential for continuing a steroid eye drop treatment without the additional complications and costs of anti-ocular hypertensives when other treatments cause IOP rises.
- IOP monitoring is recommended for all steroid eye drops.
- The specialist present explained that it was very challenging to check intraocular pressure in some young children. Therefore, the specialist does not want to start them on a treatment that may put them at risk of developing irreversible sight loss.
- The applicant stated that difficulty with arranging for on going supplies of loteprednol for patients was the issue behind her application.
- The specialist present did not anticipate an increase in prescribing as loteprednol would not be started in primary care or used for other conditions. It is about providing seamless provision of medication for those who have been prescribed treatment by a specialist in secondary care.
- GPs present noted that GPs would be being asked to prescribe an unlicensed product and may not know if patients received their safety and efficacy checks, including for IOP, in secondary care. Other ways of patients receiving their prescriptions were considered. It was suggested that secondary care send the dispensed medicines to GP practices for patients to collect.

The Committee voted unanimously in favour of recommending the routine commissioning of loteprednol 0.5% as a second line treatment for steroid responsive inflammatory conditions of the eye in patients who have a known clinically significant rise in intraocular pressure with other steroid eye drops.

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

7. Update from Clinical Policy Engagement and Consultation Panel

The committee received an update from the Clinical Policy Engagement and Consultation Panel. For the majority of items discussed the panel saw no reason for further work.

However, the panel had agreed two actions relating to continuous glucose monitoring in diabetes. Firstly, it was agreed to follow up on the NHS England pledge made in the NHS Long Term Plan that all pregnant women in Type 1 Diabetes will be offered continuous glucose monitoring by 2020/21 to query how this will be enacted. Secondly it was agreed that an explanatory leaflet be produced about the technology available for patients encountering different types of problems with the management of diabetes and the routes of access to these to accompany publication of the policy.

It was noted that the leaflet has been produced and has already proved useful.

It was also noted that the CCG continuous glucose monitoring policy will be reviewed when the new national guidance is published.

8. Update from NICE Planning Advisory Group (NPAG)

Three NPAG meetings had taken place since the last CPC meeting.

11th June 2019

NPAG had considered nine NICE Technology appraisals and one Highly Specialised Technology. Three of the NICE TAs are CCG commissioned, the Highly Specialised Technology and six of the NICE Technology Appraisals were NHS England commissioned.

NPAG had also considered seven Clinical Guidelines, two Social Care Guidelines, one Medical Technology Guideline, three Interventional Procedures Guidelines and one Diagnostic Guideline.

20th August 2019

NPAG had considered twelve NICE Technology Appraisals. One of the NICE TAs is CCG commissioned and eleven were NHS England commissioned.

NPAG had also considered two Clinical Guidelines, one Social Care Guidelines, three Medical Technology Guidelines, nine Interventional Procedures Guidelines and one Diagnostic Guideline.

1st October 2019

The minutes of the meeting held on 1st October are in draft. An update of this meeting will be provided to CPC in January 2020.

9. NICE Planning Advisory Group Annual Report 2018-19

The NICE Planning Advisory Group (NPAG) Annual Report 2018-19 was presented by Fiona Dyroff, Clinical Effectiveness Governance Support Officer, NHS Devon CCG. The 2018-19 annual report provides an account of the issues considered and the governance and operational arrangements underpinning the NPAG meetings. The Clinical Policy Committee (CPC) were asked to receive the annual report for information.

NPAG provides a forum for the CCG to fulfil its statutory commissioning responsibilities in respect of mandatory NICE Technology Appraisals and Highly Specialised Technologies; and to consider the resource and service implications for all newly published NICE guidance and guidelines.

The period of the report is prior to the merger of the CCGs and therefore refers to NEW Devon and South Devon & Torbay CCGs. However NPAG has operated on a Devon-wide basis since April 2013.

Six NPAG meetings were held in 2018-19, at which NPAG considered 135 reports relating to NICE guidance. NICE publishes several different types of guidelines and guidance. A recent growth area has been in Antimicrobial Guidelines, these were introduced in October 2017 to help manage common infections and tackle antimicrobial resistance.

In order for the CCGs to comply with their statutory commissioning responsibilities, NPAG ensures that NICE Technology Appraisals and Highly Specialised Technologies are added to the local formulary within 90 days of publication. A process is in place whereby the Formulary Team is notified of NICE Technologies considered by NPAG.

In year NPAG identified and took forward two areas of particular concern.

Firstly, procedures involving use of gynaecological mesh. NPAG had considered guidance for several procedures involving the use of mesh and was aware of a number of serious safety concerns. These had been reported to the Joint Clinical Effectiveness Group (JCEG). Responses received from local trusts regarding the use of mesh identified varied practice.

In July 2018 the Government announced a 'pause' in the use of synthetic mesh/tape for two procedural areas, and a Safety Alert was published by NHS Improvement and NHS England. This was considered by NPAG in August 2018. The outputs from this were that:

- The Safety Update was added to the JCEG agenda.
- Medical Directors should be contacted with a reminder that all non-restricted mesh procedures should be undertaken with high vigilance and that there must be clarity in trusts about what this means.
- A letter signed by the Chief Nursing Officer was sent to medical directors reinforcing this and asking for confirmation that appropriate measures were in place.

Secondly, surgical treatment options for lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH). NPAG noted a number of new surgical treatments for this indication that local trusts were interested in providing.

Local data suggested that making Urolift available on a trial-in-service basis was associated with an increase in the total number of procedures performed without a meaningful reduction in numbers of transurethral resection of the prostate (TURPs). There has been an expansion in Urology departments in recent years with additional consultant numbers, yet they struggle to meet targets including the 62-day cancer treatment target. NPAG questioned whether expansion of services for BPH was a priority or considered affordable from a financial perspective or deliverable from a clinical capacity perspective.

It was reported that a meeting had been organised to take place in September 2018 with urologists and radiologists and that a review of urology services was due to take place in 2019.

As a result, CPC was asked to consider a range of new surgical procedures for LUTS due to BPH together at one time in January 2019. The aim was to make recommendations on whether these alternative treatment options would make rational choices to help address the challenges in the local health system, and what form of commissioning and provision would be considered most suitable. These recommendations would then be used in the discussions at senior level for this service across Devon. These discussions resulted in publication of CCG policies setting out the

procedures accepted in Devon and the circumstances for their use, and those which are not accepted as treatment options.

NPAG undertakes reflective practice. In year the process by which NPAG is informed about NICE Technology Appraisals and Highly Specialised Technologies for which NHS England is the responsible commissioner, rather than the CCG, was reconsidered and streamlined. Brief summaries only are produced for these technologies.

The NPAG annual report 2018/19 has been accepted by NPAG. The NPAG Terms of Reference have recently been reviewed and refreshed. These were included in the meeting papers in addition to the annual report for reference.

The Committee received the Annual Report.

10. Devon Formulary Interface Groups Annual Report 2018-19

The Devon Formulary Interface Groups Annual Report 2018-19 was presented by Darren Wright, Joint Formulary Technician, NHS Devon CCG. The report provides an overview of the work undertaken by the two Formulary Interface Groups (FIGs) in Devon from April 2018 to March 2019. The Clinical Policy Committee (CPC) were asked to receive the annual report for information.

The FIGs collectively deliver the Devon formulary to promote prescribing which is safe, clinically appropriate and cost-effective in both primary and secondary care by providing guidance on locally recommended drug and treatment choices.

The content of the Devon formulary continues to be reviewed and updated by the FIGs with agreement reached by consensus. The FIGs reflect the natural healthcare communities clustered around the major hospitals in Devon.

From 1st April 2019 NEW Devon CCG and South Devon & Torbay CCG formally merged to become NHS Devon CCG. Whilst there is essentially one formulary in Devon, there are variations between recommendations made for North and East Devon, and South and West Devon. These differences allow the Devon formulary to reflect and support the different needs of the local healthcare communities, local specialist preferences, and local service configuration or provision.

The merger of the CCGs is not expected to affect the way in which the Devon Formulary is managed or delivered.

The annual report details the governance processes that support the FIGs, including the terms of reference, quoracy, declarations of interest, and meeting arrangements, all of which has been supported by the Clinical Effectiveness Governance Support Officer who makes sure they continue to be successful.

In order to demonstrate compliance with the CCG's statutory obligation to fund and resource medicines and treatments recommended by NICE Technology Appraisal (TA) guidance and NICE Highly Specialised Technology (HST) guidance; 63 TAs and 1 HST were added to the Devon formulary during the period of the annual report. This represents an increase of almost 54% in the number of TAs added in a year since the first Devon FIG annual report; April 2015 to March 2016.

In terms of reviewing and developing formulary content, a number of existing sections were reviewed and updated Devon-wide; examples included acute sinusitis, acute sore throat, acute otitis media, and Lyme disease in the infections chapter.

Formulary guidance on the management of asthma was also reviewed after publication of a NICE clinical guideline. The FIGs considered existing recommendations from the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN), the NICE guideline, and local specialist input. There were times that the two national guidelines differed, and the FIGs worked by consensus to agree Devon wide guidance supported by the acute trust specialists.

The emollients section was reviewed Devon-wide with input from the CCG's medicines optimisation teams and local dermatology consultants. Updated guidance contains consolidated and reduced product recommendations, with a simplified, limited number of first- and second-line options for a variety of presentations such as creams, ointments and gels. The guidance includes additional supporting information to help prescribers select the most appropriate product type and promotes savings.

In addition, applications to consider new drugs for inclusion into the Devon Formulary were received by the Formulary Team, these are considered either by CPC or by the FIGs according to the Terms of Reference of CPC. The Formulary team also receives applications for consideration or removal of products from the formulary or for a change to be made to current formulary preparations such as to the preferred brand or a change in prescribing status.

In year, both FIGs considered a range of product applications, proposed changes to formulary products and changes to product status or prescribing advice.

New drugs which fall outside of the remit of the FIGs to decide upon are considered for commissioning by CPC. In year the FIGs agreed formulary entries for the treatments which the CPC had recommended for commissioning.

In the case of CPC recommending that a drug is not recommended for routine commissioning the recommendation is added to the formulary. In year this applied to Lurasidone and Insulin degludec.

With increasing demand on FIG time, there was growth in the use of the virtual e-FIG process over the previous year to make some decisions at pace, or to free up face to face time for more complex discussions or facilitate the medicines optimisation teams to move quickly to deliver savings.

The FIG also considered national guidance from NHS England on low value items that should not be routinely prescribed in primary care, many of these recommendations had been considered by the FIGs during 2017/18 and were not covered in this report.

In year the Devon Formulary has shown an increase in use of approximately 30% over the previous year, with over 1.6 million page views in 2018/19. The accompanying app was downloaded almost 2,000 times in that period, taking total downloads since launch to around 8,500 by the end of March 2019.

At the end of 2017 the Clinical Effectiveness Formulary Team undertook a survey to understand and improve user experience and satisfaction, as a result, a number of next steps were identified. During 2018/19, the Formulary team worked with Reactor 15 to deliver technical developments and improved functionality, including the addition of a predictive search function that suggests potential search terms based on the initial characters entered in the search box.

The Clinical Effectiveness Team continue to seek best value in the running costs of the formulary.

The FIGs are ever evolving to keep up to date with the requirements of the formulary and as such will often reflect on how best the aims of the formulary can be developed. This year the duration of the North and East FIG meetings was increased from 2 to 2.5 hours and a committee development session took place to consider how best to deliver the aims of the joint formulary.

The Devon Formulary Interface Groups Annual Report for 2018/19 has been accepted by both FIGs. The FIG Terms of Reference have recently been reviewed and refreshed. These were included in the meeting papers in addition to the annual report for reference.

The Committee received the Annual Report.

The Clinical Evidence Manager thanked Darren on behalf of the committee for all his hard work in support of the Devon Formulary.

11. Any other business

Next meeting

Dr Nick D'Arcy's apologies were noted for the meeting due to take place Wednesday 15th January. This meeting will be chaired by Dr Ali Round.

Summary of actions		
	Action	**Lead**
19/21	Review: Referral Policy for surgical management of heavy menstrual bleeding. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/22	Review: Referral Policy for varicose veins. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/23	Review: Policy for referral and specialist management of haemorrhoids in adults. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/24	Loteprednol etabonate 0.5% (Lotemax®) for the treatment of steroid responsive inflammatory conditions of the eye. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn