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

Clinical Policy Committee

Minutes

Wednesday 30th January 2019, 9.30 am to 12.30
Committee Suite, County Hall, Exeter

Present:

Dr Nick D'Arcy (Chair)	Voting Member	South Devon & Torbay CCG
Dr Glen Allaway	Voting Member	NEW Devon CCG
Dr Andrew Craig	Voting member	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	Royal Devon & Exeter NHS FT
Tracey Foss	Chief Pharmacist	Royal Devon & Exeter NHS FT
Dr Lucy Harris	Voting Member	South Devon & Torbay CCG
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round	Voting Member	NEW Devon CCG
Dr Peter Rowe	Consultant Nephrologist	University Hospitals Plymouth NHS Trust
Mark Taylor	Lay Public Member	
Dr Ben Waterfall	Voting Member	NEW Devon CCG

Guests:

James Benzimra	Ophthalmologist Surgeon	Royal Devon & Exeter NHS FT
Malcolm Crundwell	Consultant Urologist	Royal Devon & Exeter NHS FT
Andrew Dickinson	Consultant Urologist	University Hospitals Plymouth NHS Trust
Michael Foster	Consultant Urologist	Northern Devon Healthcare NHS Trust
Richard Guinness	Consultant Radiologist	Royal Devon & Exeter NHS FT
Richard Haigh	Consultant Rheumatologist	Royal Devon & Exeter NHS FT
Richard Miles	Consultant Interventional Radiologist	University Hospitals Plymouth NHS Trust
Konstantinos Papadedes	Ophthalmologist Surgeon	Royal Eye Infirmary, University Hospitals Plymouth NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Naomi Scott	Healthcare Evidence Reviewer	NEW Devon CCG
Richard Seymour	Consultant Radiologist	Torbay & South Devon NHS FT
Stephen Turner	Ophthalmic Surgeon	Torbay and South Devon NHS FT
Elizabeth Wilkinson	Medical Ophthalmologist	Northern Devon Healthcare NHS Trust

Observers:

Matt Howard	Clinical Evidence Manager	NEW Devon CCG

In attendance:

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

1. Welcome and Announcements

Apologies

Richard Croker	Deputy Director for Medicines Optimisation	NEW Devon CCG
Dr Andrew Harrison	Voting Member	NEW Devon CCG
Dr Jo Roberts	Voting Member	South Devon & Torbay CCG
Simon Polak	Deputy Chief Nursing Officer	NEW Devon CCG
Emily Youngman	Consultant in Public Health	NEW Devon CCG

Tracey Foss represented Paul Foster

Confirmation of voting members and Declarations of Interest

The six voting members present were identified.

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

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Monitoring for hydroxychloroquine retinopathy	a) Suppliers of relevant retinal imaging equipment b) Providers of private ophthalmic services
Surgical treatment options for lower urinary tract symptoms caused by benign prostatic hyperplasia Holmium laser enucleation of the prostate (HoLEP); GreenLight; UroLift; Prostatic arterial embolisation (PAE); Transurethral water jet ablation (Aquablation); Rezum	a) Suppliers of equipment associated with surgery for lower urinary tract symptoms caused by benign prostatic hyperplasia b) Providers of private surgical treatment options for lower urinary tract symptoms caused by benign prostatic hyperplasia
NHS England Evidence-Based Interventions Guidance for CCGs Adult Snoring Surgery (in the absence of Obstructive Sleep Apnoea); Dilatation and curettage for heavy menstrual bleeding; Knee arthroscopy for patients with osteoarthritis; Injections for nonspecific low back pain without sciatica; Breast reduction; Arthroscopic shoulder decompression for subacromial shoulder pain; Trigger finger release	Providers of private interventions listed opposite

NAME OF ATTENDEE	ROLE	DECLARATION
Elizabeth Wilkinson	Medical Ophthalmologist	I run the National Diabetic Eye Screening Conference in conjunction with Public Health England at the Royal Society of Medicine annually which receives sponsorships from imaging companies including Heidelberg, Zeiss and Topcon as well as private screening companies including EMIS, Digital Healthcare and Health Intelligence. This sponsorship is arranged through the Royal Society of Medicine and goes toward bursaries for the meeting. I have not personal benefit. Diabetic Eye Screening in Devon will be transferring to a private provider (Health Intelligence) in April. It is likely that I will be employed by them as Clinical Lead from April.

Notification of Any Other Business

The Committee were asked if there were any items of AOB for consideration.

2. Minutes of the meeting held on 26th September 2018 and matters/actions arising

The minutes of the meeting held on Wednesday 26th September 2018 were approved.

Summary of actions		
	Action	**Lead**
18/13	*Rivaroxaban for the prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE): letter to be written to specialists stating that the committee had been unable to reach a decision in their absence as specific questions were raised during the discussion. The application may be considered at a future meeting subject to the attendance of specialists*. Dr Roberts has written to specialists. No response has been received. This has been followed up by the Clinical Effectiveness Team. This will not be pursued. Action complete.	

18/14	*Opicapone for Parkinson's Disease - Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* *Approval is awaited from the CCGs. It is hoped that the policy will be published by the end of the week.* Approval has been received and the policy published in October 2018. Action complete.	
18/15	*Assisted conception: fertilisation failure and abandon cycles - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy was published in January 2019. Action complete.	
18/16	*Assisted conception: eligibility criterion for "previous children" - Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy was published in January 2019. Action complete.	
18/17	*Fluticasone furoate, umeclidinium and vilanterol (Trelegy® Ellipta®) combination dry powder inhaler (DPI) for Chronic Obstructive Pulmonary Disease (COPD) - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy was published in November 2018. Action complete.	
18/18	*Cosmetic treatments policy: Chair to feed comments from the Clinical Policy Committee and IFR Panels into NHS England's work to produce a definition of 'cosmetic treatment'.* Chris Roome to feed this in as a suggestion to the NHS England evidence based interventions programme.	Chris Roome
18/19	*Cosmetic treatments policy: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy was published in November 2018. Action complete.	
18/20	*Reversal of male and female sterilisation policy: Paragraph to be added to the letter to specialists and GPS about ensuring that a private conversation takes place with the person requesting sterilisation.* The letter accompanied publication of the policy in November 2018. Action Complete.	

18/21	*Reversal of male and female sterilisation policy: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy was published in November 2018. Action complete.	
18/22	*Insulin Degludec (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 was published in November 2018. Action complete.	
18/23	*Insulin Degludec (Tresiba®) for use in patients with type 2 diabetes: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* The policy was published in November 2018. Action complete.	

3. Format and structure of the meeting

The Clinical Commissioning Groups have identified that CPC are a potential expert resource to help the organisations form a position regarding some aspects of the commissioning arrangements for clinical services.

Two items on the agenda for the January 2019 meeting related to this role. The first was Monitoring for Hydroxychloroquine Retinopathy for which the recommendations of CPC would be used to develop the detail of the commissioning pathway and any associated specifications. The second was Surgical Treatment Options for Lower Urinary Tract Symptoms caused by Benign Prostatic Hyperplasia, to make recommendations on which new treatment options should form part of commissioned services for the condition, to inform discussion at the senior level for this service across Devon.

The Chair asked Committee Members to confirm that they were happy with these arrangements. Committee members confirmed that they were.

4. Monitoring for hydroxychloroquine retinopathy

The Royal College of Ophthalmologists (RCO) issued updated guidance for hydroxychloroquine retinopathy in 2018. When the previous guidance was issued in 2009, evidence suggested that hydroxychloroquine retinopathy was very rare. Patients were only required to undergo an annual visual acuity test at a high street optometrist. However, recent epidemiological data indicate that the prevalence of toxicity amongst long-term hydroxychloroquine users may be around 7.5%. The 2018 RCO recommendations require all patients to have an ophthalmological review after five cumulative years of treatment and annual monitoring thereafter. In addition, selected patient groups require annual monitoring from an earlier stage in treatment. Similar recommendations were issued by the British Society of Rheumatology (BSR) in 2017 in their guidance for the monitoring of Disease-Modifying Anti-rheumatic drugs (DMARDs). They recommended formal

retinal assessment, ideally using Optical Coherence Tomography (OCT), at baseline and annually commencing after five years of treatment. The BSR noted that an important unanswered question is whether hydroxychloroquine represents a cost-effective treatment in rheumatoid arthritis beyond 5 years if OCT is required.

High street optometrists do not have the equipment to conduct the tests recommended by the RCO and an ophthalmologist is required to interpret test results. High street optometrists are no longer accepting patients receiving hydroxychloroquine for annual review.

The Committee was asked to consider the RCO guidance because currently patients in Devon do not have any form of monitoring for hydroxychloroquine retinopathy, and GPs as repeat prescribers hold the legal responsibility for prescribing hydroxychloroquine. In addition, the Clinical Commissioning Groups (CCGs) were approached by ophthalmologists from a hospital which does not have the full range of equipment recommended by RCO to provide this service. The RCO guidance covers a range of tests for hydroxychloroquine retinopathy.

The challenges in implementing the RCO pathway in Devon are that widefield fundus autofluorescence (FAF) is not available at NDDH and RD&E hospital and that Multifocal electroretinogram (ERG) with very limited capacity is available at RD&E hospital; three hospitals use this facility whilst NDDH refer patients to Bristol for multifocal ERG. Multifocal ERG is commissioned by NHS England but it is unlikely that capacity will increase significantly in time to accept many patients from a Devon service for monitoring for hydroxychloroquine retinopathy.

To overcome these factors the Clinical Policy Committee was asked to consider full implementation of RCO guidelines or a partial implementation of the RCO algorithm. Two options were proposed if partial implementation was agreed. The first, a pathway without FAF, the second, a pathway limiting multifocal ERG to patients for whom there are no alternative options to hydroxychloroquine. The proposal to limit multifocal ERG is a pragmatic approach.

The Clinical Effectiveness team consider that the pathway without FAF is supportable because RCO acknowledge that FAF is less sensitive than a visual acuity test and OCT and, there is no clear evidence for the benefit of FAF in detecting early disease or reducing the proportion of patients who may progress to multifocal ERG. Furthermore, a systematic review does not support routine use of FAF for retinal disorders. A pathway without FAF was proposed as a starting point for discussion with the specialists.

There are an estimated existing 2384 patients receiving hydroxychloroquine in Devon who meet criteria for annual monitoring. The new RCO guidance has come at a time when the Devon STP has initiated a local service review of ophthalmology departments in Devon as a result of concern over sustainability of ophthalmology services. NHS England also initiated a national review of ophthalmology services in 2018 which encompasses capacity reviews and planning from CCGs. Additional investment would be required to implement the full RCO recommendations. As hydroxychloroquine is already in use there is a duty of care to ensure adequate monitoring for safety, and to be accountable for the appropriate use of the drug. Therefore, a service for monitoring for hydroxychloroquine retinopathy within Devon is required.

A paper had been circulated to the committee prior to the meeting. The paper outlined the approached taken by the RCO to developing the guidelines including the evidence reviewed, and other factors considered. Included in the paper were estimations of the impact of the guidelines on the health community in Devon, and a proposal to partially implement the guidance taking into

account equipment currently available at local ophthalmology departments. The proposed Devon pathway showed how a pathway without FAF and with limited access to multifocal ERG may look. The detail of the pathway would be agreed with advice from ophthalmologists to ensure that it is clinically appropriate, pragmatic and can be operated efficiently. The pathway to be reviewed at a time to be agreed.

The committee discussed issues pertinent to the provision of a service for monitoring for hydroxychloroquine retinopathy within Devon:

- It was noted that the clinical lead for one ophthalmology department had responded. It was noted that staff and equipment are currently working 6 days a week. Concern was expressed regarding implementation of the full RCO recommendations, creating another list of patients waiting for review and potentially treatment of patients (particularly those with Lupus) who need hydroxychloroquine.
- Specialist rheumatologist opinion stated that there is evidence to support that patients respond best to the first drug they receive. This may be methotrexate as monotherapy or methotrexate in combination with another drug, combination therapy often being used; in particular hydroxychloroquine with methotrexate. Use of drugs usually reduces during the initial four years of treatment, historically the tendency has been to withdraw methotrexate from the combination with hydroxychloroquine. However, with these new guidelines it is likely that rheumatology practice will now be to withdraw hydroxychloroquine in preference.
- Hydroxychloroquine is considered to be a useful and safe drug which it is important that appropriate patients receive, however the current situation is that GPs are being asked to take on medical legal responsibility for patients with no monitoring in place putting them in a vulnerable position.
- Hydroxychloroquine retinopathy monitoring is for a very rare complication of a drug which is in frequent use. Specialists noted that it was rarely associated with loss of visual acuity. Ophthalmologists present indicated that they were happy with a partial implementation of the RCO guidelines and that a pragmatic approach be taken to the RCO guideline. It was noted that monitoring can identify damage to the eye at an early stage. If detected early use of hydroxychloroquine can be stopped, and progression of hydroxychloroquine retinopathy may be reduced or halted.
- As a general approach, ophthalmologists indicated support for as minimal set of tests for routine use as appropriate but that it should be up to the discretion of the ophthalmologists which particular tests to perform in a specific patient. They would not wish to see a specified series of tests.
- The importance of ensuring hydroxychloroquine is available to patients who need it was noted.
- Communication with patients was also discussed.
- The Committee felt that the guidelines lack strong evidence to support the pathway promoted by RCO.
- The Clinical Effectiveness Team had contacted the Chair of the Guideline Group regarding potential issues relating to implementation of the full monitoring programme and had gained useful feedback about implementation in one centre.

The committee made recommendations on the proposed options for monitoring of patients.

Option 1: Does the committee recommend implementation of the full RCO recommendations?

The Committee unanimously rejected the full implementation of the RCO recommendations.

Option 2: Partial implementation of recommendations:

If you support partial implementation:

- Do you support a pathway which does not include FAF?

- Do you support a pathway where access to multifocal ERG is only for those patients for whom there are no appropriate alternatives to hydroxychloroquine?

The committee agreed that the current situation of providing no monitoring for patients was not acceptable. The committee unanimously agreed that appropriate high-risk patients should be referred to ophthalmologists to decide the appropriate pathway.

The committee were asked to consider local prescribing of hydroxychloroquine for rheumatoid arthritis and whether it supports a recommendation to reconsider the place in therapy for hydroxychloroquine for rheumatoid arthritis.

The committee unanimously agreed that the approach rheumatologists had described regarding use in rheumatoid arthritis and lupus was reasonable and that further review of the place in therapy for hydroxychloroquine was not required.

5. Surgical treatment options for lower urinary tract symptoms caused by benign prostatic hyperplasia

Lower urinary tract symptoms (LUTS) in men are most commonly caused by benign prostate enlargement, which obstructs the bladder outlet. This happens when the number of cells in the prostate increases, in a condition called benign prostatic hyperplasia (BPH).

LUTS are a major burden for the ageing male population with bothersome LUTS occurring in up to 30% of men older than 65 years. If symptoms are severe, or if drug treatment and conservative management options have been unsuccessful, or are not appropriate, then patients may be referred for surgical treatment. The gold standard surgical treatment option is transurethral resection of the prostate (TURP). This is an inpatient procedure which is conducted in a general operating theatre and requires an average hospital stay of 2 days. It is common for patients who have had a TURP to report ejaculatory dysfunction after surgery.

A number of additional surgical treatments for LUTS caused by BPH have been the subject of NICE guidance in recent years. These treatment options have not been shown to achieve symptom improvement superior to TURP but offer benefits important to wider contextual considerations of the current NHS climate. The Clinical Effectiveness Team has reviewed six of these treatment options for consideration by the Clinical Policy Committee. The options are Urolift, Holmium Laser enucleation of the prostate (HoLEP), GreenLight XPS laser, Rezum, Aquablation and Prostatic artery embolisation (PAE).

An overview of the current availability, place in therapy and resources required for each treatment was provided:

UroLift is considered to be an alternative to TURP in patients with prostates smaller than 100g without median lobe obstruction, although local data and recent non-comparative evidence suggests that the latter restriction may no longer be appropriate. Locally, commissioner approval was given to the hospitals in Devon to conduct an evaluation in service to examine whether real world usage of UroLift would align with the conclusions of the NICE medical technology guidance.

UroLift requires a small capital investment of £5,200 which has been undertaken by the Royal Devon and Exeter, Torbay and South Devon NHS Foundation Trust and Northern Devon Healthcare Trust. The consumable costs associated with UroLift are dependent on the number of implants required by each patient. Local data shows on average patients require 4.5 implants at a cost of £1,485. UroLift can be performed in a minor operation suite. The procedure takes 30-60 minutes and can be performed as a day case procedure.

HoLEP it is not currently available in Devon and it requires a capital outlay cost of £200,000. This has been purchased by Taunton and Somerset Foundation Trust hospital who are now accepting tertiary referrals. HoLEP is likely to have a role for patients with larger prostates that are not suitable for TURP but as it is not possible to perform it as a day case procedure it is unlikely to be a feasible alternative to TURP in a majority of patients with the current demands on inpatient beds and theatre availability. Its likely place in therapy is an alternative for patients with large prostates who otherwise would have to have an open prostatectomy (OP).

GreenLight XPS Laser is considered to be an alternative to TURP in patients with prostates smaller than 100g. It requires a £30,000 capital investment, which has been undertaken by University Hospitals Plymouth NHS Trust. After this investment a consumable cost of £466 is required for a fibre for each patient. GreenLight requires a standard operating theatre and takes a comparable time to TURP but it can be performed as a day case procedure with patients returning to outpatient clinics for catheter removal.

Rezum is considered to be an alternative to TURP, but evidence is limited to patients with a prostate smaller than 80g. The NICE estimate of the cost of Rezum is lower than other treatment options, but as it is a new procedure for which the average length of stay or the percentage of patients that can be treated as a day case is not known, this may not be representative of the real-world cost. NICE have indicated that they are currently undertaking a full evaluation of Rezum which is expected to be published towards the end of 2019.

Aquablation is considered as an alternative to TURP but evidence is limited to patients with a prostate smaller than 80g. It has not been possible to estimate the costs associated with Aquablation so it is unknown if it requires a large capital outlay or how the per-case consumable costs compare to other procedures. The manufacturers of Aquablation suggest that it is not currently suitable to be a day case procedure.

The average tariff cost of PAE is more expensive than TURP, UroLift and GreenLight. It uses radiology equipment already available in trusts and consumable costs are estimated to be between £350 and £400 per patient. PAE is currently performed as a day case procedure 50% of the time. As PAE does not require patients to undergo a general anaesthetic it may suitable for patients who have comorbidities which render them unsuitable for other surgical treatment options. PAE is performed by radiologists so it has the potential to relieve pressure on general operating theatres, however the procedure takes longer than other surgical treatment options for BPH and the service impact on radiological theatres is not known.

The committee received an overview of the available evidence for each of the procedures:

UroLift has been compared to TURP in a Randomised Controlled Trial (RCT) with a 24 month follow up, which found that significantly more patients randomised to UroLift achieved the prostate hyperplasia BPH6 responder outcome 12 months after surgery. However, when validated measures were assessed there were no significant differences between the two groups IPSS scores until 12 months, where TURP treated patients had a significantly larger improvement

over UroLift treated patients. TURP outperformed UroLift in terms of Qmax and PVR at all time points to the 24 months follow up.

A second study, which randomised patients to UroLift or sham treatment found UroLift to outperform sham after 3 months. Patients randomised to UroLift were subsequently followed for five years, finding that a clinically and statistically significant improvement in IPSS and Qmax was maintained. No significant change in PVR was observed over a three year follow up. Within the five year follow up 4.3% of patients required additional implants and 9.3% underwent TURP or laser ablation.

UroLift was not found to impact on erectile function significantly differently to TURP. No differences between groups were observed for ejaculatory bother, but UroLift treated patients had an improvement in ejaculatory function scores whilst TURP treated patients had a worsening, resulting in a significant difference between groups.

HoLEP has been compared to OP in five RCTs which were included in a single meta-analysis. This found no significant differences between the two treatments in terms of IPSS, IPSS Quality of life or Qmax at 12 or 24 months following treatment, and PVR 12 months after treatment. However HoLEP is associated with a shorter bed stay, a lower tariff cost per patient and is a less invasive procedure than OP.

In comparison to TURP meta-analyses found no significant differences between IPSS or Qmax scores at 1 or 6 months following treatment but found significant differences in favour of TURP at 12 months. When assessing PVR, HoLEP was found to produce significantly better results at 12 months. The outcomes of RCTs not included within the meta-analyses are broadly comparable with the meta-analyses conclusions.

No significant differences in erectile function were observed following HoLEP or TURP. Retrograde ejaculation and anejaculation appear to be common following HoLEP, but not at a significantly worse rate than found in the TURP arms of each trial.

GreenLight XPS laser was found to be non-inferior to TURP for IPSS and Qmax 6 months after treatment. PVR and IPSS quality of life were tested for superiority and failed to find a significant difference between groups. Results were consistent through to the 24 months follow up, during which 10% of GreenLight and 7.5% of TURP patients had re-treatment. In a subsequent study an off-label use of GreenLight was found to be non-inferior to HoLEP in improving IPSS scores 12 months after treatment. HoLEP was found to outperform GreenLight in improving Qmax, but no significant differences were observed in the comparison of treatments impact on IPSS QOL or PVR. A single arm study with a 60 month follow up suggests that the clinically meaningful improvements demonstrated with GreenLight could be expected to be sustainable. Single arm studies assessing the efficacy of GreenLight in patients with larger prostates suggest that they are associated with a longer operating time, use more fibres and have a higher rate of conversion to TURP.

There were no significant differences found between the impact of GreenLight in comparison to TURP or HoLEP on erectile function. Significantly fewer patients were reported to be unable to ejaculate during sexual activity following GreenLight than TURP however this may be confounded by the high degree of retrograde ejaculation reported at baseline.

Aquablation has been shown to be non-inferior to TURP at improving IPSS at 6 months. Superiority testing failed to find significant differences between the treatments' IPSS QOL, Qmax and PVR at 6 months or IPSS, IPSS QOL, Qmax and PVR at 12 months. Within the 12 month

follow up 2.6% of patients who had received Aquablation underwent surgical re-treatment with TURP.

Erectile function was reported to be stable following Aquablation and the only significant difference in comparison to TURP was found for overall satisfaction 6 months after treatment. Ejaculatory function was found to be stable following Aquablation but decrease after TURP, resulting in a significant difference between groups at 6 months. Rates of anejaculation and retrograde ejaculation were found to be significantly lower following Aquablation than TURP.

The only RCT evidence for Rezum compares it to a sham treatment and found Rezum to result in significantly larger improvements in IPSS, IPSS QOL and Qmax three months after treatment. Rezum was not found to significantly improve PVR. Following the Rezum allocated patients for 36 months showed patients had a significant improvement in IPSS, IPSS QOL and Qmax from baseline. 4.4% of patients required re-treatment within the 36 month follow up. As Rezum has not been compared to TURP in an RCT it is not possible to ascertain its comparable effect on erectile and ejaculatory function.

PAE is compared to TURP in three studies which were included in a single meta-analysis, however as one study only reports 12 week outcomes and the other two report 12 month outcomes combining these into one analysis is questionable.

One study following patients for 24 months found TURP to result in significantly better IPSS scores at 1 and 3 months but no significant differences following this time point. At 12 months another study with a small sample size found TURP to have a significant improvement in IPSS over PAE. The final study failed to demonstrate non-inferiority of PAE to TURP in IPSS scores at 12 weeks.

In the assessment of Qmax one study found TURP to have a significantly larger improvement at 3 months, after which PAE treated patients continued to improve resulting in no further significant differences through to a 24 month follow up. Another study found TURP to have a significantly larger improvement than PAE at 12 months.

Within the first 12 months after treatment one study reported that 9.4% of PAE treated patients required re-intervention with a TURP. No significant differences were found between the change in erectile function scores following PAE and TURP when results from two studies were meta-analysed. One study found that more patients experienced ejaculatory dysfunction following TURP than PAE, although the result did not reach statistical significance. Another study found 13% of PAE treated patients reported a reduction in ejaculatory function whereas 100% of TURP patients reported retrograde ejaculation.

Specialists present were asked for a view on each of the procedures, the main points noted were:

- Specialists indicated that HoLEP filled a niche place in therapy for men with obstructive prostate hyperplasia. This procedure is not undertaken locally, and patients are referred to Berkshire or Taunton.
- There is evidence for an improvement in lower urinary tract symptoms following treatment with GreenLight XPS laser. This procedure is provided locally although there is a learning curve for surgeons. Specialist opinion stated that GreenLight was useful for men who were not fit enough for TURP. The fibre in new machines is of good quality and the procedure is expected to be helpful in patients at high risk of bleeding.
- The conversion rate from GreenLight to TURP was noted and thought to be similar to the rates of subsequent procedures following any primary procedure in this condition.

- Urolift has the advantage of being able to be undertaken as a day case and that a catheter is not needed. Men can return to work quickly and do not experience sexual dysfunction. Written comments received from specialists indicated that the time for the procedure was short (about 30 minutes).
- PAE is a difficult procedure involving mapping of fine arteries but it is a minimally invasive procedure. The procedure is carried out as a day case procedure and patients do not need a general anaesthetic. The procedure takes longer than alternatives and there is a learning curve for radiologists. In some cases, it is only possible to treat one side of the prostate. Specialists indicated PAE could be used in patients with large prostates although it was noted these patients were not included in the clinical trials. It provides an alternative for men who would otherwise need a long-term catheter. The benefits of the procedure are not immediate; PAE cuts off the blood supply and the prostate size deceases over time.
- Specialist opinion stated that Aquablation looks promising but the technique is still relatively new and has limited clinical evidence of safety and efficacy.
- Specialists noted that a small number of patients request Rezum where it is not only the medical outcomes that are important.

The committee discussed issues pertinent to surgical treatment options for lower urinary tract symptoms caused by benign prostatic hyperplasia:

- Because there is some experience with the use of many of these new procedures Devon is in a good position with regard to provision of surgical treatment options for urinary tract symptoms caused by benign prostatic hyperplasia. Patient choice should be taken into account. It was noted that the choices patients make are not always solely based on medical outcome. The committee felt it would be useful to understand the reasons patients make the choices they do.
- There are significant learning curves for surgeons associated with HoLEP, Greenlight and PAE. Would this be a problem if such treatments were offered at a number of sites reducing the number of procedures undertaken by individual surgeons?
- Since the rationale place for HoLEP is only for the treatment for very large prostates it was suggested that only one site was needed in the South West. Currently patients are refereed further afield.
- Embolisation of prostates and other parts of the body is a common procedure. The equipment and skills are widely available in Devon.
- Prostates continue to grow after treatment.
- Most patients can have a TURP.

The committee were asked to make recommendations on which procedures should be commissioned and to make recommendations on a rational provision of these within Devon; which should be available from all acute centres in Devon providing surgical treatment for benign prostatic hyperplasia, which should only be available from a limited number of centres, and which would it be satisfactory to be available at specialist centres outside Devon

- Because of the relatively limited use and the high capital outlay required the committee unanimously recommended that HoLEP continues to be commissioned outside Devon for the treatment of large prostates. It was noted that HoLEP could become available in Devon if a surgeon is appointed by UHPNT to develop the service and is supported by an appropriate internal business case.
- The committee unanimously recommended that PAE be commissioned from selected centres locally for suitable patients with bladder outflow obstruction. Concerns were raised about availability of theatres and specialists and the length of time for symptom improvement and

how patient's suitability would be assessed. It was suggested that commissioning criteria be worked up.

- The committee recommended unanimously that Aquablation should not be commissioned as this is a new technique for which data are limited. It may be reconsidered as further trials become available.
- The committee recommended unanimously that that Rezum should not be commissioned as it is a new procedure for which data are limited and which is being evaluated by NICE.
- GreenLight and Urolift are already carried out at some sites in Devon, providers have a good track record and both procedures can be undertaken as day cases. The committee recommended unanimously to commission Urolift from each of local acute centres if internal business cases to provide it are approved. Other centres should consider providing Greenlight due to its low cost per case advantage and adequate supportive clinical data, however it was recognised that internal business cases will be needed due to the capital outlay.

It was noted that the Exceptional Funding Panel and Individual Funding Panel routes were available through which funding could be sought for patients on an individual basis.

ACTION: Committee recommendations to be submitted to the CCGs to inform senior level commissioning discussions for services for this condition.

6. NHS England Evidence-Based Interventions Guidance for CCGs

NHS England issued statutory guidance to Clinical Commissioning Groups (CCGs) in November 2018 to introduce and implement commissioning policies for selected interventions. This was published in partnership with NHS Clinical Commissioners, the Academy of Medical Royal Colleges, NHS Improvement and NICE.

The guidance sets out clinical criteria for seventeen interventions outlining when they should be commissioned or offered, separated into two categories. There are four "Category 1" interventions that should not be routinely commissioned, with patients only able to access such treatments where they successfully make an individual funding request (IFR) and thirteen "Category 2" interventions that should only be commissioned or performed when specific criteria are met. NHS England has set challenging goals for a reduction in local activity for these interventions.

The CCGs in Devon already have policies in place for the majority of these interventions. Where this is the case, NHS England have stated that it does not intend to reverse legitimate local decision-making; however the CCGs will need to be able to demonstrate that they have had regard to the new national guidance.

It was proposed that the CCGs in Devon adopt the NHS England commissioning policy recommendations for the seven interventions for which no local policy is currently in place to ensure that policy positions are in place by April 2019 and review the ten interventions for which existing local policies are in place with regard to the new national guidance. This will be undertaken through the Clinical Policy Committee (CPC) as the established local decision-making process via a rolling programme of work during 2019/20. It will include engagement with relevant local specialists, consideration of the existing policy position and the NHS England policy position, and any areas of variance.

The committee was asked to accept and recommend adoption of the NHS England commissioning policy recommendations for the seven interventions set out in the paper. These comprise four "category 1" interventions (adult snoring surgery, Dilatation and curettage for heavy

menstrual bleeding, knee arthroscopy for osteoarthritis, and injections for nonspecific low back pain without sciatica) and three "category 2" interventions (breast reduction, arthroscopic shoulder decompression and trigger finger release).

The committee discussed issues pertinent to the NHS England commissioning policy recommendations for the seven interventions for which no local policies are currently in place.

- It was noted that the CCGs' Cosmetic Treatments policy lists breast reduction among other commonly encountered cosmetic procedures which are not routinely commissioned.
- The committee expressed concern that implementation of the NHS England commissioning policy may increase breast reduction surgery because this details criteria under which individual patient applications would previously have been rejected on cosmetic grounds.
- It was agreed that further work needs to be undertaken to develop a local policy for breast reduction with regard to the NHS England commissioning recommendations. It was noted that there was a small window of opportunity to undertake consultation with local specialists and to present the issues and an alternative policy proposal to the CPC meeting in March.

The Committee unanimously accepted and recommended adoption of the NHS England commissioning policy recommendations for the four "category 1" interventions (adult snoring surgery, dilatation and curettage for heavy menstrual bleeding, knee arthroscopy for osteoarthritis, and injections for nonspecific low back pain without sciatica) and two of the three "category 2" interventions (arthroscopic shoulder decompression and trigger finger release).

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

ACTION: Clinical Effectiveness team to liaise with local specialists to present the issues and an alternative policy proposal for breast reduction for discussion at the CPC meeting in March 2019.

7. Update from NICE Planning Advisory Group (NPAG)

The committee received updates from two NICE Planning Advisory Group Meetings.

16th October 2018

NPAG had considered nine Technology appraisals the majority of which were NHS England commissioned.

Other guidelines and guidance considered by NPAG included three pieces of Antimicrobial Prescribing Guidance, seven Clinical Guidelines, one piece of Diagnostic Guidance and two pieces of Interventional Procedures Guidance.

It was noted that NICE had taken on responsibility for Primary Care Guidance.

4th December 2018

At the meeting held on 16 October it had been agreed that a short a short summary of NICE Technology appraisals commissioned by NHS England would be produced rather than the more detailed papers produced up until then.

NPAG considered two Technology appraisals for CCG commissioned technologies. A summary had been produced outlining for information four Technology appraisals for NHS England commissioned technologies.

Other guidelines and guidance considered included two pieces of Public Health Guidance, four Clinical Guidelines, two social care guidelines and seven pieces of Interventional Procedures Guidance.

8. Update from Clinical Policy Engagement and Consultation Panel

The committee receive an update from the Clinical Policy Engagement and Consultation Panel meeting which took place on 10th October 2018.

Six items were discussed:

- Assisted conception
- Fluticasone furoate, umeclidinium and vilanterol (Trelegy® Ellipta® combination dry power inhaler for Chronic Obstructive Pulmonary Disease (COPD)
- Cosmetic treatments policy
- Insulin Degludec (Tresiba®) for use in patients with type 1 diabetes
- Insulin Degludec (Tresiba®) for use in patients with type 2 diabetes
- Reversal of male and female sterilisation policy

The panel recommended that no further engagement or formal consultation was required for any of the items discussed. However, it was agreed that in the case of the policy for male and female sterilisation policy a letter should be sent to specialists to accompany publication of the policy which refers to the fact that patients who opt for sterilisation would be rendering themselves ineligible for future assisted conception as the Assisted Conception policy specifically excludes those who have had sterilisation reversed.

9. Any other business

Attendance of Registrars at CPC meetings

A GP present raised the issue of a registrar attending a CPC meeting to observe. This was considered but agreed not to be possible due to the likelihood of other such requests being made (several such requests have been received in the past) and the possibility of creating capacity issues in meeting rooms and meetings potentially becoming unmanageable.

Change of time of next meeting

The committee agreed that the next meeting would commence at 9.30 am in Ivybridge. This is different from the previously advised 10.00 am start as it was felt to be better for GPs to be able to attend their afternoon clinics.

An e-mail confirming this will be circulated by Rebecca Heayn.

ACTION: Rebecca Heayn to e-mail confirmation of the start time of the next Clinical Policy Committee meeting to the committee.

Summary of actions		
	Action	**Lead**
18/18	Cosmetic treatments policy: Chair to feed comments from the Clinical Policy Committee and IFR Panels into NHS England's work to produce a definition of 'cosmetic treatment' Chris Roome to feed this in as a suggestion to the NHS England evidence based interventions programme.	Jo Roberts Chris Roome
19/01	Surgical treatment options for lower urinary tract symptoms caused by benign prostatic hyperplasia. Committee recommendations to be submitted to the CCGs to inform senior level commissioning discussions for services for this condition.	
19/02	NHS England Evidence-Based Interventions Guidance for CCGs: Policy recommendations and QEIAs to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
19/03	Clinical Effectiveness team to liaise with local specialists to present the issues and an alternative policy proposal for breast reduction for discussion at the CPC meeting in March 2019.	Chris Roome
19/04	Confirmation of the start time of the next Clinical Policy Committee meeting to be circulated by e-mail.	Rebecca Heayn