Northern, Eastern and Western Devon
Clinical Commissioning Group

South Devon and Torbay
Clinical Commissioning Group

Clinical Policy Committee

Minutes

Wednesday 26th July 2017, 10.00 am to 12.00

The Watermark, Ivybridge

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Glen Allaway*	GP Clinical Commissioner	NEW Devon CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker*	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Dr Andrew Gunatilleke*	Consultant in Pain Management & Anaesthesia	T&SD NHS FT
Dr Lucy Harris*	GP Clinical Commissioner	South Devon & Torbay CCG
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Simon Polak	Deputy Chief Nursing Officer	NEW Devon CCG
Tracey Polak	Assistant Director/Consultant of Public Health	Devon County Council
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Mark Taylor	Lay Public Member	

Guests:

Jacob Akoh	Consultant Surgeon	Plymouth Hospitals NHS FT
Robert Bethune	Consultant Colorectal Surgeon	Royal Devon & Exeter NHS FT
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Hannah Jones	Healthcare Evidence Reviewer	NEW Devon CCG
William Knight	Consultant Neurologist	T&SD NHS FT
	Honorary Consultant Neurologist	Plymouth Hospitals NHS Trust
Anthony Lambert	Consultant Surgeon	Plymouth Hospitals NHS Trust
David Sanders	Consultant Surgeon	Northern Devon Healthcare NHS Trust
Naomi Scott	Healthcare Evidence Reviewer	NEW Devon CCG
Karl Trimble	Associate Medical Director & Consultant Orthopaedic Surgeon	Plymouth Hospitals NHS Trust
Rob Turner	GP	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

Post meeting note: Some of the items for discussion were not discussed in the order in which they appeared on the agenda.

1. Welcome and introductions

Attendees were welcomed to the meeting.

Apologies

Dr Andrew Craig	GP Clinical Commissioner	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Miles Earl	Contract Accountant	NEW Devon CCG
Paul Foster	Chief Pharmacist	T&SD NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Dr Ben Waterfall	GP Clinical Commissioner	NEW Devon CCG

The seven voting members present were identified.

Dr Ben Waterfall had deputised voting to Richard Croker
Dr Andrew Craig had deputised voting to Dr Andrew Gunatilleke

Declarations of interest

Declarations of interest were collected. The chair reviewed the Declarations of interest. All Declarations of interest are reported in the minutes.

Notification of Any Other Business

Members were asked if they had any items of AOB to discuss. It was noted that several members of the committee had to attend a meeting in north Devon following the Clinical Policy Committee meeting.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Safinamide (Xadago®) for mid- to late-stage fluctuating Parkinson's Disease	**Profile Pharma Limited**
Alternative treatments: **Selegiline hydrochloride** (Eldepryl®, Zelapar®, plus generics) **Rasagiline** (Azilect®, plus generics)	**Orion Pharma (UK) Limited, Cephalon (UK) Limited (Teva UK Ltd)**, various manufacturers **Teva Pharmaceuticals Ltd**, various manufacturers
Tiotropium bromide monohydrate and olodaterol hydrochloride (Spiolto® Respimat®) combination inhaler for chronic obstructive pulmonary disease (COPD)	**Boehringer Ingelheim Limited**
Alternative treatments: **Other long-acting muscarinic antagonist (LAMA) / long-acting beta-2 agonist (LABA) fixed dose combination inhalers** (Ultibro Breezhaler®, Duaklir Genuair®, Anoro Ellipta®) **LAMA or LABA individual component inhalers**	**Novartis Pharmaceuticals UK Ltd, AstraZeneca UK Limited, GlaxoSmithKline UK** various manufacturers
The specialist management of abdominal wall hernia in adults	As a provider of private treatments for patients with hernia

NAME OF ATTENDEE	ROLE	
Dr Mick Braddick	GP Clinical Commissioner	*Hospitality received where the drug(s)/devices(s)/intervention(s)/treatments(s) under consideration were discussed by a representative of a drug /manufacturing company/companies.* Attended meetings sponsored by Teva with supper provided, presentation by local respiratory physicians and medicines optimisation pharmacists.
Mr Robert Bethune	Consultant Colorectal Surgeon	Provides management of private patients with hernia.
Rebecca Heayn	Clinical Effectiveness Governance Manager	A family member has been diagnosed with Parkinson's disease.
Dr William Knight	Consultant Neurologist	Honorarium for Advisory board participation Bial Pharma 2017. In receipt of transport/hospitality to attend international meeting (EAN2017) Bial Pharma.
Mr David Sanders	Consultant Surgeon	In receipt of £1,000 fee for attending advisory Board meeting.

2. Minutes of the meeting held on 24th May 2017 and matters/actions arising

The minutes of the meeting held on 24th May 2017 were approved.

Summary of actions		
	Action	**Lead**
17/04	*Letter to be written to NHS England regarding commissioning of narcolepsy with cataplexy.* A letter was written and a reply has been received from NHS England. The reply was included in the meeting papers. Action complete.	
17/05	Sodium oxybate for narcolepsy with cataplexy: policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. The policy recommendation and QEIA have been signed off by the executive committees of NEW Devon CCG and of South Devon and Torbay CCG. The policy has subsequently been published. Action complete.	
17/06	Lecicarbon A suppositories for constipation: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication. The policy recommendation and QEIA have been signed off by the executive committees of NEW Devon CCG and of	

	South Devon and Torbay CCG. The policy has subsequently been published. Action complete.	
17/07	CPC Annual report to be submitted to the appropriate bodies of the CCGs to be received and ratified. Action complete.	
17/08	*Once ratified the CPC annual report will be published and made publically available via the CCG website.* Action complete.	
17/09	*Summary of NPAG Annual Report to be produced for CPC.* This was included on the agenda. Action complete.	
17/10	*Clarification to be sought on the corporate governance requirements in respect of receipt of Declarations of Interest.* Declaration of Interest forms must be completed even where there is a nil declaration. Action complete.	

3. Safinamide (Xadago®) for mid- to late-stage fluctuating Parkinson's Disease

A formulary application has been received from Dr William Knight, Consultant Neurologist, T&SD NHS FT for the use of Safinamide (Xadago®) to treat mid- to late-stage idiopathic Parkinson's disease in adults who are experiencing motor fluctuations, as an add-on treatment to a stable dose of levodopa. Naomi Scott, Healthcare Evidence Reviewer, NEW Devon CCG presented an evidence assessment. Dr William Knight took part in the discussion of this item.

Safinamide (Xadago®) is a Monoamine oxidase B (MAO-B) inhibitor.

Motor fluctuations are common in mid- to late-stage Parkinson's disease patients as a consequence of the 'wearing off' of Levodopa medication or disease progression. Adjunctive treatments are then required to reduce motor complications and improve quality of life. Treatment options include dopamine agonists, MAO-B inhibitors and catechol-O-methyl transferase (COMT) inhibitors. Two MAO-B inhibitors, Selegiline and Rasagiline, are currently licenced for this indication. Safinamide has pharmacological differences from these agents, but it is not clear what clinical effects might be related to this. Safinamide (Xadago®) would provide an additional treatment line for patients where other MAO-B inhibitors are not tolerated, or are ineffective, or who also require antidepressant therapy. The application is supported by Dr Camille Carroll, Plymouth Hospitals NHS Trust, who is currently involved in the stage IV Synapses study and has highlighted the potential use in patients with existing dyskinesia.

A systematic literature search did not identify any head-to-head comparison studies of safinamide and the current formulary MAO-B inhibitors. The two RCT studies assessing safinamide demonstrated its efficacy against placebo to elicit a clinically relevant improvement of 30 minutes to 1 hour of 'on' time and a similar reduction in 'off' time. Significant improvements were also found in the motor component of the Unified Parkinson's Disease Rating Scale. These results were found to still be significant at a 2 year follow up when comparing 100mg safinamide to placebo, however the primary efficacy variable within this follow up study was not met. Post hoc analysis suggests that improvements in 'on' and 'off' time are generally independent of the effects of additional medication or level of baseline motor fluctuations. Authors of a further post hoc analysis conclude that safinamide can improve motor

fluctuations without worsening dyskinesia; however this used data from the follow up study that did not meet its primary endpoint. The RCT studies did not specify if patients had been previously prescribed selegiline or rasagiline, so it is not possible to determine whether non-responders to the current MAO-B inhibitors would have a favourable response to safinamide.

The European Public Assessment Report (EPAR) denotes that dyskinesia could be considered a risk for people treated with safinamide and the Summary of Product Characteristics (SPC) suggests that it may worsen symptoms in patients with pre-existing dyskinesia. Within the reviewed Randomised Controlled Trials (RCTs) safinamide did not improve Dyskinesia Rating Scale scores; however it also did not negatively impact upon them.

No cost utility analysis for safinamide were identified. It is more expensive than current MAO-B inhibitors: however if it is successful for patients who fail to respond or are unable to tolerate existing MAO-B inhibitors, it has the potential to delay the requirement for more expensive non-oral treatments.

The committee discussed issues pertinent to this recommendation:

- Specialist opinion stated that few drugs get beyond the laboratory and that good quality trial evidence is rare.
- Specialist opinion stated that most patients with Parkinson's disease have considerable periods of sleep each day. Any increase in 'on time' and activities of daily living will provide a noticeable benefit to patients. The specialist also stated that 'off' time can happen at any point in the day, including during activity. There are also non motor benefits including psychological benefits that could last for longer than motor benefits. It is anticipated that the benefits of safinamide (Xadago®) could last for one to two years.
- Research shows that safinamide is effective; however there is no clinical trial evidence that it is effective for the treatment of patients where other MAO-B inhibitors are not tolerated, or are ineffective.
- Safinamide is more expensive than currently available MAO-B inhibitors but may delay the need for progression to complex, more costly, non-oral therapies.
- Specialist opinion stated that treatment with safinamide would not be continued if there was no benefit to the patient. Benefits to patients should be clear in weeks to months, if treatment was not effective the patient would progress to more complex treatments.
- Safinamide would require a clearly defined place in therapy.

The committee voted 4 to 3 against recommending Safinamide (Xadago®) for mid- to late-stage fluctuating Parkinson's Disease.

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

Specialist opinion stated that no head to head studies will be undertaken comparing safinamide against other MAO-B inhibitors. However the evidence would support safinamide as a first line treatment.

The committee also considered whether there was another route available to patients who might benefit from safinamide and concluded that outside of clinical trials applications via the Individual Funding Request panel would be the only appropriate route.

4. Tiotropium bromide monohydrate and olodaterol hydrochloride (Spiolto® Respimat®) combination inhaler for chronic obstructive pulmonary disease (COPD)

A formulary application has been received from Dr Georgina Hands, Respiratory Consultant, Northern Devon Healthcare NHS Trust for the use of Spiolto® Respimat® for treating COPD. Hannah Jones, Healthcare Evidence Reviewer, NEW Devon CCG presented an evidence assessment. Dr Georgina Hands sent her apologies for being unable to attend the meeting but submitted written comments. Subsequent to the circulation of the board pack a comment supporting the application was received from David Halpin, this was similar to those submitted by three other consultants.

Spiolto® Respimat® is a new LAMA/LABA combination soft mist inhaler containing tiotropium bromide monohydrate and olodaterol hydrochloride. This is the only non-dry powder LAMA/LABA combination inhaler. The Respimat® inhaler does not require coordinating actuation with inspiration. It was approved in the UK to treat COPD in June 2015. The clinical efficacy evidence comes from four phase three randomised controlled trials. Two of the trials compared Spiolto® Respimat® with the individual components of tiotropium and olodaterol, and the other two trials compared Spiolto® Respimat® with the individual component of tiotropium and with placebo. There are currently no head-to-head randomised controlled trials comparing Spiolto® Respimat® with the other fixed dose combination inhalers.

Spiolto® Respimat® has been shown to improve trough FEV_1 the St George's Questionnaire scores and the Transition Dyspnoea Index scores, but this is in relation to tiotropium and olodaterol monotherapies or placebo. Differences reach or exceed the minimum clinically important difference compared with placebo. Statistical improvements in FEV_1 and the St George's Questionnaire were also found compared to tiotropium, but the minimum clinically important difference between Spiolto® Respimat® and individual component monotherapies was generally not reached.

A network meta-analysis suggests that Spiolto® Respimat® has roughly the same effect as other LAMA/LABA fixed dose combination inhalers. The acquisition cost is also exactly the same as the other LAMA/LABA fixed dose combination inhalers. A cost-utility analysis with many limitations based on this network meta-analysis suggests that Spiolto® Respimat® is equal to two other LAMA/LABA fixed dose combinations, and dominates the Duaklir Genuair® fixed dose combination inhaler which contains aclidinium and formoterol.

Budget impact assessments suggest that Spiolto® Respimat® may be cost neutral compared to other fixed dose combination inhalers or possibly cost saving compared to combinations of individual LAMA and LABA inhalers. The main consideration for Spiolto® Respimat® is that it would provide an alternative option at no additional cost for patients with a clinical need for a LAMA/LABA fixed dose combination inhaler, who either require or prefer a soft mist inhaler over a dry powder inhaler, and it would allow patients currently on tiotropium to step up from an individual component inhaler without changing their device or LAMA.

The committee discussed issues pertinent to this recommendation:

- A query was raised as to whether the cardiovascular risk associated with tiotropium remained and specifically whether this was associated with the Respimat® inhaler. The Clinical Effectiveness Team reiterated the MRHA advice reported in the paper still applies with regards to tiotropium and relates to both the Handihaler® and Respimat® devices. The Formulary Interface Groups will consider what supporting information should be contained in the formulary.

The committee voted unanimously in favour of recommending Spiolto® Respimat® combination inhaler for the treatment of chronic obstructive pulmonary disease (COPD).

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

5. Review: Policy for the specialist management of abdominal wall hernia in adults

The Devon-wide policy for the specialist management of abdominal wall hernia in adults was originally developed in conjunction with the GPs who act as Planned Care Leads for each locality in NEW Devon CCG and for South Devon and Torbay CCG. Surgeons from all four acute trusts in Devon were consulted throughout the development process. The policy was accepted by CPC in June 2015 and published in September 2015. At the request of local specialists, a review of the content of the policy has been undertaken. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented a paper. Mr Jacob Akoh, Consultant Surgeon, Plymouth Hospitals NHS Trust, Mr Robert Bethune Consultant Colorectal Surgeon, Royal Devon and Exeter NHS FT, Mr Anthony Lambert, Consultant Surgeon, Plymouth Hospitals NHS Trust, Mr David Sanders, Consultant Surgeon, Northern Devon Healthcare NHS Trust and Mr

Karl Trimble, Associate Medical Director (and Consultant Orthopaedic Surgeon), Plymouth Hospitals NHS Trust took part in the discussion of this item.

Following a request for feedback, extensive comments were submitted by specialists. The presented paper addressed these comments and considered the evidence presented in support of them. No comments were received with respect to the policy position on referral of femoral and inguinal hernias, specialist management of umbilical hernias; or the definition of significant functional impairment. Therefore no additional work has been undertaken in these areas.

Local specialist opinion questioned the benefit of recommending weight management and smoking cessation support prior to elective inguinal hernia surgery. The current policy does not obligate patients with inguinal hernias to lose weight or stop smoking but indicates that patients should be encouraged to do so. This guidance does not form part of the criteria for accessing treatment or funding. This is in line with current BHS/RCS guidance.

Local specialists raised concerns that the current CCG policy is not in line with the BHS/RCS commissioning guide for groin hernia. The presented paper focussed on the points of difference between these two documents. The CCG policy places no additional restrictions on referral, but does contain criteria for surgical repair of inguinal hernias in men. The BHS/RCS guide cites two reports supporting their positon, both of which considered activity levels of elective and emergency repairs before and after introduction of local commissioning policies for hernia. They report that a higher proportion of patients with hernia repair required emergency surgery in the period after introduction of local policies. Comparative local data show a reduction in the overall volumes of both elective hernia repair operations and emergency procedures in the period following introduction of the Devon policy. However, activity levels are likely to be affected by several confounding factors and caution must be exercised when making such comparisons.

In support of the statement that “asymptomatic hernias can be managed conservatively… but there is a likelihood of requiring surgery in the future, outcomes are worse and conservative management is not cost effective for the healthcare community” the BHS/RCS guide cites a systematic review with data analysis, long term observational data following an RCT and the two reports previously discussed.

The systematic review with data analysis modelled the mean life expectancy for 50-year old men with an asymptomatic or mildly symptomatic inguinal hernia. Analysis suggested that following elective hernia repair, a mean benefit of around three and a half days additional life would be accrued. A number of threshold and sensitivity analyses were conducted and concluded that “life expectancy between the groups differs very little”, and that “there seems to be no difference in pain relief between watchful waiting and operation”. The long-term observational study is a follow up of one group from an earlier RCT. This suggests that 72% of men with asymptomatic inguinal hernia will cross over to surgery after 7.5 years. This was considered and accepted during the original policy development.

Citing the forthcoming World Guidelines for Groin Hernia Management, and an additional retrospective study, the BHS/RCS guide states that “Surgical repair should be offered to patients with a symptomatic inguinal hernia and should be considered in patients less than 65 years of age with an asymptomatic inguinal hernia”. The retrospective study used hospital records of patients who had undergone surgical repair for groin hernias to estimate the overall risk of strangulation in these patients. It is unclear if patients were symptomatic or asymptomatic. The World Guidelines authors conducted a systematic literature review and report consensus statements based on their findings. The majority of the evidence cited in the World Guidelines document was considered during development of the current policy which supports the view that complication risk is low in asymptomatic or minimally symptomatic men with inguinal hernias. Although most patients will develop symptoms and need surgery, watchful waiting for these patients is safe since the risk of hernia complications is low. The authors of the World Guidelines found no evidence to support watchful waiting as a

management strategy in men with symptomatic inguinal hernias, and report that no data exist on the risk of incarceration or strangulation in this population.

A point for discussion for the committee was the treatment of patients whose symptoms lie between “minimally symptomatic” and “pain or discomfort sufficient to cause significant functional impairment” as defined in the policy.

Local specialists raised concerns regarding the policy position for incisional hernias; specifically that referral for specialist advice and surgery will only be routinely commissioned when both pain or discomfort is sufficient to cause significant functional impairment and appropriate conservative management has been tried first. Specialists stated that such hernias will not resolve with conservative management and increase with size over time. They may be more difficult to repair, with a higher risk of complications and increased costs.

High quality data regarding the natural history of ventral hernias are lacking. The authors of a systematic review concluded that non-operative management of ventral hernias was safe; but accepted limitations in study quality.

Two retrospective cohort studies reported reasonably high crossover rates from watchful waiting to surgery in patients with incisional hernias; one of these reported a significantly higher mortality rate in patients who crossed from watchful waiting to surgery (however it is noted that co-morbidities were the reasons for choosing watchful waiting in 22% of patients, suggesting these patients may not have been considered fit for elective surgery). The other found no difference in mortality rates between elective cross-over and initially surgically treated patients. Large hernia size was reported to be a risk factor for poor early outcomes, and recurrence. An RCT of watchful waiting vs. surgical repair is ongoing which it is hoped will provide further data.

A cost-utility analysis that considered watchful waiting vs. surgery for groin hernia from a UK payer perspective suggested that elective repair would be considered cost effective over the 25-year term of the model. The model is subject to several limitations and should be interpreted with caution. No high quality, long-term data are available with which to build a more sophisticated model. No relevant cost-utility analyses considering repair of ventral hernia were identified. Since the introduction of the current Devon-wide policy, activity volume for both elective and emergency hernia repair has decreased. If activity levels returned to pre-policy levels an annual increase in costs of approximately £1,010,000 per annum is expected. The Clinical Effectiveness team assume that the lower rate of emergency repair observed following introduction of the policy would not return to the higher rate seen prior to the policy change. It is important to note, activity levels are likely to be affected by a number of confounding factors, and caution must be exercised when making comparisons of this type.

The committee were asked to consider whether the presented evidence was sufficient to withdraw the current Devon policy. The committee discussed issues pertinent to the current Devon policy including:

- The severe financial position of the NHS in Devon was acknowledged but it was noted that the role of the Clinical Policy Committee is to make recommendations to the Governing Bodies of the Clinical Commissioning Groups in Devon after considering all the issues in the round. It is the role of the Board to resolve the financial implications and accept or reject the recommendation.
- The definition of ‘functional impairment’, the impact of ‘functional impairment’ on the quality life of a patient, including on their ability to work, and the cost to society of looking after people with functional impairment rather than treating their condition earlier. In the view of the hernia specialist hernia surgery was one of the most cost effective treatments in terms of quality of life.
- Specialist opinion stated that the current policy was not in the best interest of the patient. Hernias do not get better by themselves and the majority of patients cross over to surgery at some point. Patients are then older and more likely to have co-morbidities or experience complications. Specialists felt that patients were not being offered best care; some clinicians expressed a view that they were obligated to tell patients that they were not being offered best care.

- In order to be eligible for treatment the symptoms of patients in Devon have to be more severe than outlined in the new British Hernia Society guidelines.
- One hernia surgeon stated that he now does not apply the current policy and offers surgery to all patients who request it (where surgically appropriate and after gaining informed consent).
- There are other conditions where symptoms need to be advanced in order to meet commissioning criteria for treatment, however the consequences to the patient were not as potentially serious as in the case of hernia.
- The potential variation in symptoms that could exist between the definition of minimally symptomatic used in the RCTs and the description of functional impairment used in the current policy. A specialist suggested that Gloucestershire CCG had a policy which might be suitable and could be considered as a starting point for a revised policy wording.

The committee voted unanimously in favour of reviewing the current policy for specialist management of abdominal wall hernia in adults.

ACTION: The wording of the policy for the specialist management of abdominal wall hernia in adults to be compared with that of the Gloucestershire policy, further local specialist input sought and their suggested revisions to be brought back to the committee.

6. NICE Planning Advisory Group (NPAG) Annual Report 2016-17 Summary

NPAG provides expertise to enable commissioning in response to NICE guidance and guidelines to be undertaken through a systematic approach to business planning. Through NPAG there is an established process for ensuring that NICE Technology Appraisals and Highly Specialised Technology Appraisals are added to the local formulary within 90 days of publication so that as commissioners the CCGs comply with statutory funding responsibilities.

The Committee received a summary of the NPAG Annual Report 2016-17. It was noted that there had been a sixty-five percent increase in the volume of guidance produced by NICE since 2013-14.

The NPAG Annual Report 2016-17 has been received by both the South Devon and Torbay CCG and NEW Devon CCG Quality Committees for information and assurance.

7. Update from NICE Planning Advisory Group (NPAG)

The committee received an update from the NPAG meeting which had taken place on Wednesday 9th May 2017.

8. 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 7th June 2017.

It was reported that the group had considered two policy recommendations from the Clinical Policy Committee meeting held on 24th May 2017 and agreed that no further engagement or public consultation action was required.

At its meeting the Clinical Policy Engagement and Consultation Panel had noted the emergence of a new South Devon and Torbay Joint Clinical Effectiveness Group (between the CCG and the acute trust).

9. Clinical Policy Engagement and Consultation Panel Annual Report 2016-17

The committee received the second Clinical Policy Engagement and Consultation Panel annual report.

The Clinical Policy Engagement and Consultation Panel exists to support the CCGs in Devon to determine the need for any further engagement or formal public consultation on clinical policy recommendations made by the Clinical Policy Committee.

The first annual report last year had explained the development and subsequent operation of the process; the second annual report reflects a year of functioning and refinement of an established process.

One of the most significant additions to the process has been routine consideration of the information available to patients via NHS Choices in respect of the treatment and condition under review. It was felt that this is often the first point of reference for patients, and therefore an awareness of the NHS public information available, and hence patient expectations, was a useful addition to considering the patient interest issues. This has in turn had an impact on the processes of the Clinical Effectiveness team, with this being a routine consideration when looking at drugs and treatments for particular conditions.

Five meetings were held last year, considering and making recommendations to the CCGs on a total of 15 clinical policy recommendations.

On discussion of these recommendations, the panel had been satisfied that the public interest issues had been fully considered and that further engagement or formal public consultation activity would not yield additional insights. However the panel formally documented their views and made some additional recommendations for action arising from the consideration of specific policies. This included:

- seeking further intelligence and data to establish a baseline position prior to the publication of certain policies to enable understanding of the impact of these,
- to understand the uptake of the Clinical Policy Patient Support Information that had been produced.

Following presentation of the previous year's Annual Report to the CCGs, the clinical policy communication process has been strengthened to ensure that community representatives routinely received details of the publication of new or updated policies, in conjunction with the communication and engagement team.

The annual report is being submitted to the first joint engagement committee of the two CCGs for assurance and will be made publicly available once accepted by the CCGs.

A discussion took place and a question was put to the Clinical Policy Committee with regard to whether there was any update on the new South Devon and Torbay Joint Clinical Effectiveness Group (JCEG). It was noted that JCEG deals with guidelines and current practice not policies; snoring was cited as an example of the areas of work undertaken. South Devon and Torbay CCG do not have the resources to undertake full reviews. However Torbay librarians have undertaken literature searches. JCEG has good engagement with GPs in Devon and from commissioners and consultants and ideally would want to use the same approach across Devon.

10. Joint Formularies Annual Report 2016-17

The committee received the Devon Formularies Annual Report 2016-17. This is the second Devon Formularies annual report. The report has been received and approved by the two Devon Formulary Interface Groups (FIGs).

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 two (FIGs) which reflect natural healthcare communities. Representatives from both primary and secondary care sit on each FIG.

The report provides an account of the work undertaken by the FIGs and the governance processes that underpin the formularies. The annual report also provides an account of use of the formulary website and app. The key points noted were that:

- In the year, each FIG met 6 times.

- There is also a virtual e-FIG process which takes place as required in the months when FIG meetings do not take place.
- A number of pieces of guidance were developed and added to either the South and West Devon formulary or the Northern and Eastern Devon formulary as detailed in the report.
- The publication of new or revised national guidance prompted review of 8 formulary chapters in year.
- In year, forty-eight NICE TAs and one HST have been added to the formularies.
- After approval by the Clinical Policy Committee and the CCGs the FIGs consult with appropriate clinicians to position the drug entry within the each of the formularies. In year this process was undertaken for four drugs.
- Seventeen new product applications were received.
- The FIGs approved the inclusion of 8 formulary preferred brands. The brands had been identified by the Medicines Optimisation teams and underwent a standardised assessment of key criteria.
- The FIGs approved the removal of seven products from one or both of the formularies.
- Seven applications for a change in formulary status were considered by one or both of the formularies.
- The Devon Formularies each have a website to reflect the decisions of the FIGs. These sites are available on a single app. From February 2015 the South and West Devon App and the North and East Devon App were merged. Between April 2016 and March 2017 the App has been downloaded 1010 times to different mobile devices.
- There were around one hundred thousand (100,000) page views per month across both formularies.

11. Any other business

There was no other business to report.

The meeting closed at 12.30 pm.

Summary of actions

	Action	Lead
17/11	Safinamide (Xadago®) for mid- to late-stage fluctuating Parkinson's Disease: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
17/12	Tiotropium bromide monohydrate and olodaterol hydrochloride (Spiolto® Respimat®) combination inhaler for chronic obstructive pulmonary disease (COPD): Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
17/13	The wording of the policy for the specialist management of abdominal wall hernia in adults to be compared with that of the Gloucestershire policy, further local specialist input sought and their suggested revisions to be brought back to the committee.	Matt Howard