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

Clinical Policy Committee (CPC)
Minutes

Wednesday, 3rd December 2014, 9.30 am to 12 noon

Committee Suite, County Hall, Exeter

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Jono Broad	Lay Member	
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker*	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS Foundation Trust
Paul Foster	Chief Pharmacist	SDHC NHS Foundation Trust
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Dr Peter Leman*	GP Clinical Commissioner	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Samantha Morton	Head of Contracting and Procurement	South Devon and Torbay CCG
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Dr Thomas Beech	ENT Consultant	NDHC NHS Foundation Trust
Mr John Charity	Associate Specialist in Trauma and Orthopaedics	RD&E NHS Foundation Trust
Dr Caroline Court	Consultant in Public Health Medicine	Cornwall Council
Rebecca Cowie	Principal Embryologist	RD&E NHS Foundation Trust
Sally Doidge	Senior Embryologist	RD&E NHS Foundation Trust
Mr Keith Eyres	Consultant Orthopaedic Surgeon	RD&E NHS Foundation Trust
Emma Hewitt	Joint Formularies Pharmacist	NEW Devon CCG
Mr Mike Hockings	Clinical Director / Consultant Orthopaedic Surgeon	SDHC NHS Foundation Trust
Mr Jonathan Howell	Consultant Orthopaedic Surgeon	RD&E NHS Foundation Trust
Dr Simon Jameson	Orthopaedic Fellow	RD&E NHS Foundation Trust
Dr Lisa Joels	Consultant Gynaecologist	RD&E NHS Foundation Trust
Emma Kain	Speciality Registrar	Cornwall Council
Mr Jonathan Keenan	Consultant Orthopaedic Surgeon	Plymouth Hospitals NHS Trust
Mr Jonathan Lord	Consultant in Obstetrics and Gynaecology	Royal Cornwall Hospital Trust
Joe Maguire	Medication Safety Pharmacist	RD&E NHS Foundation Trust
Miss Gurpreet Pandher	Consultant Obstetrician and Gynaecologist	SDHC NHS Foundation Trust
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Dr Jacqueline Ruell	Consultant Haematologist	RD&E NHS Foundation Trust
Dr Nichola Rymes	Consultant Haematologist	SDHC NHS Foundation Trust
Mr Andrew Temple	Consultant Orthopaedic Surgeon	NDHC NHS Foundation Trust

In attendance:

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

* Denotes voting members

1. Welcome and introductions

Attendees were welcomed to the meeting.

Dr Stephen Hunt has resigned from the committee. A representative for the Northern Locality is being sought. It was subsequently confirmed that this would be Dr Ben Waferfall from 2015.

Due to the volume and complexity of the business to be discussed, the meeting had been scheduled to take place from 9.30 am to 12 noon. The meeting closed at 1.20 pm.

Dr Tawfique Danesmend left the meeting after item 5
Dr Philip Melluish left the meeting at 12.30 pm
Paul Foster left the meeting at 12.45 pm

Dr Alison Round had deputised voting to Richard Croker.
Samantha Morton represented the CCGs' contracting departments.
No public health representative was able to attend the meeting.
No Patient Safety and Quality representative was able to attend the meeting.

Apologies

Dr Alison Round	GP Clinical Commissioner	NEW Devon CCG
Andrew Kingsley	Lead Nurse, Healthcare Acquired Infections	NEW Devon CCG
Tracey Polak	Assistant Director/Consultant in Public Health	Devon County Council

Confirmation of voting members and Declarations of interest
The seven voting members present were identified.

Notification of Any Other Business (AOB)
No items for discussion under AOB were identified.

Declaration of interest forms were collected. The chair informed the committee of declarations of interest received.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
NICE guidance for thromboprophylaxis in hip and knee surgery	**Manufacturers of anticoagulants and antiplatelets**
Fluticasone propionate and azelastine hydrochloride (Dymista®) Alternative treaments: **Fluticasone furoate** (Avamys®) **Desloratadine and other antihistamines**	**Meda Pharmaceuticals** **GlaxoSmithKline** **Various manufacturers**
Assisted conception and cryopreservation	**Providers of assisted conception and cryopreservation services**

NAME OF ATTENDEE	ROLE	
Dr Tom Beech	ENT Consultant	Hospitality received where the drug(s) /device(s)/intervention(s)/treatment(s) under consideration were discussed by a representative of a drug /manufacturing company/companies. • During one of the regular hospital meetings (which is likely to have taken place within the last 2 to 3 years) at a previous trust, a Meda representative gave a talk on Dymista®. Lunch may have been provided.

Mr Jonathan Keenan	Orthopaedic Surgeon	Personal: BAYER THROMBOSIS ADVISORY GROUP: Birmingham, February 2007 Birmingham, February 2008 Birmingham, February 2009 Transport and hospitality to attend EFORT, Vienna. June 2009. Bayer Orthopaedic Surgery Advisory Board Meeting 28th March 2014, London (VTE in cast immobilised patients). Non Personal: Thrombosis Publications funded by Sanofi Aventis (? Thrombosis nurse funding Sanofi)
Jonathan Lord	Consultant in Obstetrics and Gynaecology	Employee of the provider of fertility services in Cornwall (Royal Cornwall Hospitals Trust, RCHT); person responsible under the HFEA Act at RCHT for assisted conception. Director of Cornwall IVF who administers the satellite service for NHS and self-funded IVF in Cornwall in partnership with RCHT and the IVF units. Partner of GAIA Health (not trading, but established to facilitate community gynaecology services in an interface-type service). Complete DoI available on file at RCHT, but nil else directly relevant to fertility (e.g. sponsored study leave for gynae, but not fertility; employee of Peninsula Medical School).
Jacqueline Ruell	Consultant Haematologist	In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. Bayer pharmaceutical company meeting – expenses paid only.
Nichola Rymes	Consultant Haematologist	In receipt of lecture fees in excess of £150 in the last year from above pharmaceutical / manufacturing company / companies. 2014: Pfizer (Fragmin) provided light refreshments for a nurse – led 'VTE Ambassadors'' meeting in Torbay Hospital. 2012: presented a talk on anticoagulation at SW VTE materclass. Event sponsored by Bayer (Rivaroxaban). 2013: presented a talk to local GP's on NOACs. Event sponsored by Bayer (Rivaroxaban). Fees for the last 2 events donated to charity.
Mr Andrew Temple	Consultant Surgeon	Received lecture fees from Smith and Nephew (Orthopaedic Implant Company). Delivered lectures on hip and knee replacement course in 2013 and 2014.

2. Minutes of the meeting held on 22nd October 2014 and matters/actions arising

The minutes of the meeting held on 22nd October 2014 were approved.

Summary of actions		
	Action	**Lead**
14/15	*Recommendation and summary of clinical discussion to be taken to CCGs' executive groups who will decide whether to implement the recommendation from NICE taking into account prioritisation of funding. (CG168 Referral for varicose veins)* *A paper is due to be submitted to NEW Devon CCG's Executive Group in November 2014.* This item was included on the meeting agenda. Action complete	
14/19 and 14/22	Proposal to be framed for e-mail discussion to agree process and remit for CPC clinical and financial responsibility. A meeting had taken place to discuss the above and a further meeting is due to take place in January 2015 regarding antipsychotics and repatriation. Action complete	
14/20	Details of CPC dates until December 2015 to be e-mailed to committee members with the latest dates highlighted. Action complete.	
14/21	Commissioning policies for depot injections of aripiprazole, olanzapine and paliperidone for schizophrenia to be published. The policy had been drafted and is awaiting accompanying formulary updates prior to circulation.	Rebecca Heayn
14/23	Commissioning policy for Subcutaneous Tocilizumab for rheumatoid arthritis to be published. The policy has been drafted and is awaiting accompanying formulary updates prior to circulation.	Rebecca Heayn

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

Due to the complexity of other issues to be discussed, this item was deferred until the next meeting.

4. Update on committee recommendation of referral for patients with varicose veins

The recommendation from the CPC meeting which took place on 10th September 2014 had been taken to the executive groups of NEW Devon CCG and South Devon and Torbay CCG. Both executive groups have taken a decision not to align with NICE.

Local criteria for treatment will be developed with input from surgeons. The executive group of NEW Devon CCG and South Devon and Torbay CCG will both develop a form of words to articulate why there is a variation from NICE guidance.

5. Aspirin for the prophylaxis of Venous Thromboembolism following Elective Hip Replacement and Elective Knee Replacement

Venous Thromboembolism (VTE) is a serious complication which can occur following major orthopaedic surgery. NICE issued CG92 (Venous thromboembolism: reducing the risk) in January 2010 and recommend several anticoagulants used in combination with medical prophylaxis to prevent VTE following total hip or total knee replacement. NICE does not consider aspirin adequate prophylaxis for VTE. Locally there is some non-alignment with NICE which varies both between trusts and within orthopaedic departments. Bethan Rogers, Clinical Evidence Pharmacist, NEW Devon CCG presented a paper which detailed the clinical evidence and cost-effectiveness analyses considered in the NICE full Clinical Guideline. A complete independent review of the literature was not undertaken. The principal aim of the review was to understand the rationale behind NICE's decision not to include aspirin as an appropriate treatment option. Mr John Charity, Mr Keith Eyres, Mr Jonathan Howell, Dr Simon Jameson, Joe Maguire, and Dr Jaqueline Ruell from Royal Devon and Exeter (R&DE) NHS Foundation Trust, Mr Jonathan Keenan from Plymouth Hospital Trusts, Mr Michael Hockings and Dr Nichola Rymes from South Devon Healthcare (SDHC) NHS Foundation Trust and Dr Andrew Temple from Northern Devon Healthcare (NDHC) NHS Trust took part in the discussion.

The British Orthopaedic Association have raised some objections to NICE and in 2011/2012 the American Academy of Orthopaedic Surgeons (AAOS) and the American College of Chest Physicians (ACCP) issued guidance supporting the use of aspirin for thrombroprophylaxis following major orthopaedic surgery. NICE state that this is due to a difference in interpretation of the same evidence. NICE have scheduled an update for July 2016.

The committee were asked to make a recommendation on whether commissioned services should align with NICE and use anticoagulants in preference to aspirin in patients undergoing total hip or knee replacement.

NICE undertook a comprehensive network meta-analysis to determine the most effective prophylaxis strategy. Primary outcomes considered included deep vein thrombosis (DVT) (which is regularly used as a surrogate outcome for pulmonary embolism [PE]), PE and major bleeding. Uncertainties exist regarding the base-line risk of VTE following major orthopaedic surgery as well as the appropriateness of using of DVT as a surrogate outcome. Due to a lack of evidence, low-dose aspirin was not included in the network meta-analysis for knee replacement. There was also no data for the risk of major bleeding associated with low-dose aspirin. Effectiveness results from the meta-analysis found that:

- Aspirin reduced the risk of DVT when compared to no prophylaxis following hip replacement but the reduction was smaller than that seen for several other interventions.
- Aspirin was ranked considerably lower than other strategies in preventing PE following hip replacement.

The new oral anticoagulants (NOACs) were not included in the meta-analysis for hip replacement due to the duration of prophylaxis used in clinical trials. Pivotal randomised control trials (RCTs) report that they are at least as effective as low molecular weight heparin in preventing VTE, but that adverse events including bleeding may vary between agents. There are concerns that anticoagulants, in particular NOACs, may increase the rate of return to theatre and wound complications. NICE acknowledge that clinical trials may not reflect the risk of wound complications due to differences in the definition of 'major bleeding'. However, high quality evidence to support this is lacking.

NICE also undertook a cost-effectiveness analysis which ranked each intervention according to its Incremental Net Benefit within each surgical population. Key drivers within the model for differences between strategies in costs and effects were risk reduction of VTE and increased risk of major bleeding. Despite being cheaper low-dose aspirin was found to be less cost-effective than other

strategies in the standard duration prophylaxis group for hip replacement and only the most-cost effective strategy in limited scenarios in sensitivity analyses. Due to a lack of evidence and differences in treatment duration, cost-effectiveness of low-dose aspirin was not considered in the total knee replacement subpopulation or when compared to the NOACs.

The committee discussed a number of issues pertinent to this NICE guidance:

- Local variation in approach: Some trusts currently align with NICE and therefore do not offer aspirin as a treatment option. However, the RD&E employ a multi-modal approach, which includes aspirin as pharmacological prophylaxis in carefully selected patients. The RD&E policy has been approved through a governance process that includes the anticoagulation committee and final sign off by the medical director. Implementation and compliance with the policy was stated to be good and included patient consultation, patient information leaflets and regular audit. Patient consent to depart from NICE is obtained prior to surgery.

- Evidence for the use of aspirin in major orthopaedic surgery is limited and difficult to interpret. Both American bodies support the use of aspirin, however NICE note this is due to a difference in interpretation of the same evidence. Specialists state that studies included by NICE were restricted to RCTs and therefore did not account for more recent large data registry sets. This data, although not randomised, was considered significant as it is derived from large numbers of patients. Specialists also commented that clinical practice and surgical techniques have advanced significantly since publication.

- Primary outcomes included in the NICE analysis were discussed. Specialists highlighted that death from all causes was not considered despite coronary events being a more frequent cause of death that PE. They also stated that wound complications including deep infection and return to theatre, which represent an important concern for both patients and surgeons, were not considered. Specialists from RD&E report they regularly audit patient outcomes following surgery. Northern Devon Healthcare and South Devon Healthcare Trusts agree their clinical experience suggests there is an increased risk of wound complications associated with the NOACs. Outcomes relating to wound complications have not been reviewed in Plymouth Hospitals Trust where a NOAC is currently used as per NICE.

- The committee acknowledged the importance of NICE guidance and therefore the need to clearly articulate reasons for local variation leading to non-alignment with NICE. It was agreed that detailed VTE prophylaxis policies and robust governance procedures must be in place.

The two options for recommendation identified were:

1. Trusts should align VTE prophylaxis in major orthopaedic surgery with NICE guidance; or

2. Trusts should offer services which include VTE prophylaxis options as per NICE guidance. However, specialists may also choose to offer aspirin as VTE prophylaxis in total hip or total knee replacement, following appropriate risk assessment and patient consultation. Where Trusts elect not to align with NICE they must ensure that robust governance arrangements are in place, including ratification of their VTE prophylaxis policy by the appropriate Clinical Risk Committee. This policy should apply to all clinicians in the Trust. Trusts should also undertake audit as part of their governance arrangements.

The committee voted unanimously in favour of recommending option 2 “Trusts should offer services which include VTE prophylaxis options as per NICE guidance. However, specialists may also choose to offer aspirin as VTE prophylaxis in total hip or total knee replacement, following appropriate risk assessment and patient consultation”.

ACTION: Recommendation and summary of clinical discussion to be taken to the CCGs’ executive groups for a decision.

6. Dymista® for moderate to severe allergic rhinitis

An application has been received requesting the inclusion of Dymista® for the treatment of severe allergic rhinitis into local formularies. Dymista® is an "all-in-one treatment" containing several medications; this aids compliance and effectively treats the entire rhinitis symptom complex in patients with moderate to severe allergic rhinitis. Emma Hewitt, Joint Formularies Pharmacist, NEW Devon CCG presented an evidence review. Dr Tom Beech, NDDH took part in the discussion.

Specialist opinion is that the current active comparator treatment for Dymista® would be intranasal steroid and oral antihistamine, not intranasalantihistamine. Avamys® (fluticasone furoate) intranasal spray and oral desloratidine were suggested.

The committee reviewed the evidence for Dymista®. Four randomised, placebo-controlled, double blind trials conducted in patients with seasonal allergic rhinitis support the licensing of Dymista®. A meta-analysis of three of the trials has been published. Dymista® was compared to placebo and the individual components used separately, not current practice comparator treatments.

Dymista® is a combination of a steroid (fluticasone) and an antihistamine (azelastine) delivered in a combined nasal spray. Dymista® achieved a statistically significant improvement in nasal symptom scores from baseline compared to monotherapies with the difference between treatments being greater than the minimal clinically important difference of 0.55 units. A significant mean improvement of ocular symptom scores were found for Dymista® compared to fluticasone but not azelastine. Disease specific quality of life scores improved from baseline with Dymista® but the scores compared to monotherapies do not exceed the minimum clinically importance difference. Responder analyses found that compared to monotherapies 5-15% more patients receiving Dymista® reached a 50% reduction in nasal symptom scores and 3-10% more patients achieved complete or near complete resolution of nasal symptoms at day 14. The main adverse events for Dymista® are bitter taste, headache and epistaxis.

Long term safety data was limited to a 12 month study. Dymista® was compared to active control intranasal fluticasone. The incidence of adverse events relating to Dymista® do not increase over time. Long term efficacy data found that Dymista® and fluticasone both improved nasal symptom scores above the minimally clinical important difference from baseline, however the difference was non-significant at 52 weeks compared to short term data. Quality of life met a clinically important change of 0.5 units in both groups, from month 1 to month 12. The mean number of symptom free days was significantly different for Dymista® in the 12 month study for perennial allergic rhinitis patients.

No papers reporting cost effectiveness of Dymista® from a UK or NHS perspective were identified. Current costs for 28 days treatment for a single patient with Dymista®, versus oral desloratadine and Avamys® are £17.65 and £4.20. From 1st January 2015 the unit price of Dymista® will be reduced, resulting in a 28 day cost of £13.81. Although there is substantial uncertainty on the potential uptake of Dymista® and the resultant budget impact the benefit observed by combining two treatments for allergic rhinitis in one single device must be considered against the increased expenditure associated with the treatment when commissioning this treatment.

The committee discussed a number of issues pertinent to this therapy including that:

- in clinical trials Dymista® had not been compared to the current practice treatment and hence evidence is limited in support of this treatment at the present time;
- this is an all in one preparation which may improve patient compliance, however some of the alternatives are once daily treatments whereas this is a twice daily use treatment. Additional oral antihistamine treatment may be required concomitantly with Dymista® treatment.
- Costs: this drug is more expensive than current practice treatment however the company plans to reduce the cost of Dymista® from January 2015. Dymista® is usually used in allergy clinics. Treatment costs are increased by patients having to go to clinics for diagnosis and tests prior to prescription of Dymista®. Dymista® is not a commonly used medication but there may be a niche role for it in some patients.

- GPs could be asked to prescribe Dymista® in primary care, however there is potential for its use to increase. If Dymista® became a formulary drug it could be marketed to GPs.
- It was noted that the CCGs position on use of non-routinely commissioned drugs allows clinicians to go back to their trust and apply for local trust funding for occasional ongoing consultant prescription for occasional use subject to certain criteria being met, the details of which had been agreed with trust Drugs and therapeutics chairs. Future evidence can be brought to the CPC after a minimum of twelve months for a review.

The committee voted unanimously against commissioning Dymista® for the treatment of moderate to severe allergic rhinitis.

ACTION: Commissioning policy for Dymista® for the treatment of moderate to severe allergic rhinitis to be published.

7. Fertility: policy recommendations

A Peninsula wide policy is currently in place. Representatives from Cornwall were present and stated that they would like to continue with a Peninsula wide policy if possible.

The committee were asked to make recommendations to the executive group of NEW Devon CCG and to the executive group of South Devon and Torbay CCG regarding the commissioning policy for Assisted Conception and on the commissioning policy for Cryopreservation to preserve fertility. Bethan Rogers, Clinical Evidence Pharmacist, NEW Devon CCG presented papers on a number of key recommendations made by NICE which are at variance to the existing policy.

- **Assisted Conception**

  The committee considered the draft commissioning policy for Assisted Conception. Bethan Rogers, Clinical Evidence Pharmacist presented papers discussing the relevant clinical evidence and cost-effectiveness analyses considered by NICE.

  Should the age limit for access to in vitro fertilisation (IVF) treatment be increased to include women up to 42 years?

  The current Peninsula Policy provides NHS funding for IVF in women up to 40 years of age; this reflects previous NICE guidance (2004). However, the NICE Clinical Guideline for Fertility (2013) recommends that one cycle of IVF should be offered to women aged between 40 and 42 years, provided they meet a number of criteria.

  NICE undertook a cost-effectiveness analysis which considered women with a variety of causes of sub-fertility across a range of ages. They found that IVF is only cost-effective in this age group, if women have a low chance of natural conception with expectant management; however NICE concluded it is not possible to identify these women in clinical practice. As a result, based on clinical opinion, the majority of the guideline group agreed that women between 40 and 42 should be offered one cycle of IVF. The cost of expanding the eligibly criteria is estimated to be between £124,000 and £177,000 per year.

  The committee were asked to make a recommendation on whether the age limit for access to IVF treatment should be increased to include women up to 42 years.

  The committee discussed a number of issues pertinent this policy recommendation:
  - The diminishing success rate of IVF as age increases, which is evidenced by data published by the Human Fertilisation and Embryology Authority (HFEA).
  - Specialists commented that they do not support increasing the age limit, as resources would be better used to fund infertility treatment in other patient groups.
  - Uncertainties in the estimated budget impact including the potential for service demand to increase, if IVF in this age group is commissioned.

  The committee voted unanimously that the age limit should not be increased. Therefore it will be recommended that the upper age limit remains, to fund IVF in women up to 40 years of age.

How should a cycle of in vitro fertilisation (IVF) be defined?

The current Peninsula Policy provides NHS funding for one fresh embryo transfer, unless women elect to receive single embryo transfer (eSET). The current eSET policy provides funding for one fresh embryo transfer, followed by up to a maximum of two frozen embryo transfers. NICE CG156 states that women should receive a 'full cycle' of IVF which is defined as including one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos.

Single embryo transfer is associated with a lower birth rate but significantly fewer multiple births compared to double embryo transfer. As a result, NICE state the transfer of a single embryo with freezing of supernumerary embryos is required to maximise the cumulative pregnancy rate from a 'full cycle 'of IVF. This strategy also reduces the need for ovarian stimulation and egg harvesting as well as reducing the risk of multiple births. Specialists suggest that due to the number of viable embryos produced which are suitable for freezing, expanding the definition of a 'full cycle' to include all frozen embryo transfers will have a minimal budget impact. However, this is based on the assumption that current behaviours will not change. Considering HFEA reports and British Fertility Society guidance, there appears to be the potential for multiple subsequent frozen embryo transfers. As a result the Clinical Effectiveness team, NEW Devon CCG estimated a potential budget impact of between £280,000 and £575,000.

The committee were asked to make a recommendation on how a cycle of IVF should be defined.

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

- The definition provided by NICE does not specify an upper limit to the number of frozen embryo transfers patients can receive as part of their NHS funded IVF cycle.
- The health risks associated with multiple births, including obstetric complications in the mother and stillbirth, neonatal death, prematurity and disability in the baby.
- The increased risk of morbidity associated with fresh IVF cycles compared to frozen embryo transfers. These include ovarian hyperstimulation syndrome, pelvic infection and complications associated with the surgical removal of eggs.
- The current low uptake of eSET locally. This highlights the potential for a significant increase in the number of subsequent frozen embryo transfers should patient behaviours change.
- Specialists stated that based on clinical experience women do not normally produce enough viable embryos to enable them to receive more than two frozen embryo transfers. Hence the above budget estimates may overestimate the impact.
- Embryologists reported that four or less embryos are produced in 77% of IVF treatments, of these, 80% of embryos survive cryopreservation.

The committee voted 5 to 1 in favour of recommending that an IVF cycle should consist of one fresh and one frozen embryo transfer.

The committee also considered a number of other issues including:

- The significant uncertainties in the estimated budget impact, based on the clinical experience of specialists.
- The potential adverse reputational impact associated with funding a part cycle of IVF and the destruction of unused frozen embryos.

It was therefore agreed that the CCG's executive groups would also be given the option to adopt the definition provided by NICE; that is a full cycle of IVF is defined as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). It was also agreed that specialists would provide further data to help quantify the potential budget impact.

How many cycles of in vitro fertilisation (IVF) should be commissioned?

The current Peninsula Policy provides NHS funding for one cycle of IVF in women under 40. However current NICE guidance recommends that three cycles of IVF should be offered to women under 40 years of age. NICE undertook a cost-effectiveness analysis which considered women with a variety of causes of sub-fertility across a range of ages. They found that up to three cycles of IVF is cost-effective for all women aged 39 and younger, following very small adjustments in the sensitivity analysis. NICE concluded that their analysis does not provide strong evidence that the current recommendation of providing three cycles should be changed. The estimated cost of funding an additional cycle of IVF was estimated to be between £484,399 and £491,543 per annum, with a further £346,000 if a total of three cycles was funded. It should be noted this is based on current activity and does not consider additional costs if a 'full cycle' is provided.

The committee were asked to make a recommendation on how many cycles of IVF should be commissioned.

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

- Specialists felt it is unreasonable to fund an additional cycle of IVF unless a 'full cycle' is commissioned. This is because it would be inappropriate to undertake a second episode of ovarian stimulation in women who have frozen embryo(s) remaining in storage.
- Some specialists indicated they would support decommissioning the routine use of stimulated intrauterine insemination (IUI) to offset the cost of a second cycle of IVF. The net budget impact of decommissioning stimulated IUI and providing two cycles of IVF was estimated to be £415,886 per annum.
- Specialists commented that savings associated with a reduction in multiple births following decommissioning of stimulated IUI had not been considered.

The committee voted unanimously that the CCG should continue to fund one cycle of IVF.

Embryo Transfer Strategies in In Vitro Fertilisation (IVF)

There is currently a separate policy in place across the Peninsula for elective single embryo transfer (eSET). This states that all women under 35 years who have 5 or more top quality embryos are required to receive a single embryo transfer. NICE CG156 provides a detailed embryo transfer strategy which is based on the results of a formal consensus survey conducted within the guideline group.

The aim of an effective embryo transfer strategy is to preserve the cumulative live birth rate, whilst reducing the number of multiple births. It was noted that the embryo transfer strategy recommended by NICE is contingent on the funding of three cycles of IVF; which is not in place locally. Specialists have also indicated that the current eSET policy is not meeting its objectives and suggest that this is reflected in its low uptake. As a result an amended embryo transfer strategy was proposed by the Clinical Effectiveness Team following small amendments by the Peninsular Centre for Reproductive Medicine (PCRM). It was felt that this would address the current low uptake of eSET whilst clearly seeking to minimise multiple births.

The committee were asked to consider if the proposed embryo transfer strategy should replace and update the current eSET policy.

The committee discussed a number of issues pertinent to the proposed embryo transfer strategy:

- The number of embryos that should be transferred if two or more top quality embryos are available.
- The cost of funding cryopreservation of resulting embryos for up to one year.
- The potential cost savings following a reduction in the number of multiple births as a result of an increased uptake of eSET.
- Specialists commended that selective implementation of NICE guidance would mean that statistical calculations on which their transfer strategy is based, can no longer be assumed correct.

The committee voted unanimously in favour of recommending that the current eSET policy be updated. They all agreed that the embryo transfer strategy proposed by specialists should be adopted; which is as follows:

- When considering the number of fresh and frozen embryos to transfer in IVF treatment, single embryo transfer should be undertaken if 2 or more top quality embryos are available.
- No more than 2 embryos should be transferred per transfer episode.
- The NHS in Devon will fund cryopreservation of remaining embryos resulting from IVF treatment for up to one year.

Should intrauterine insemination (IUI) with ovarian stimulation be routinely commissioned?

The current Peninsula Policy provides NHS funding for up to 4 cycles of IUI in women under 40. However NICE CG156 (2013) recommends that stimulated IUI should not be routinely offered for people with unexplained infertility, mild endometriosis or mild male factor infertility who are having regular unprotected sexual intercourse. Specialists from PCRM have suggested that stimulated IUI provides an appropriate treatment option in specific patient groups, as it is less invasive, cheaper and has a lower risk of ovarian hyperstimulation when compared to IVF. However, other local providers have indicated they support the decommissioning of stimulated IUI in order to offset the cost of providing an additional cycle of IVF.

NICE concluded it was not possible to determine if stimulated IUI is more effective than expectant management in all patient groups, but that it appears to be associated with an increased risk of multiple pregnancies. Evidence comparing stimulated IUI and IVF was not considered by NICE. The current Devon-wide spend on IUI was estimated to be £228,896; an additional cost of £92,000 to fund one cycle of IVF in women who would have previously become pregnant following successful stimulated IUI was also noted. Therefore the net budget impact of decommissioning IUI and funding two cycles of IVF was estimated to be £416,000 per year.

The committee discussed a number of issues pertinent to stimulated IUI:

- The potential increased risk of multiple birth following stimulated IUI compared to expectant management.
- That stimulated IUI is not routinely recommended by NICE.
- The varying success rates following stimulated IUI reported by local fertility centres were acknowledged.
- Some specialists commented that IUI is a popular treatment option amongst patients, and further highlighted the reduced costs and clinical risk compared to IVF.
- The committee noted that decommissioning stimulated IUI would release funds but that the use of these funds was for the CCG executive to decide and not for the CPC to reallocate within the fertility service.
- However, it was acknowledged that a potential CCG position could be to fund a more effective embryo transfer strategy.

The committee voted unanimously to recommend that stimulated IUI should be decommissioned in patients with unexplained infertility, mild endometriosis or ‘mild male factor infertility’ who are having regular unprotected sexual intercourse.

Surrogacy

The committee considered whether funding should be provided for implantation in a surrogate mother.

The committee voted unanimously in favour of not excluding funding implantation of embryos in a surrogate mother.

Should same-sex couples be eligible for referral and subsequent assessment after 6 cycles of privately funded artificial insemination (AI) over a period of 12 months?

The current Peninsula eligibility criteria allows same-sex couples to receive NHS assessment and possible treatment following insemination with 12 un-stimulated cycles over 2 years. NICE considered the cost to couples of privately funding AI as well as the availability of donor sperm, time taken and cumulative success rates. They concluded that 6 cycles of AI over a period of 12 months should be considered equivalent to 12 months of expectant management in heterosexual couples. This represents the point at which same-sex couples are eligible for NHS fertility assessment and possible treatment.

As a result, same-sex couples are expected to have earlier access to NHS treatment than they currently have under the existing eligibility criteria. Costs will primarily be associated with an additional 6 cycles of unstimulated IUI which is recommended for same sex couples with unexplained infertility, mild endometriosis or 'mild' male factor infertility. A budget impact of £103,000 has been estimated based on limited data. Additional costs associated with investigations and other infertility treatments are predicted, however it was not possible to realistically estimate these.

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

- Some specialists highlighted that fertility centres are experiencing ongoing difficulties obtaining sperm from the UK and as a result have been importing sperm from Denmark.
- Specialists were concerned about the high cost of sperm and therefore the cost associated with treating same-sex couples with multiple cycles of IUI.
- It was also noted that some specialists view 'do-it-yourself techniques' as being associated with risk taking behaviours.
- Although supportive of the concept, specialists stated that they are currently unable to implement this recommendation as per NICE, due to practical limitations related to sperm availability.
- The committee agreed that further work was required to fully understand the practical barriers which are currently preventing fertility centres from aligning with NICE.

It was agreed that the Clinical Effectiveness Team, NEW Devon CCG would undertake further work on the Commissioning policy: 'Assisted Conception' and that it would be brought back to the CPC meeting in February 2015.

ACTION: Clinical Effectiveness Team to undertaken further work on the proposed Assisted Conception policy. The policy will be taken to the CPC meeting in February 2015.

- **Cryopreservation to preserve fertility**

The committee received a draft commissioning policy for NHS funded Cryopreservation to preserve fertility. The committee were asked to make a recommendation to the CCGs' Executive Teams on whether this policy should be accepted for use.

The committee considered a number of issues pertinent to this policy:

- Specialists were broadly supportive of the proposed policy. However, they expressed concerns that it does not provide clarity on the full range of interventions which may result in patients requiring cryopreservation to preserve fertility.
- The committee agreed that further work was required and that the policy should be taken back to the CPC meeting in February 2015.

ACTION: Clinical Effectiveness Team to undertaken further work on the proposed cryopreservation policy. The policy will be taken to the CPC meeting in February 2015.

8. Any other business

There was no other business to report.

Summary of actions		
	Action	**Lead**
14/21	Commissioning policies for depot injections of aripiprazole, olanzapine and paliperidone for schizophrenia to be published. The policy has been drafted and is awaiting accompanying formulary updates prior to publication.	Rebecca Heayn
14/23	Commissioning policy for Subcutaneous Tocilizumab for rheumatoid arthritis to be published. The policy has been drafted and is awaiting accompanying formulary updates prior to circulation.	Rebecca Heayn
14/24	Recommendation and summary of clinical discussion on Aspirin for the prophylaxis of Venous Thromboembolism following Elective Hip Replacement and Elective Knee Replacement to be taken to the CCGs' executive groups.	Chris Roome
14/25	Commissioning policy for Dymista® for the treatment of moderate to severe allergic rhinitis to be published.	Rebecca Heayn
14/26	Further work to be undertaken on the proposed Assisted Conception policy and the policy to be taken to the CPC meeting in February 2015.	Bethan Rogers
14/27	Further work to be undertaken on the proposed cryopreservation policy and the policy to be taken to the CPC meeting in February 2015.	Bethan Rogers