

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

**Clinical Policy Committee (CPC)
Minutes**

Wednesday 4th February 2015, 10.00 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
Paul Foster	Chief Pharmacist	SDHC NHS FT
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Phil Melliush*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Samantha Morton	Head of Contracting and Procurement	South Devon and Torbay CCG
Anna Richards	Consultant in Public Health	Devon County Council
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Dr Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG
Dr Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Carole Brewer	Consultant Clinical Geneticist	RD&E NHS Foundation Trust
Jane Bush	Associate Specialist	The Centre (Exeter, Mid & East Devon)
Di Cameron	Trust Breast Physician	RD&E NHS Foundation Trust
Rachael Currie	Consultant Breast Radiologist	RD&E NHS Foundation Trust
Sam Cush	Patient Communications Specialist	NEW Devon CCG
Rebecca Green	Consultant Radiologist	South Devon Healthcare
Karen Hillman	Clinical Nurse Specialist Breast Care	North Devon District Hospital
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Kathy Huxham	Manager	RD&E NHS Foundation Trust
Maggie Jenkin	Advanced Practitioner Radiographer	Plymouth Hospital Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Richard Stackhouse	Speciality Doctor with Interest in Family Health	South Devon Healthcare
Petrina Trueman	Joint Formularies Pharmacist	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

1. Welcome and introductions

Attendees were welcomed to the meeting.

Sam Cush left the meeting at 11.00 am

Paul Foster left the meeting at 11.30 am

Andrew Gunatilleke left the meeting at 12.15 pm

Apologies

Tawfique Daneshmend Consultant Gastroenterologist and Hepatologist RD&E NHS Foundation Trust
 Peter Leman GP Clinical Commissioner NEW Devon CCG

Notification of Any Other Business (AOB)

No items for discussion under AOB were identified

Confirmation of voting members and Declarations of interest

The seven voting members present 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 on annual mammography for women at risk of familial breast cancer	–
Surgery for hallux valgus (bunions)	–
Jaydess® Alternative treatments: Mirena® Other contraceptives	Bayer Bayer Various manufacturers
Assisted conception and cryopreservation	Providers of assisted conception and cryopreservation services
NICE guidance on cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease	Multiple pharmaceutical companies manufacturing drugs to lower blood lipids

NAME OF ATTENDEE	ROLE	
Dr Jane Bush	Associate Specialist	<i>Received gifts, benefits or sponsorship of any kind, whether refused or accepted worth over £25 or several small gifts worth a total of over £100 from the above or closely related pharmaceutical / manufacturing company.</i> Had received sponsorship from Bayer for a training day for GPs. They provided lunch. <i>In receipt of lecture fees in excess of £150 in the last year from above pharmaceutical/manufacturing company/companies.</i> Has been paid for giving a contraception update lecture at a Women's Health update afternoon by Bayer.
Matt Howard	Clinical Evidence Manager	In previous position attended a number of LPC organised training/CPD evenings – refreshments may have been sponsored by pharmaceutical company.

Margaret Jenkin	Advanced Practitioner Radiographer	<i>Have taken part in drug trial for the above drug/s devices/intervention/treatment.</i> Research Tomosynthesis study for Siemens equipment on research log.
Dr Ben Waterfall	GP Clinical Commissioner	<i>Any other family or business interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s) /intervention/treatment under consideration.</i> Has 3 children through assisted conception (Derriford).

Proposed 'this is how CPC work's' video

The NEW Devon CCG Communications team had proposed that a short 2 to 3 minute video be created to show how CPC works. The video will be made available to the public via the CCG's website and YouTube.

Prior to the meeting Sam Cush, Patient Communications Specialist, NEW Devon CCG had briefly discussed the proposed video with the chair and lay members of the group. Sam joined the meeting in order to provide the rationale and background to the proposed project to CPC members.

The discussion with the chair and lay members of the committee had concluded that the video should be fronted by the committee chair rather than lay members. The view of lay members of the committee was that they were part of the committee and happy to be engaged but did not feel it appropriate that the video should be fronted by lay members. It is proposed that the filming be undertaken during the meeting due to take place on Wednesday 29th April. Consent to being filmed already provided by members will be carried forward to that date.

The group discussed issues pertinent to the proposed video including that:

- the main focus will be on the chair and lay members of the committee;
- including an audio recording might impede the discussion at CPC. It was suggested that audio recordings be made of specific sections of the meeting. This would avoid the need for further filming to be undertaken at a later date;
- Filming will not take place during the parts of the meeting where clinical specialists are present;
- if any members do not wish to be filmed this can be accommodated;
- CPC is chaired by a committee member from South Devon and Torbay CCG; this shows the pan Devon approach being taken. It was noted that a vice-chair for the group is needed.

2. Minutes of the meeting held on 3rd December 2015 and matters/actions arising

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

The committee discussed the wording of recommendation. It was agreed that 'counselling' should be amended to read 'consultation'.

Therefore the recommendation now reads:

"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".

Subject to the amendment being made the minutes of meeting held on 3rd December 2014 were approved.

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. Action complete.	
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. Action complete.	
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. This will be taken the March meetings of the CCGs' Executive Groups.	Chris Roome
14/25	Commissioning policy for Dymista® for the treatment of moderate to severe allergic rhinitis to be published. Action complete.	
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. This item was included on the main meeting agenda. Action complete.	
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. This item was included on the main meeting agenda. Action complete.	

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

The committee received a summary of the NPAG meetings which had taken place on Tuesday 16th December 2014 and Tuesday 11 November 2014. In particular with regard to the discussions on prostate cancer, acute kidney injury and the Geko device for reducing the risk of venous thromboembolism discussed at the meeting in December and chronic kidney disease which had been discussed at the November meeting.

As part of NEW Devon CCG's cost savings NPAG will now meet approximately every other month rather than monthly. In order to cover the necessary business these meetings will be extended from 2 to 3 hours.

4. Annual mammography for women at risk of familial breast cancer

NICE issued CG164 (classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer) in June 2013. It updates previous guidance issued in 2004 and 2006. Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented a paper. Carole Brewer, Di Cameron, Rachael Currie, Kathy Huxham from RD&E NHS Foundation Trust, Rebecca Green, Richard Stackhouse from South Devon Healthcare, Karen Hillman from North Devon District Hospital and Maggie Jenkin from Plymouth Hospital Trust attended for the discussion.

The new NICE guidance recommends annual mammography from age 50 to 59 years for 3 groups of women previously recommended mammography every 3 years. This includes 2 groups of women at high risk of breast cancer and 1 group at moderate risk. In line with the previous guidance, all 3 groups receive annual mammography from age 40 to 49 years. Annual mammography from age 50 to 59 years would be funded by the CCGs as the groups do not meet the NHS National Breast Screening Programme (NBSP) high risk criteria which would make them eligible for annual screening. At 60 years of age, these women would receive mammography every 3 years through the NHS NBSP. There is no indication that the NBSP intend to change their criteria for high risk of breast cancer to align with NICE.

The committee was asked to make a recommendation on whether commissioned services should align with the NICE recommendations in preference to 3-yearly mammography through the NBSP for these three groups of women age 50 to 59.

The committee considered the evidence reported in the NICE full clinical guideline supporting changes to surveillance for women at risk of familial breast cancer. Review of the full clinical guideline did not identify clinical evidence for women aged 50 years and over at risk of familial breast cancer and none of the evidence compares annual mammography with 3-yearly mammography. No published or de-novo cost-utility analysis is reported comparing annual mammography with 3-yearly mammography in women aged 50-59 years at moderate or high risk of breast cancer. The NICE guideline development group did not specifically discuss the benefits, risks or cost effectiveness of recommending annual mammography rather than 3-yearly mammography in women aged 50 to 59 years. No patient decision aid has been provided by NICE outlining the benefits/risks of annual mammography for these women. The NICE costing template does not provide an estimate of costs for providing annual mammography for these three groups of women. NICE considered that the budget impact would not be significant. In addition, estimating the numbers of women has been difficult because these women are usually discharged to the NHS NBSP and the categorisation of women at high risk into different categories by NICE has meant that the total number of women who fall into these groups is difficult to determine without considering each individual case. For moderate risk women, the Clinical Effectiveness team estimated £107,000 per year for NEW Devon CCG and £24,000 for Torbay and South Devon CCG. For high risk women, the cost is estimated to be between £18,600 and £32,643 per year for NEW Devon CCG and £4,600 for Torbay and South Devon CCG. There is a high degree of uncertainty associated with these costs.

The committee discussed issues pertinent to the commissioning of NICE CG164 including:

- **Costs:** It was noted that the costs associated with screening are not limited to the cost of conducting a mammogram. The costs associated with recalling women for further investigation also need to be considered. It was noted that the costs included in the paper were taken from a cost-utility analysis which considered the wider costs associated with screening.
- **Definition of risk:** The specialists noted that the groups of women at moderate and high risk of cancer include a spectrum of risk and that it can be difficult to be accurate with regard to risk / family history. Patients who have a BRCA mutation are screened annually until age 70. It was noted that if a consultant geneticist assesses a woman who is BRCA negative or has not been tested to be at equivalent high risk the NHS NBSP will accept these women into their high risk screening programme. The committee were reassured that the option to refer these women to the high risk screening programme existed.

- Evidence, risks and benefits of breast screening: NICE did not present any evidence on the benefits and risks of annual mammography versus 3-yearly mammography for these groups of women. The expectation is that more women in groups identified as being at high and moderate risk will be recalled than from the general population. The committee were concerned that the increase in false positive results resulting from the increased frequency of screening would be a source of considerable anxiety to the women concerned while these findings were investigated.
- Patient choice: However specialists noted that the issues were complicated and that these women already attended for annual screening from age 40 to 49 and were likely to continue to do so if given the option from age 50 years.
- Position of the Advisory Committee on Breast Screening: The Advisory Committee has not aligned with NICE on the criteria for high risk of breast cancer. The committee noted that the Advisory Committee and NICE were not working together and that NICE had not provided any evidence for deviation from the guidance of the NHS NBSP.

The committee voted unanimously to recommend to the CCGs' Executive Groups that commissioned services should align with the NHS NBSP recommendations for breast cancer screening.

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

5. Surgery for hallux valgus (bunions)

As part of the work being undertaken to align commissioning policies across Devon consideration has been given to surgery for hallux valgus. The committee were asked to consider the policy as part of the harmonisation process agreed by NEW Devon CCG and South Devon and Torbay CCG.

NHS Plymouth Clinical Effectiveness Commissioning Group approved a policy for removal of bunions in November 2010. The Healthcare Funding Request Group of Torbay Care Trust approved a policy in June 2011. NHS Devon does not have a policy for this condition.

Foot and ankle surgeons across Devon and Devon Referral Support Services were contacted as part of the consultation. The policy has been agreed by GPs who act as Planned Care Leads for each locality in NEW Devon CCG.

The Devon-wide commissioning policy is based on guidance from the Royal College of Surgeons and the British Orthopaedic Foot and Ankle Society and is very similar to the policies adopted by NHS Plymouth and Torbay Care Trust.

The committee agreed unanimously to ratify the policy.

ACTION: Policy for surgery for hallux valgus (bunions) to be published.

6. Jaydess® levonorgestrel 13.5mg intrauterine system

An application had been received from Dr Catherine Ackford, Clinical Lead on Contraception, Torbay Sexual Medicine Service, requesting the inclusion of Jaydess® into local formularies as an option for women wishing to use an LNG-IUS for a shorter time (3 years) than the other currently available LNG-IUS Mirena® which is designed for 5 year use. Petrina Trueman, Joint Formularies Pharmacist, NEW Devon CCG presented an evidence review. Jane Bush, The Centre (Incorporating Contraception, GU Medicine and HIV services for Exeter, Mid and East Devon) took part in the discussion.

Jaydess® is a new levonorgestrel-releasing intra-uterine system licensed for the prevention of pregnancy for up to 3 years. It is a T-framed system containing 13.5 mg total dose LNG. Mirena® the other currently available LNG-IUS contains 52 mg total dose levonorgestrel. In September 2014 NICE issued updated Clinical Guideline 30 (Long-acting reversible contraception [LARC]) which

recommends that women requiring contraception should be given information about and offered a choice of all methods, including LARC.

The committee reviewed the evidence for Jaydess®. 2 Randomised controlled trials were identified. These were (i) a Phase II study of Jaydess® in 738 healthy nulliparous and parous women aged 21-40 years compared with LNG-IUS 19.5mg (not commercially available), and Mirena® and (ii) a Phase III study in 2885 healthy nulliparous and parous women aged between 18 and 35 years in which Jaydess® was compared to the same, not commercially available, LNG-IUS 19.5mg used in the phase II study. Pregnancy rate was the primary outcome for both studies. In the phase II study, over 3 years, 1, 5, and 0 pregnancies occurred in the Jaydess®, LNG-IUS19.5 mg and Mirena® groups respectively. The 3-year cumulative failure rates were 0.5%, 2.5% and 0% respectively. The phase III study found the failure rate for the Jaydess® group during the 1st year to be 0.4%, which is similar to failure rates seen in other hormonal LARC methods. The 3 year cumulative failure rate was estimated to be 0.9%. NICE guidelines quote a failure rate for Mirena® of less than 1.0% at 5 years. There is a lack of published phase III studies comparing Jaydess® with Mirena®. The phase II study that included Mirena® was not sufficiently powered to establish non-inferiority of Jaydess® to Mirena®.

Secondary outcomes included pain during placement and bleeding patterns. More women in the Jaydess® and LNG-IUS 19.5 mg groups reported placement as easy with Jaydess® and LNG-IUS19.5 mg than with Mirena®. 'No pain' was reported by more women with Jaydess® and LNG-IUS 19.5 mg than with Mirena®. The inserter device used for Mirena® in the study was larger than is used in current practice, which limits the applicability of the results. Reduced bleeding was seen with all 3 devices in the phase II study. Bleeding and spotting days decreased similarly over time in all 3 groups, although twice as many Mirena® users reported amenorrhoea than Jaydess® and LNG-IUS 19.5mg users after 3 years.

The unit cost of Jaydess® is £69.22 making it a cheaper option over three years; if use is continued beyond three years it becomes more expensive than Mirena® for which the unit cost is £88.00. The number of women having these devices removed early is not known.

The overall safety profile for Jaydess® is consistent with that expected for a levonorgestrel-containing intra-uterine contraceptive and there is no evidence that Jaydess® provides a major advantage in terms of efficacy, safety, or user acceptability.

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

- Evidence is limited but Jaydess® provides a 3rd intrauterine contraceptive device.
- Patient choice: the committee expressed concern that Jaydess® may be offered as an alternative to Mirena® rather than a distinct 3rd choice. The products are different and each method has its own length of use and bleeding pattern.
- LARCs are cost effective at year 1 due to the reduction in unwanted pregnancies. Costs are difficult to predict as it is not known how long women will wish to use either Jaydess® or Mirena®.
- Funding of fitting in primary care and for the device: in Torbay the device is funded by the CCG and fitting is funded by the local authority. Confirmation is needed from Devon County Council with regard to funding of fitting the device in NEW Devon. (Since the meeting funding has been agreed by Devon County Council)

ACTION: Confirmation of funding arrangements to be sought from DCC.

- The place in formulary will be defined by the Formulary Interface Groups.

The committee voted unanimously in favour of approving the Jaydess® levonorgestrel 13.5mg intrauterine system as an option for women wishing to use long-acting reversible contraception.

ACTION: Commissioning policy for the Jaydess® levonorgestrel 13.5mg intrauterine system to be published.

7. Fertility policies – agreement of final committee recommendations on:

- **Assisted Conception**
 - **Cryopreservation to preserve fertility**
-

A number of key recommendations relating to the Devon-wide commissioning policy for assisted conception were made at the Clinical Policy Committee meeting on 3rd December 2014. Due to the complexity of the recommendations to be made there was insufficient time to fully discuss two of the papers. The outstanding papers were deferred. Bethan Rogers, Clinical Evidence Pharmacist, NEW Devon CCG presented a summary of the fertility policy recommendations made at the last meeting together with the draft policy for 'Assisted Conception'. The two deferred papers relating to the access to NHS infertility assessment for same-sex couples and the draft policy for 'Cryopreservation to Preserve Fertility' were presented. An additional paper which considered the definition of a cycle of IVF was also discussed, following further work undertaken by the Clinical Effectiveness Team.

Fertility Policy – Assisted conception

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

The committee had previously voted that *'a cycle of IVF should be defined in the CCGs' Assisted Conception policy as one (1) fresh and one (1) frozen implantation of embryos. A frozen embryo transfer episode will only be available if there are embryos generated from the fresh cycle suitable for freezing'*. However, due to concerns raised by specialists and uncertainties in the budget impact, it was also recommended that the executive group could opt to implement 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)'*.

Since the meeting in December further work had been undertaken by the Clinical Effectiveness Team and local specialists. This included a revised budget impact as specialists felt that the original estimate was a significant overestimate due to the number of viable embryos which are generally suitable for freezing in clinical practice being less than predicted. The results of this additional work should allow the committee to make a clear recommendation for one of the two proposed definitions of a full cycle of IVF so that the executive groups may be presented with a preferred option. The committee were asked to consider if a cycle of IVF should be defined as one fresh and one frozen embryo transfer episode or if it should be defined as per the NICE Clinical Guideline.

Both proposed definitions are associated with a cost pressure to the CCGs. This is due to a change from the current service provision which is required in order to implement a raft of changes recommended by NICE. Increased costs are primarily associated with the alternative embryo transfer strategy proposed by specialists, which was agreed at the CPC meeting in December and is in line with NICE's aim to reduce multiple births by increasing the uptake of eSET.

Although uncertainties remain it is estimated that funding one fresh and one frozen embryo transfer would be associated with a budget impact of £84 to £101k per annum. Whilst adopting the NICE definition of a full cycle is estimated to be associated with a budget impact of £131 to £149k per annum. It was noted that specialists also raised concerns in December relating to adverse reputational impact associated with funding a part cycle of IVF and the destruction of unused embryos, as well as the potential for multiple births following double frozen embryo transfer, should just one frozen transfer be provided.

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

- Their concerns that embryos implanted at a later stage may be of poorer quality, as higher quality embryos are likely to be used first. As a result the chance of pregnancy may reduce with each subsequent frozen embryo transfer and thus further transfers may be less cost-effective.
- Specialists had raised concerns in December that given the choice the majority of women would elect to receive a double embryo transfer, if they were limited to one subsequent frozen embryo transfer, in order to maximise their chance of pregnancy. Specialists suggested that funding a 'full cycle' of IVF as defined by NICE, will further encourage the use single frozen embryo transfer

and allow them to use clinical discretion to maximise pregnancy rates whilst minimising the risk of multiple birth.

- Budget impact: although both definitions are associated with a cost pressure to the CCG, it was noted that there is a relatively small difference between the costs of implementing the two proposed definitions.
- Concerns were raised that if a 'full cycle' of IVF was commissioned women who produce multiple viable embryos would be eligible for NHS funding for several frozen embryo transfers and therefore offered more opportunities to conceive than women who produce for example just two viable embryos.
- Reputational risk: Specialists highlighted the potential adverse reputational impact associated with funding a part cycle of IVF. However the committee noted that treatments which are not affordable should not be commissioned solely because of concerns relating to reputational risk.

The committee voted 5 to 2 in favour of recommending that a 'cycle' of IVF is defined in this policy as one (1) fresh and one (1) frozen implantation of embryos. A frozen embryo transfer episode will only be available if there are embryos generated from the fresh cycle suitable for freezing.

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 committee were asked to consider if the CCGs should provide access to NHS assessment and treatment (including 6 unstimulated cycles of IUI) in same-sex couples after 6 privately funded unsuccessful cycles of AI in 12 months.

The current Peninsula eligibility criteria allows same-sex couples to receive NHS assessment and treatment following unsuccessful insemination with 12 un-stimulated cycles over 2 years. In making their recommendation NICE considered the cost to couples of privately funding AI as well as the availability of donor sperm, the time taken and the cumulative success rate. 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 therefore represents the point at which same-sex couples are eligible for NHS fertility assessment and treatment. As a result, same-sex couples will have earlier access to the NHS than they currently receive under the existing eligibility criteria. Costs will primarily be associated with funding an additional 6 cycles of unstimulated IUI, which is recommended in couples with unexplained infertility, mild endometriosis or 'mild' male factor infertility, prior to considering IVF. A budget impact of £228,000 has been estimated based on limited data; this does not include the cost of donor sperm, since NHS funding is not available for donor sperm in female same-sex couples or surrogacy arrangements in male same-sex couples. This is because their childlessness is due to the absence of gametes, rather than as a result of a medical condition. Additional costs associated with investigations and other infertility treatments are predicted, however it was not possible to realistically estimate these. This recommendation raises some equality issues and as a result legal advice has been sought. This suggests that without a clear rationale, not implementing this recommendation may be potentially challengeable.

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

- Equity: the committee discussed the equity of the NICE recommendation; with some members suggesting that implementation would prioritise same-sex couples.
- Legality: Legal advice was sought by the Clinical Effectiveness Team indicated that should the CCGs' decide not to align with NICE there would be little defence if a legal challenge was made by a same sex couple. The potential for challenge by a heterosexual couple was also noted, but it was felt that this was defensible given current NICE guidance.
- Budget Impact: It was noted that the current Peninsula Eligibility Criteria is at variance to NICE and therefore associated with a cost pressure to the CCG. This is due to earlier access to NHS funded infertility assessment and treatment.

The committee voted 4 to 3 to recommend alignment with the NICE recommendation that same-sex couples should be eligible for referral and subsequent assessment after 6 cycles of privately funded AI over a period of 12 months.

ACTION: Recommendation and summary of clinical discussions to be taken to the CCG executive groups.

Policy on 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.

This policy had previously been presented to CPC in December 2014. A decision was not reached at the meeting due to lack of time for discussion. In December 2014 specialists had raised concerns that the eligibility criteria did not include patients about to start lifelong teratogenic treatment. Following the meeting agreement with local specialists has been reached via e-mail and wording to such effect has been added to the proposed policy. No other concerns have been raised by local specialists. A number of other amendments to the existing policy including the duration of storage, upper age limit and specific access criteria were highlighted to the committee.

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

- Renewal of storage for up to 10 years following the initial 5 year period should only be funded following application to the appropriate panel of the relevant CCG.
- Continued storage of cryopreserved sperm, beyond 10 years, should not be routinely offered to men who remain at risk of significant infertility. It was felt that indefinite storage potentially poses a significant cost pressure to the CCG and that this statement should be removed from the policy. This decision is at variance to NICE, but it was noted that applications for exceptional funding could be considered.
- NICE state that recommendations relating to cryopreservation should only be extended to the cryopreservation and storage of fertility material, eligibility for assisted conception should be considered separately as per the policy in place at that particular time.
- Legal advice sought by the Clinical Effectiveness Team indicated that exclusion of patients on the transgender pathway would be unethical and unjustifiable. They agreed that this criterion should therefore be removed from the policy.

The committee voted unanimously in favour of recommending that the commissioning policy for NHS funded cryopreservation to preserve fertility is adopted by the CCGs. With the caveat that the time limit for NHS funded cryopreservation specified in the policy is 10 years.

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

8. Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease

This item was not considered an urgent priority to discuss since the meeting was overrunning. Consideration will be given to what information should come to CPC in future.

9. Any other business

Future meeting timing and venue

Due to the complexity and volume of work expected to come to CPC meetings it was suggested that meetings be extended from 2 to 3 hours and that further consideration be given to the venue. It was agreed that the secretariat would circulate timing and venue options and that the committee members would respond with their preferences.

ACTION: Secretariat to circulate timing and venue option in order that committee members can state their preferences.

Meeting closed at 12.30 pm

Summary of actions		
	Action	Lead
14/24	<i>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.</i> <i>This will be taken the March meetings of the CCG Executive Groups.</i>	Chris Roome
15/01	NICE CG164 familial breast cancer: Recommendation and summary of clinical discussion to be taken to the CCGs' executive groups.	Chris Roome
15/02	Surgery for hallux valgus (bunions) to be published.	Rebecca Heayn
15/03	Confirmation of funding of fitting of Jaydess [®] to be sought from Devon County Council.	Petrina Trueman
15/04	Commissioning policy for the Jaydess [®] levonorgestrel 13.5 mg intrauterine systems to be published.	Rebecca Heayn
15/05	Fertility policy: Assisted conception - recommendation and summary of discussion to be taken to CCGs' executive groups.	Chris Roome
15/06	Fertility policy: Cryopreservation – recommendation and summary of discussion to be taken to CCGs' executive groups.	Chris Roome
15/07	Future meetings: timing and venue options to be circulated to the committee in order that members can state their preferences.	Fiona Dyroff