Agenda Item No 12

Briefing paper to Birmingham/Black Country CCGs and OSC – Proposed changes to IVF policy in Birmingham, Solihull and the Black Country

Executive summary

Seven CCGs within the West Midlands have collectively reviewed the variance in the level of service provision for IVF treatment inherited from historical PCT policies. The aim is to ensure that policies are fair and consistent instead of the existing 'postcode lottery' in which the service offered to women varies according to where they live (see Appendix 1).

A working group was set up in April 2013 to review all current policies with the aim of:

- Reviewing all historical PCT/CCG assisted conception/IVF policies
- Realising NICE changes and the impact on current policies
- Relevant developments in Individual Funding Request processes for IVF
- Developing a collaborative policy across Birmingham, Solihull and Black Country CCGs
- Simplifying the administrative process for service providers to make the service more effective

Key areas of proposed changes:

- Clear criteria to ensure those entering the IVF pathway are most likely to benefit from treatment i.e. are in optimal health to be able to conceive
- All CCGs currently offer one cycle both fresh and/or frozen. The policy change proposes the provision of one fresh cycle only
- The policy will allow same sex female couples, transgender males, single women and heterosexual women to access one cycle of IVF, provided they meet the eligibility criteria
- The area of Sandwell which sits within Sandwell and West Birmingham CCG will be reducing its offer from two cycles to one
- Further discussion is needed to determine the cut off paternal age for accessing IVF

Participating CCGs:

- Birmingham CrossCity
- Birmingham South Central
- Solihull
- Walsall
- Sandwell and West Birmingham
- Wolverhampton
- Dudley

Recommendations

Given the potentially emotive subject matter as well as the changes proposed in the revised policy, it is recommended that a full statutory consultation is carried out across the CCGs.

The key principles are listed below:

- There is clinical evidence that using a fresh cycle results in higher success rates
- Consistent service – should be the same for all across each CCG involved
- Inclusive
- Making fair decisions – not a postcode lottery
- Engagement with Primary Care to ensure that women are aware of the IVF pathway and services

The NHS has an obligation to pursue best endeavours to inform the public about the proposed changes; in particular to those deemed to be in 'hard to reach' groups. These groups will be identified through an Equality Impact Assessment, and special effort will be made to reach out to these groups.

Next steps

The working group is currently seeking final approval from all CCGs involved and the HOSC's views on the proposed policy changes. The proposed stages are set out below:

- All CCG chairs in principal to agree to a single policy – End of November, 2013
- Finalise draft consultation plans - End of November, 2013
- Engagement to take place for up to four weeks to get feedback from the public about the proposed changes. A short survey is being formulated and the results will be evaluated – December, 2013
- Present proposal to HOSC – December, 2013
- Web communications across CCGs and focus groups – January to March, 2014
- Draft policy, incorporating feedback from engagement process, to go out to public consultation for 12 weeks – January to March, 2014
- Revised policy presented to CCG boards – April, 2014

Further information

A more detailed document is available on request from hamira.sultan@nhs.net

Appendix 1: Policy comparison

Differences in the Key Criteria for Eligibility

Criterion	Wolverhampton April 2012	Sandwell March 2009	Dudley Jan 2012	Walsall	Birmingham 2006	Cov, N & S Warw, Rugby and Solihull, 2005
Cycles (fresh/frozen)	1 fresh cycle	2 cycles	1 cycle (+ frozen dependent on provider chosen)	1 cycle	1 cycle fresh or frozen (only Birmingham East and North policy is stated)	1 fresh and 2 associated frozen (2 embryo maximum)
Fertility problems	Failure to conceive for 2 years after regular unprotected sexual intercourse	Failure to conceive for 2 years after regular unprotected sexual intercourse	Failure to conceive for 3 years after regular unprotected sexual intercourse	2 years' duration of unidentified cause	Failure to conceive for 2 years after regular unprotected sexual intercourse	--
Stable relationship		--	--	2 years	--	yes
Childlessness	No living, including adopted	No surviving children	No existing, including adopted	No children either partner	No living children	No children under 16 living with them
Sterilisation	Neither partner	Neither partner	Neither partner	Neither partner	Neither partner	Neither partner
Previous treatment – exclusion criteria	Any NHS/private cycles	>2 private cycles	2 cycles	Taken into account	Any NHS or 3 total cycles	Any NHS or >2 private cycles

Female Age	23-39	23-39 (at 1st consultation at tertiary)	23-39	25-39	23-39	23-39
Male Age	--	--	--	<55	--	--
BMI	19-30 Male <30	19-30	19-30	<30	19-30	--
Smoking	Both non-smokers (3 months prior)	Women must have stopped smoking	Both non-smokers (12 months prior)	Both non-smokers	Both non-smokers	--
Child welfare	HFEA Regulations	--	considered	Assessment undertaken	--	No indications of inability to cope
Alcohol	NICE Guidelines	--	Alcohol intake within guidelines	Abuse assessed as part of child welfare	--	--
Same Sex Couples	--	--	If proven sub-fertility	--	yes	--
Single women	--	--	If proven sub-fertility	--	yes	--
Other	Surrogacy, saviour siblings, PGD, HIV treated separately	18 week waiting target	Couple need to be considered likely to comply with treatment and adopt healthier lifestyles and not using recreational drugs.	Weight-related amenorrhea	Must conform to HFEA code of practice	--

Appendix 2: Policy Rationale

Ref		NICE Guideline	Proposed Criterion	Rationale
-	Definition of Infertility	A woman of reproductive age: - who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner Following the first year and clinical investigation: - In the absence of any known cause of infertility, the couple should be offered NHS infertility treatment after a further 1 year of regular unprotected vaginal sexual intercourse - Where the cause of infertility is known, the couple should be offered NHS infertility treatment without further delay. - Where the woman is aged between 36<39 years of age, the couple should be offered NHS infertility treatment without further delay.	Adopt NICE Guideline	NICE Recommendation.
-	Definition of infertility exceptions (Same Sex Female Couples, single women and transgender men)	For a woman in same sex relationships, who has not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, offer a further 6 cycles of IUI before IVF is considered. *[NICE 1.9.1.2]*	For people in same sex relationships, who have not conceived after 6 cycles of self-funded donor or partner insemination undertaken at a HFEA registered clinic, offer infertility treatment. Clinic documentation detailing the procedures undertaken, outcomes and relevant clinical notes are to be provided	Where sub-fertility/ infertility is not a known issue, IUI is as successful as trying to conceive naturally. Therefore sub/infertility is indicated and this policy would apply. (Mackenna A.I., Zegers-Hochschild F., Fernandez E.O., Fabres C.V., Huidobro C.A., Guadarrama A.R. Intrauterine insemination: Critical analysis of a therapeutic procedure.

		For a single woman i.e. without a partner, they will be expected to follow the same definition of infertility as women in a same sex relationship For a transgender men, they will be expected to follow the same definition of infertility as women in a same sex relationship	at referral.	Human Reproduction. 1992; 7/3: 351-354; Peek J.C., Godfrey B., Matthews C.D. Estimation of fertility and fecundity in women receiving artificial insemination by donor semen and in normal fertile women. British Journal of Obstetrics and Gynaecology.1984; 91/10:1019-1024). Therefore in cases of single women, women in a same sex relationship and transgender males, we would expect them to self fund conceiving in this way. Use of a HFEA registered clinic to ensure a safe and clinically effective procedure is undertaken. BWH have provided us with data on number of women in infertility exceptions accessing IVF. In 2012-13, no transgender sought NHS funded IVF. Of those living in Birmingham, one single woman and 1 woman in a same sex relationship accessed NHS funded IVF. According to HFEA, across the whole of the UK (population of ~63 million), 418 women in a same sex relationship accessed IVF in 2010. For a population of 1.2 million people (roughly the size of Birmingham), one would expect there to be 7-8 women in a same sex relationship accessing IVF. In 2012-2103, 431 Birmingham residents accessed assisted conception treatment – using modelled figures for same sex women, this would represent 2% of last years of cohort accessing assisted conception treatment. In reality, numbers of women in a same

				sex relationship accessing this treatment are likely to be less as not all women will fulfil eligibility criteria.
-	Definition of a Cycle	This term is used to define a full IVF treatment, which should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).	A fresh cycle will consists of ovulation induction, egg retrieval, fertilisation and embryo transfer/implantation of an embryo to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.	Whilst NICE Guidance recommends the transfer of any resultant frozen embryos, frozen embryo transfers have a lower success rate [14% live births using FET vs 22% using fresh cycle] and are therefore not funded. A fresh cycle provides the optimum opportunity for conception.
-	Abandoned Cycles		Further consideration required.	
-	# of cycles per couple	[CG 1.11.1.3] In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without ICSI. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. [CG 1.11.1.4] In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled: • they have never previously had	For couples in whom this is clinically indicated and who fully meet the criteria detailed in Appendix 1, the Commissioner will fund 1 cycle of In Vitro Fertilisation (IVF) or Intra-Cytoplasmic Sperm Injection (ICSI).	Resource Allocation: to be able to provide an equitable service across as many eligible couples as possible. Offering two cycles (compared to 1) would increase costs by 64%; offering three cycles (compared to 1) would increase costs by over 100 %.

		IVF treatment • there is no evidence of low ovarian reserve there has been a discussion of the additional implications of IVF and pregnancy at this age.		
-	Donor Egg/ Sperm Procedures	[CG 1.14.1.1] The use of donor insemination is considered effective in managing fertility problems associated with the following conditions: • obstructive azoospermia • non-obstructive azoospermia [CG 1.15.1.1] The use of donor oocytes is considered effective in managing fertility problems associated with the following conditions: • premature ovarian failure	The commissioner will fund donor sperm procedures where the male partner has Azoospermia or Oligospermia. The commissioner will fund donor egg procedures for women who have undergone premature ovarian failure.	Support the completion of a fresh cycle and provide the optimum opportunity for conception.

Appendix 3: Eligibility Criteria Rationale

Ref	Feature	NICE Guideline	Proposed Criterion	Rationale
1.	Childlessness	n/a	NHS infertility treatment will only be funded if neither partner has no living children of any age; this includes an adopted child or a child from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple will no longer be considered childless and will not be eligible for NHS funded treatment.	Resource Allocation: The priority of infertility treatment for childless couples.
2.	Sterilisation	n/a	NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.	Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequent on this.
3.	Previous Infertility Treatment	n/a	NHS infertility treatment will not be offered for couples who have already undertaken any previous fertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded.	The ability of the commissioner to provider assisted conception services to the optimal number of couples.
4.	Age of Female Partner	[CG 1.11.1.3] In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without ICSI.	Maintain NICE guideline of 2004 with the addition of: Referrals for NHS infertility treatment should be made on or before the females 39th birthday to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday.	Consistent with 2004 NICE Guideline. Fall off in treatment success with increasing maternal age. Increased maternal and child complication rate.

		If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. [CG 1.11.1.4] In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled: • they have never previously had IVF treatment • there is no evidence of low ovarian reserve • there has been a discussion of the additional implications of IVF and pregnancy at this age.	If infertility is clinically identified in a female from the age of 20 years old - NHS infertility treatment should be offered without delay.	Prevention of delays in treatment where appropriate Whilst NICE recommend an extension of the female age to 42 where specific criteria are met, the success rates for this cohort of patients is low. For women aged uder 34, success rates are 41%; in women aged 40-42, this drops down to 21%. (Taken from http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf)
5.	Age of Male Partner	n/a	The age of the male partner at the time of treatment must be 41 years of age or less.	Donor sperm donation ceases at age 41 due to reduction in sperm quality (http://www.hfea.gov.uk/sperm-donation-eligibility.html). Also men aged over 40 are half as likely to conceive with IVF compared to 30 year old men when their female partner is aged 35-39 years (de La Rochebrochard E, de Mouzon J, Thépot F, Thonneau P. Fathers over 40 and increased failure to conceive: the lessons of in vitro fertilization in France. Fertil Steril. 2006; 85 (5):1420-4.) Communication with BWH indicates that 90% of opposite sex couples undergoing

				IVF have fathers aged less than 42 yrs.
6.	Body Mass Index [Medical]	Women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female BMI outside this range is likely to reduce the success of assisted reproduction procedures. . [CG 1.1.4]	NICE Guideline Applies with clinical discretion regarding application of the lower female BMI limit.	Consistent with NICE Guideline. Female body mass index of >30 and <19 kg/m² is likely to reduce the success of assisted reproduction procedures. Men who have a body mass index of more than 30kg/m² are likely to have reduced fertility.
7.	Smoking Status [Medical]	Women who smoke should be offered referral to a smoking cessation programme to support their efforts in stopping smoking. [CG 1.2.4] Where one or both partners smoke, couples will only be eligible for fertility treatment if they agree to take part in a supportive programme of smoking cessation. [CG 1.1.4]	Only non-smoking couples (opposite sex and same sex; single women) will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral to the assisted conception service. E cigarettes – further consideration needed.	Maternal and paternal smoking can adversely affect the success infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Women should be informed that passive smoking is likely to affect their chance of conceiving. Sperm genesis cycle is approx 3 months.
8.	Alcohol Intake	Women who are trying to become pregnant should be informed they should drink no more than 1 or 2 units of alcohol once or twice per week and avoiding episodes of intoxication reduces the risk of harming a developing foetus. Men should be informed that alcohol consumption within the Department of Health's recommendations of 3 to 4 units per day for men is unlikely to affect their semen quality. Men should be informed that excessive alcohol intake is detrimental to semen quality.[CG 1.2.3]	Further consideration needed as measurement is difficult.	Excessive alcohol intake can decrease the success of conceiving. Therefore potential recipients of IVF should be given advice to adhere to DoH guidelines for alcohol intake prior to being referred for treatment.

		People should be informed that the consumption of more than 1 unit of alcohol per day reduces the effectiveness of assisted reproduction procedures, including IVF [CG1.10.5)		
9.	Caffeine consumption	People should be informed that maternal caffeine consumption has adverse effects on the success rates of assisted reproduction procedures, including IVF treatment. [CG1.10.5)	Further consideration needed as measurement is difficult.	Maternal caffeine consumption has adverse effects on the success rates IVF treatment. Therefore potential recipients of IVF should be given advice to adhere to caffeine guidelines prior to being referred for treatment.