Audit Risk Level:

(Risk level will be added by EQIA steering group)

3. Rapid Impact Assessment summary report

Each of the numbered sections below must be completed

Interim report [ ] Final report [x] (Tick as appropriate)

1. **Title of plan, policy or strategy being assessed.**
   Reintroduction of NHS Lothian funded Donor Insemination service.

2. **What will change as a result of this proposal?**
   NHS Lothian has not had a Donor Insemination service for many years (since legislation removing the right to anonymity of donors). We will seek and hopefully recruit new sperm donors and reintroduce a Donor Insemination service to couples that meets criteria based on national IVF criteria. The service will, as in the past, be offered to both heterosexual and same sex couples. However, in a change from before, the service will not be available to single women (to ensure consistency with the national IVF criteria).

3. **Briefly describe public involvement in this proposal**
   There has not been public involvement in this proposal. With a long "holding list" for treatment, and with demand once the service is introduced likely to be high, we have not promoted the service. The Edinburgh Fertility and Reproductive Endocrine Centre (EFREC) Management Team has reviewed complaints about a lack of service and considers such cases through a "difficult decisions" panel.

4. **Date of RIA**
   23 October 2013

5. **Who was present at the RIA? Identify facilitator and any partnership representative present**

Name	Job Title	Date of RIA training	Email
Scott Justice	Equality and Diversity Support Officer, NHS Lothian	October 2013	Scott.Justice@nhslothian.scot.nhs.uk
Jules Stapleton Barnes	Community Development Worker, LGBT Health		jules@lgbthealth.org.uk
Daniel Aldridge	Policy manager,		daniel.aldridge@stonewallscotland.org.uk

	Stonewall		
Sheila Smith	Charge Nurse, EFREC, NHS Lothian		Sheila.M.Smith@luht.scot.nhs.uk
Liz Dickson	Staff Nurse, EFREC, NHS Lothian		Liz.Dickson@luht.scot.nhs.uk
Joo Thong	Gynaecology Consultant, NHS Lothian		Joo.Thong@luht.scot.nhs.uk
Graham Mackenzie	Consultant in Public Health, NHS Lothian	14 October 2008	graham.mackenzie@nhslothian.scot.nhs.uk

6. Evidence available at the time of the RIA

Evidence	**Available?**	**Comments: what does the evidence tell you?**
Data on populations in need	Yes - some information available	We heard a summary of numbers on the holding list, and whether they were still eligible using new criteria based on national IVF criteria (from CEL 9 May 2013). The total number of new people who would seek donor insemination once the service is reintroduced is not known.
Data on service uptake/access	No	There is no service in Lothian at present, due to a shortage of sperm donors. We heard about successful recruitment of donors from a London clinic, and discussed the possibility of learning from their communications team.
Data on quality/outcomes	Yes - some information available	We heard about the yield of donors (7% of those expressing an interest will become actual donors following screening for genetic conditions, communicable disease and other considerations). We also heard about the success rate of treatment, which declines with age.
Research/literature evidence	No	There is a NICE guideline that covers aspects of the service. We did not refer to this specifically, but members of the group were familiar with the details of the guidance.
Patient experience information	Some	We had a verbal report on experience of delivering an NHS Lothian funded DI service in the past. We also heard feedback from LGBT Health about the likely demand for a service from discussions with a family group. There is evidence of considerable demand

		(currently unmet), and a frustration that there is not a service at present.
Consultation and involvement findings	No	
Good practice guidelines	No	See comment re NICE guidelines above.
Other (please specify)		Draft eligibility criteria for DI, adapted from national IVF eligibility criteria and discussions about eligibility at EFREC management team meetings

7. Population groups considered

	Potential differential impacts
Older people, children and young people	**Age**: Donor Insemination is only offered to women up to their 40th birthday. Beyond 40 the treatment has a very low success rate. The proposed local criteria clearly state this. Nonetheless, there will be a need to manage expectations and frustrations resulting from these changes, and the slow recruitment of donors. Prioritising patients approaching 40 years of age would help those couples, but would divert resources away from couples with a higher success rate. **Other children**: Donor Insemination is currently only offered to couples without a child in the home. The service would like to provide a self-funded service in the future for couples seeking a sibling via the same donor. Shortage of donors will not allow this initially.
Women, men and transgender people (include issues relating to pregnancy and maternity)	**Transgender**: The draft criteria do not discriminate against transgender people. Care will be required, however, in addressing the needs of transgender people and respecting their legal status. The specific circumstances around pregnancy for transgender people are not included in the criteria (e.g. a FtM patient should not take male hormones if trying to become pregnant; a MtF patient in a relationship with a woman may not consider using own stored sperm, if available, as it may compromise gender identity). The detail could be included in a Standard Operating Procedure.

	Access to infertility services, and Donor Insemination, requires referral from GP or the Sexual Health service. The "gatekeepers" (receptionists, GPs, Sexual Health staff) need to know the eligibility criteria and should be trained in equality and diversity. Training is available from LGBT organisations. **Surrogacy**: Relationships between two men require surrogacy treatment. Surrogacy is not provided on the NHS. **Women**: We talked briefly about egg donation. While there is already a service for couples requiring donor eggs, the number of donors is very small. This was not discussed further.
Disabled people (includes physical disability, learning disability, sensory impairment, long term medical conditions, mental health problems)	There should not be barriers to treatment on the basis of the criteria or the equipment available in EFREC. Would need to consider welfare of the child and seek GP/ social work involvement for some cases.
Minority ethnic people (includes Gypsy/Travellers, non-English speakers)	There is a shortage of donor sperm generally, but for some ethnic minority groups in particular (sometimes due to ethnicity, sometimes due to a couple's concerns about the religion of the donor). It will be important to manage expectations in this regard. It will be challenging to recruit donors that meet expectations of all couples, even if purchasing sperm from other centres. Language will be a barrier for some couples. However, translation of the criteria may result in differences in interpretation. Access to an interpreter will be preferable for these couples and is already available for NHS Lothian services.
Refugees & asylum seekers	Such cases would be referred to the NHS Lothian overseas treatment team.
People with different religions or beliefs	See above for ethnic minority groups (e.g. discussed example of Muslim couple and Hindu donor). Service should respect opinions but also manage expectations.
Lesbian, gay, bisexual and heterosexual	The proposal has largely positive

people	implications for this group. It provides a service for this group when there are few other options available (in contrast, a heterosexual couple may have options including sperm retrieval that are not open to couples in a same sex relationship). The positives extend beyond simply accessing the DI service. They include wider benefits including LGBT couples being part of the community, part of society as a family. These positives will, of course, also apply to heterosexual couples. One point that should be considered by the service, that relates specifically to same sex couples, is about language and the communication as “couple who need DI” rather than “fertility problem”.
People who are unmarried, married or in a civil partnership	The relevant criterion here relates to a stable relationship (minimum of two years). This will apply regardless of sexuality and regardless of marital status. Nonetheless, there are points to consider regarding legal parenthood. If a couple is not married or in a civil partnership the woman needs to agree to give permission to include the other partner on the birth certificate. For any couple, regardless of status the welfare of the child is taken into consideration before treatment is offered.
People living in poverty / people of low income	This is an NHS Lothian funded service. There is no differential impact.
Homeless people	There has not been an application in the past by a homeless couple. However, there is nothing specifically in the criteria that would preclude such treatment. There would need to be an assessment of the welfare of the child.
People involved in the criminal justice system	There would need to be an assessment of the welfare of the child.
People with low literacy/numeracy	Understanding the criteria may be challenging for this group, even though technical language has been kept to a minimum. Going through the criteria with a member of staff (GP, EFREC staff) will be important. While information could be tailored this is not desirable as different versions of the criteria may be interpreted

	differently.
People in remote, rural and/or island locations	Lothian does not have remote areas, but it does have rural locations. LGBT couples may find that there are reasons for not accessing EFREC through local services. Having information available on the EFREC website and RefHelp (open access) will be useful. Referrals can also be made via family planning at Chalmers and this may be preferable for some couples.
Carers (including parents, especially lone parents; and elderly carers)	See below for single women. There were no specific additional points for carers that would not be covered in consideration of welfare of the child.
Staff (including people with different work patterns e.g. part/full time, short term, job share, seasonal)	The stress of running a service where demand is likely to exceed supply is an important consideration and extends beyond access to funding. The demand for the service is unknown, but likely to be high once the service is reintroduced, particularly from same sex couples. The supply of donor sperm is also unknown, but likely to be lower than in the past. Pre 2004, and the change to legislation, the number of DI treatments provided in NHS Lothian was 200/month. While many men with lower quality sperm now have ICSI (thereby reducing the demand), there will continue to be considerable demand, particularly from same sex couples. It is possible, and indeed likely, that a mismatch between supply (availability of donor sperm) and demand (number of couples seeking donor insemination) will result in increasing waiting lists, increasing demands and pressure on staff, and general dissatisfaction. There are implications for staff in rest of NHS (e.g. GP receptions) about access to fertility services for LGBT couples. See above for training.
OTHERS (PLEASE ADD):	Couples seeking treatment through "**named donors**": this is not a service that is currently offered in NHS Lothian. Treatment on this basis limits the number of patients that can be treated per donor (with general donation, treatment can

	"create" up to 10 families, with named donors only one couple can be treated). Men seeking to donate on a named patient basis could be asked if they wish to donate to the general bank. The rules for treatment on that basis (i.e. for the couple originally seeking treatment with sperm from that donor) would need to be drawn up carefully. **Single women** (not a protected characteristic) are not eligible for treatment using these new criteria. That is consistent with the new national IVF criteria. There are some women on the Donor Insemination holding list who are seeking treatment on this basis. No commitment to treatment has been given to these women and the current decision by the EFREC Management Team is that these women will be declined treatment. Human Fertility and Embryology Authority (HFEA) rules do not require that healthcare organisations provide treatment for single women. Aberdeen is the only NHS funded IVF centre in Scotland to offer this option. Some Primary Care Trusts in England do offer treatment to single women, and Infertility Network UK documentation states that this treatment should be provided. At present, therefore, there is no binding requirement to provide this treatment. Some members of the group were uncomfortable about this decision. The group agreed that the EFREC Management Team should keep this under review. (See also further documentation at end of this document – information received subsequently from Scott Justice and Andy Jackson). **Overweight/ obese**: The criteria are consistent with the national IVF criteria (i.e. not to provide treatment at BMI >= 30kg/m^2. No changes were recommended. **Army couples** were discussed: These couples move around frequently. There is agreement between centres to transfer

	position on waiting list when the couple moves.

8. **What positive impacts were identified and which groups will they affect?**

Impacts	Affected populations
Reintroducing the service will have positive impacts on the couples eligible for treatment (see criteria). It will increase available NHS funded options for infertility treatment for Lothian residents.	All couples who meet the eligibility criteria.

9. **What negative impacts were identified and which groups will they affect?**

Impacts	Affected populations
Limited access to donor sperm may mean that patients' expectations are not met. Changes to the criteria (single women, smoking and obesity) mean that some patients eligible under previous criteria are not eligible now.	Single women Smokers Obese women Other groups not meeting the criteria.

10. **What communications needs were identified? How will they be addressed?**

There has already been written communication with couples/ individuals on the holding list. Once the holding list has been validated against the new criteria, and donors recruited, the couples/ individuals will be contacted again.

Options for communicating with potential donors were also discussed – need to discuss with the communications team in NHS Lothian, and also work with LGBT Health and Stonewall to explore options for recruiting donors from the LGBT community.

Options for communicating with the wider group of people who may be considering Donor Insemination in the future, but who are not on any holding/ waiting list, were also discussed. As noted above, there has been some dissatisfaction noted (e.g. at LGBT Health family meetings) about fertility options currently available to LGBT people. However, as noted by representatives of LGBT organisations participating in this RIA, NHS Lothian has a long history of providing services for this group, interrupted by the change to rules around donor anonymity. Reintroducing the Donor Insemination service will go some way towards amending this situation, but there is also a considerable risk of demand outstripping supply (especially due to availability of donor sperm), so we will need to manage expectations. We will need to watch this closely once the service has been introduced.

Need to communicate with staff groups across NHS Lothian – e.g. GP practices and reception staff, regarding new criteria and LGBT training; and colleagues in the Sexual Health Service about new criteria.

11. **Additional Information and Evidence Required**

If further evidence is required, please note how it will be gathered. If appropriate, mark this report as interim and submit updated final report once further evidence has been gathered.

See above (section 10) about challenges matching supply with demand. It is not possible to document level of demand until the service has been reintroduced.

12. **Recommendations**

The proposal is generally positive, but there are some points of detail that need to be addressed, and sensitivities around communication to sperm donors and couples seeking the service.

13. **Specific to this RIA only, what actions have been, or will be, undertaken and by when? Please complete:**

Specific actions (as a result of the RIA)	Who will take them forward (name and contact details)	Deadline for progressing	Review date
Communication a) To share information about successful donor recruitment programmes elsewhere in the UK	Daniel Aldridge to share information on London Clinic with Sue Pickering	November 2013	
b) To adapt approaches for local donor recruitment and provision of local Donor Insemination service more generally.	Sue Pickering/ Sheila Smith to discuss options around donor recruitment and Donor Insemination service more generally with NHS Lothian communications team	December 2013	March 2014
c) To inform staff about new criteria and availability of LGBT training (e.g. primary care, Sexual Health service)	Need to find out more about LGBT training available beyond local mandatory training (LGBT organisations), then	March 2014, then again before service introduced	March 2014 and ongoing.

	EFREC MT to consider. Sheila Smith/ Liz Dickson to discuss new service with Sexual Health service		
2. EFREC Management Team (MT) to consider whether women close to their 40th birthday, and close to the top of the list, should have treatment prioritised.	EFREC MT	March 2014	June 2014 The decision was made not to prioritise.
3. EFREC MT to consider whether rules around surrogacy should be included in the criteria for DI/ IVF.	EFREC MT	December 2013	March 2014
4. EFREC MT to consider options for purchasing sperm from other centres if suitable supply for some ethnic minority groups is not available locally.	EFREC MT	March 2014	June 2014
5. EFREC MT to consider extending service (e.g. for self funded service for couples seeking sibling) under review	EFREC MT	March 2015	March 2015
6. EFREC to consider more detailed SOP (e.g. for detail about transgender patients noted above)	EFREC	March 2014	June 2014

14. **How will you monitor how this policy, plan or strategy affects different groups, including people with protected characteristics?**

We will discuss progress regularly at the EFREC Management Team, identifying areas for further work that will be progressed between meetings.

We will review the uptake of the service and collect information and feedback from patients accessing the service.

We will review complaints and Freedom of Information requests that may provide further information and adapt the service accordingly.

Manager's Name: Fiona Mitchell, Director of Operations

Date: 8th October 2014

Please send a completed copy of the summary report to:

James Glover, Head of Equality and Diversity
James.Glover@nhslothian.scot.nhs.uk

Note that you **will** be contacted by a member of NHS Lothian's impact assessment group for quality control and/or monitoring purposes.

Information about provision for single women:

1. Further information from Scott Justice (received by email 24 October):

The HFEA guidance notes that different clinics have different eligibility criteria - http://www.hfea.gov.uk/79.html#single

The Journal of Medical Ethics had an article debating equity of access in assisted reproductive technologies (Australia) - http://jme.bmj.com/content/31/5/280.full.pdf+html – and questions the practice of using the "welfare of the child" argument as:

"With the failure rate of modern marriages approaching 40–50% in many countries which also have the highest number of ART services, a significant number of families have

minimal or no contact with a father figure and there are obviously no guarantees that heterosexual couples will remain married or as a couple throughout their offspring's childhood.2 5 18 26 Thus, it would constitute an inappropriate discrimination to exclude lesbian, single heterosexual, or postmenopausal women from access to ARTs because of concern for the welfare of their potential offspring."

The most likely potential challenge could come via the Human Right Act through Articles 8 (Right to family life) or Article 12 (Right to marry and found a family) although Liberty note:

"Once a family has been 'founded', issues relating to the relationship between the child and parent will fall within Article 8 – the right to respect for family life, rather than Article 12. It is unlikely that Article 12 guarantees the right to found a family by medically assisted means, but the matter has not yet been considered by the ECHR."

(Source: http://www.yourrights.org.uk/yourrights/the-human-rights-act/the-convention-rights/article-12-right-to-marry-and-found-a-family.html). This means the position could be challenged in the future but there do not appear to be previous cases recorded by European Human Rights Commission or any ongoing cases going through the courts at the moment.

This confirms discussions at the RIA – single parenthood is not a legally protected characteristic and it is up to the service to determine its own eligibility criteria but the behaviour could be viewed a discriminatory.

There is a need for regular review as the criteria of other centres and the legal landscape changes. Worth noting that should supply ever exceed demand (which we know is unlikely to happen) then consideration could be given to widening the criteria.

2. Information received from Andy Jackson (24 October, from Infertility Network UK website, by email):

"Requests for treatment from single women or lesbians are considered and treatment normally provided. Independent counselling is required."
http://www.infertilitynetworkuk.com/uploaded/Fact%20Sheets/Donor%20Insemination.pdf

3. Information from discussions with Norwegian delegates at a recent conference (Graham Mackenzie, 15 November 2013)
GM met with maternity and infertility specialists from Norway, to discuss the "difficult decisions" process. Following the meeting GM discussed treatment of single women with some of the delegates. This discussion demonstrated that rules (and, in some cases, legislation) around treatment of single women varies across Europe.