Equality Analysis and Impact Assessment

<table>
<thead>
<tr>
<th>Name of project/ proposal</th>
<th>In-Vitro Fertilisation (IVF) and Intra-Cytoplasmic Sperm Injection (ICSI) review by Clinical Commissioning Groups (CCGs) across Hampshire and Isle of Wight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact name</td>
<td>Nick Birtley, Equality and Diversity Lead West Hampshire Clinical Commissioning Group</td>
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</tbody>
</table>
| Department                | Joint project between the 8 CCGs across Southampton, Hampshire, Isle of Wight and Portsmouth (SHIP):  
|                           | • Fareham & Gosport CCG  
|                           | • Isle of Wight CCG  
|                           | • North Hampshire CCG  
|                           | • North East Hampshire and Farnham CCG  
|                           | • Portsmouth CCG  
|                           | • South Eastern Hampshire CCG  
|                           | • Southampton City CCG  
|                           | • West Hampshire CCG |
| Intended publication date | To be decided by each CCG |

Summary
The review of the IVF and ICSI policy has a high equality impact on the protected characteristics defined in the Equality Act 2010 of age, disability, gender, pregnancy and maternity, and sexual orientation.

The eligibility criteria for access to NHS-funded IVF have a positive equality impact for women under the age of 35 years (including single women and women in same sex couples), as well as for men of any age, who have confirmed infertility problems. People with disabilities and health conditions that do or may impact on their fertility can also access NHS treatment under the policy. The policy also has a positive impact for partners and close relatives of people who are unable to conceive.

For women over the age of 35 years NHS funded fertility treatment is not available locally, and this may have a negative equality impact on them and their partner, especially if they are unable to afford to pay for infertility treatment privately.

This is mitigated to some extent by the fact that people who do not meet the criteria set out in the local policy, can – in exceptional circumstances – make an Individual Funding Request via their clinician, to have their case looked at again.
The local policy is more restrictive than the guidelines published by the National Institute for Health and Care Excellence (although the CCGs are not legally obliged to implement NICE guidelines in full). Again this may have a negative equality impact for people who fall outside the local criteria. Whether any negative impacts are discriminatory against groups protected by the Equality Act 2010 depends on whether the policy can be reasonably justified on the basis of evidence.

The review of evidence of clinical and cost effectiveness suggests:

- Although female age is a key predictor of the likely success of IVF treatment, the success rate for women aged 35-37 years is only around five percentage points less than for those aged under 34 (27.4% and 32.2% respectively). CCGs should consider increasing the current upper age limit to reduce inequity.
- There is good clinical evidence to support use of frozen embryos (the Priorities Committee have proposed that one cycle now include up to two separate embryo transfers (fresh or frozen, or frozen/ frozen as clinically indicated).

In terms of an Equalities Impact Assessment it is recommended that:

- The CCGs consider increasing the upper age limit to 37 years.
- The CCGs consider bringing the SHIP policy in line with that of Surrey CCG.
- Decision making processes are demonstrably fair and transparent to reduce risk of Judicial Review.
- To support demonstration of due regard to Equality Act 2010, that collection and analysis of equalities information about people who receive NHS funded infertility treatment, and those who apply for Individual Funding Review is commenced by providers and the CSU. As a minimum this should include age, gender, disability status, sexual orientation and post code. Where this data highlights differential access for equality groups this can be considered as part of future reviews of this policy in order to demonstrate fairness.

**Purpose for the project or proposal**

**Background**

In February 2013 the National Institute for Health and Care Excellence (NICE) published updated clinical guidelines regarding NHS funding for assisted conception.

In response, NHS commissioners across Hampshire and the Isle of Wight agreed an interim policy position in March 2014. Then in July/ August 2014 they asked an independent organisation called Solutions for Public Health to review recent evidence of clinical and cost-effectiveness for In Vitro Fertilisation (IVF) and Intra-

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1 National Institute for Health and Care Excellence, February 2013, *NICE clinical guideline: Fertility: Assessment and treatment for people with fertility problems (CG 156)*

2 *Southampton, Hampshire, Isle of Wight and Portsmouth PCTs priorities Committee, February 2013)*, *Priorities Committee Statement – Assisted Conception/IVF*
Cytoplasmic Sperm Injection (ICSI). This review helped the joint CCG Priorities Committee to develop a proposed new policy in August 2014. As a final step, the new recommendations need to be agreed by each individual CCG.

Infertility
- The evidence review\(^3\) says that infertility is a recognised medical condition and can occur at any age. It may be due to a variety of causes such as ovulatory disorders (25%), tubal damage (20%), and factors in the male causing infertility (30%). In 25% of cases, the cause is unexplained.
- NICE has defined infertility as a failure to conceive after regular unprotected sexual intercourse for one or two years.
- The Human Fertilisation and Embryo Authority (HFEA) estimate that infertility affects 1 in 7 heterosexual couples in the UK. A total of 13,703 pregnancies were reported as a result of IVF treatment which started in 2011. 40.3% of IVF treatment cycles were funded by the NHS in 2011\(^4\).
- In Vitro Fertilisation (IVF) is a technique by which eggs are collected from a woman and fertilised with a man’s sperm outside the body. Usually one or two resulting embryos are then transferred to the womb. If one of them attaches successfully, it results in a pregnancy.
- Intra-Cytoplasmic sperm injection (ICSI) is a variation of IVF in which a single sperm is injected into an egg.

Cost
- A full cycle of fresh IVF can cost the NHS around £3,000 (which includes ovarian stimulation, removing the woman’s eggs, insemination of the eggs in the laboratory, embryo culture, transfer of 1 or 2 embryos back into the body, and freezing of any spare suitable embryos)
- A cycle of Intra-Cytoplasmic sperm injection (ICSI) costs the NHS about an extra £500 in addition to the £3,000
- The thawing and transfer of frozen IVF embryos costs the NHS significantly less than fresh IVF.

Currently, the local NHS funds one cycle of IVF treatment to women who meet the following eligibility criteria:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Current SHIP access criteria</th>
<th>2013 NICE guidance</th>
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<tbody>
<tr>
<td>Age of woman at time of referral</td>
<td>Up to 35 years old (treatment must start before the woman is 35)</td>
<td>Up to and including 42 years old</td>
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<tr>
<td>Availability of fresh and</td>
<td>Fresh cycle only</td>
<td>Full fresh cycle and all</td>
</tr>
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\(^3\) Solutions for Public Health, August 2014, *Review of the clinical and cost effectiveness of infertility treatments*

\(^4\) Human Fertilisation and Embryo Authority, 2013, *Fertility treatment in 2012: Trends and figures*
<table>
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<tr>
<th>frozen cycles available</th>
<th>subsequent frozen cycles</th>
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<tbody>
<tr>
<td>Number of cycles available</td>
<td>One cycle</td>
</tr>
<tr>
<td>Three cycles to women under 40 years old (one cycle for women aged 40 to 42 years)</td>
<td></td>
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<tr>
<td>BMI eligibility</td>
<td>Women must have had a BMI of between 19.0 and 29.9 for six months or more</td>
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<tr>
<td>Offer advice to women with a BMI of 30 or over to lose weight in order to increase the success rate and reduce complications during their pregnancy</td>
<td></td>
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<tr>
<td>Smoking status</td>
<td>Couples must be non-smoking for at least six months in order to improve the likelihood of success.</td>
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<tr>
<td>Offer advice and refer to a local smoking cessation programme</td>
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Based on the evidence, Solutions for Public Health set out a number of commissioning options for consideration by the SHIP Priority Committee and individual CCGs (see page 2 of report below)

The Priorities Committee have proposed that the existing policy be extended to allow one fresh and one frozen cycle, otherwise to remain unchanged:

Consultation
Has a consultation been carried out?
Yes.

In addition to the review of evidence, the 8 Clinical Commissioning Groups (CCGs) serving Fareham and Gosport, Isle of Wight, North East Hampshire and Farnham, North Hampshire, Portsmouth, South Eastern Hampshire, Southampton and West Hampshire, have sought the views of local people.

The public’s feedback will be considered as part of each CCG’s decision about funding of, and eligibility for, IVF treatment.

The CCGs in Southampton, Hampshire, the Isle of Wight and Portsmouth (SHIP 8 CCGs) undertook a period of involvement with local people, their representatives, GPs and interest groups.

This commenced on Monday 22 September 2014 and initially ran until Sunday 19
October 2014. This deadline was then extended to 7 November 2014.

The aim was to:
- Gather views on whether funding for IVF is a priority for the NHS and,
- On the access criteria for treatment.

The information shared with members of the public and other stakeholders is below:

In total 1,133 responses were received. Also more than a quarter of respondents had direct experience (either themselves or a partner) of IVF. This is the report outlining the views gathered from local people:

Statutory considerations

<table>
<thead>
<tr>
<th>Impact</th>
<th>High/ medium/ low</th>
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<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td></td>
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<tr>
<td>Sexual orientation</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Religion or belief</td>
<td></td>
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<tr>
<td>Gender reassignment</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Marriage and civil partnership</td>
<td></td>
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<tr>
<td>Pregnancy and maternity</td>
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Other policy considerations

<table>
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<tr>
<th>Impact</th>
<th>Medium impact on people with low incomes</th>
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<tr>
<td>Poverty</td>
<td>Low impact on people living in rural areas</td>
</tr>
<tr>
<td>Rurality</td>
<td>High impact on partners of infertile/ sub-fertile people, medium impact on relatives and carers</td>
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Geographical impact

On populations of Hampshire and the Isle of Wight, including cities of Portsmouth and Southampton

Have you identified any medium or high impact

Yes

Equality statement
This equality analysis aims to identify any unlawful discrimination, and opportunities to advance equal opportunities and foster good relations, in line with each CCG’s public sector equality duties (part of the Equality Act 20105).

The SHIP 8 CCGs have considered the equality impact of the proposed local guidelines for NHS funded assisted conception, and identified the following:

**Positive impacts**
The local clinical guidelines regarding NHS funding for assisted conception have a positive equality impact for:

- Women and men who have unexplained infertility or who have an identified cause of infertility (that has lasted for more than 36 months)

- Women in same sex couples/ and women not in a partnership who are infertile/ sub-fertile. To comply with the Equality Act 2010 assisted conception services must be available to gay, lesbian and bi-sexual people and well as heterosexuals

- The partners (same sex and opposite sex) of infertile individuals, in that they may be able to conceive/ have a child when previously unable to. There is a similar positive impact for relatives and carers of individuals with fertility problems

- People with a disability or long-term health condition. Some physical disabilities may impede sexual intercourse. Also some medical treatments can cause long-term infertility and so an individual may request harvesting of eggs or sperm prior to treatment. Where a disability is a cause of infertility (for example male factor infertility related to spinal injury) the applicant is considered in the normal way.

Equality related issues like previous pregnancy, childlessness, same sex couples and single women were outside the scope of the evidence review completed by Solutions for Public Health. However, the proposed eligibility criteria for NHS funded IVF and ICSI do include these equality groups and so have a positive impact:

- ‘Sub fertility treatment will be funded for women in same sex couples or women not in a partnership if those seeking treatment are demonstrably sub fertile’

- ‘Treatments for sub fertility will be funded if the couple does not have a living child from their relationship or from any previous relationship. This includes a child adopted by the couple or in a previous relationship’.

Individuals who fall outside of the criteria for NHS funded fertility treatment can make an Individual Funding Request (IFR). Most of the cases the CCGs supported outside of policy related to cryo-preservation ahead of chemotherapy.

The number of people that have received NHS funded IVF under the existing policy and so benefited positively:

**Fareham and Gosport CCG locality**

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5 HMSO, 2010, *Equality Act 2010*
27 individuals in 2013/14  
Isle of Wight CCG locality  
Data not available  
North Hampshire CCG  
43 individuals in 2013/14  
North East Hampshire and Farnham CCG locality  
39 individuals in 2013/14  
Portsmouth CCG locality  
32 individuals in 2013/14  
South Eastern Hampshire CCG locality  
39 individuals in 2013/14  
Southampton CCG locality  
61 individuals in 2013/14  
West Hampshire CCG locality  
75 individuals in 2013/14  

If individuals are turned down because they do not meet the criteria set out in the IVF policy, they can appeal by making an Individual Funding Request (IFR). The number of IFR applications is outlined below:

2013/14  
Fareham and Gosport CCG  
5 requests – all declined  
North East Hampshire and Farnham CCG  
13 requests, 5 supported, 8 declined.  
North Hampshire CCG  
8 requests, 2 supported, 5 declined, 1 further info was sought but none provided  
Portsmouth CCG  
10 requests, 5 supported, 5 declined  
South Eastern Hampshire CCG  
7 requests, 2 supported, 5 declined  
Southampton CCG  
10 requests, 4 supported, 6 declined  
West Hampshire CCG  
21 requests, 12 supported, 8 declined, 1 awaited info which was not received  

2014/15 (to 30 Sept)  
Fareham and Gosport CCG  
2 requests, both declined  
North East Hampshire and Farnham CCG  
No requests pre 30/9  
North Hampshire CCG  
3 requests, 2 supported, 1 declined  
Portsmouth CCG  
5 requests, 1 supported, 3 declined, 1 awaiting info which wasn’t received  
South Eastern Hampshire CCG  
2 requests, both supported  
Southampton CCG  
4 requests, none supported
West Hampshire CCG
9 requests, 5 supported, 3 declined, 1 currently with our Panel

The CCGs only collect equalities information that is directly relevant to the decision for eligibility to NHS funded fertility treatment (age and gender). Where disability is a factor in the cause of infertility, this is captured.

As a result it is not possible to breakdown access to NHS funded IVF by all the protected characteristics defined in the Equality Act 2010. The Human Fertilisation and Embryo Authority do collect data from fertility clinics, but only publish information for the equality characteristics of age and gender.

This lack of information means identifying potential differential access by equality groups to NHS funded IVF, or in applications for Individual Funding Requests is problematic. For example, we cannot analyse how many same sex female couples received NHS funding for infertility treatment locally compared to the expected local population of gay female couples/ prevalence of infertility.

Potential negative impacts

- Women who are infertile/ sub-fertile and over the age of 35 years, are excluded from the local eligibility criteria. The NICE guidance recommends at least one cycle of IVF to women up to the age of 42 years. Of the people that responded during the consultation 47.47% felt that NICE guidelines should be implemented, compared to 22% for existing SHIP criteria (35 years), and extending eligibility to 38 years at 27%. This upper age limit is not discriminatory if it can be justified on the basis of clinical evidence/ effectiveness.

  The evidence summary produced by Solutions for Public Health concludes that increasing maternal age is a key predictor of failure to have a live birth following IVF treatment, and so arguably it can be justified. The previous version of the local IVF policy was amended to remove the lower age limit (set at 30 years of age) in line with Department of Health guidance on age discrimination. Also keeping NHS funding to a single cycle may have the benefit of allowing more people to access treatment and reduce waiting times.

- The local eligibility criteria limit individuals to one cycle of IVF funded by the NHS. This compares to 3 cycles as recommended by NICE. This may have a negative impact on local people with fertility problems, although is not discriminatory if it can be reasonably justified on the basis of evidence.

  The evidence review notes that there is good evidence that singleton pregnancies after the transfer of frozen thawed embryo are associated with better perinatal outcomes, compared to those after fresh IVF embryo transfer. Given this, the CCGs need to consider whether more than one cycle should be funded. 66% of local people that responded to the consultation felt that we should implement NICE guidelines so people up to 40 years can have up to 3 cycles.

- The policy disqualifies couples who have children from their current or previous
relationships. This can be reasonably justified as spending on IVF and ICSI by the NHS prioritises childless people.

- One cycle of NHS funded infertility treatment is available to any woman/couple that meet the eligibility criteria, irrespective of their income. People that can afford to self-fund infertility treatment also have that option. People on low incomes are potentially less likely to be able to pay for treatment privately and so have reduced options. The local NHS does not analyse post code details of patients who receive NHS funded IVF and ICSI against areas of multiple deprivation. This may help identify any differential access so that the policy could be adjusted to advance equal opportunities.

- Psychological impact of infertility. Parenthood is one of the major transitions in adult life for both men and women. The stress of the non-fulfilment of a wish for a child has been associated with emotions such as anger, depression, anxiety, marital problems and feelings of worthlessness. Partners may become more anxious to conceive, ironically increasing sexual dysfunction and social isolation. Relationship discord often develops in infertile couples, especially when they are under pressure to make medical decisions. Couples experience stigma, a sense of loss, and diminished self-esteem in the setting of their infertility.

- The evidence review notes that there are some patient sub groups whose needs have not been addressed by the review or the NICE guidelines, and for whom the recommendations may not be appropriate or applicable. Any negative impact here can be reduced by sensitive clinical interventions, and promotion of the Individual Funding Request process to diverse groups. Also equality monitoring will help identify whether equal opportunities are advanced when implementing the policy.

- Additional local commissioning policy restrictions may increase inequalities for people outside of the eligibility criteria

- The Surrey CCG policy is less restrictive than the SHIP policy and creates inequalities within the North Hampshire and Farnham CCG locality

When considering these potential negative equality impacts, and whether to maintain the more restrictive local policy compared to the NICE guidelines, the CCGs must make a decision that strikes a balance between:

- The needs of a proportionately small number of people with fertility problems who are likely to be experiencing significant cultural and psychological issues as a result of not being able to conceive

- With the potential to have a greater positive impact by spending finite NHS funds on tackling other health conditions and inequalities.

Interestingly the public feedback suggests that local people do not think funding for

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IVF is a priority for the NHS (Do you think funding for IVF is a priority for the NHS? ‘Yes’ = 44.40%, ‘No’ = 46.98%)

Potential mitigating actions and recommendations

- The CCGs should consider raising the upper age limit to 37 years in light of clinical evidence

- The CCGs should consider the most recent clinical evidence to identify whether maintaining a single NHS funded IVF cycle can be reasonably justified. The evidence seems to suggest that the likelihood of success of individual, subsequent IVF cycles is particularly influenced by embryo viability and the ability of the mother to become pregnant, rather than the number of cycles per se. Arguably keeping NHS funding to a single cycle may have the benefit of allowing more people to access treatment and reduce waiting times

- The CCGs should consider bringing SHIP policy in line with that of Surrey CCG which funds 3 full cycles for women up to 39 years of age

- The CCGs need to ensure their decision making processes are fair and transparent due to the risk of claims by individuals or Judicial Review

- Collection and analysis of the protected characteristics of individuals should be completed who
  - Have received NHS funding for assisted conception services and,
  - Made an individual funding request for assisted conception services

  In addition to age and gender as a minimum this should include the protected characteristics of sexual orientation, disability status, and post code (to identify fair access for lower socio-economic groups). Ideally race, and religion or belief should also be monitored. This will provide better evidence of equitable access and due regard to the Equality Act 2010. This data can be used to inform future policy review decisions.

Date to review actions

**Final decision date:** Different for each CCG depending on governance timetable

Final decision date due

Decision to be made by