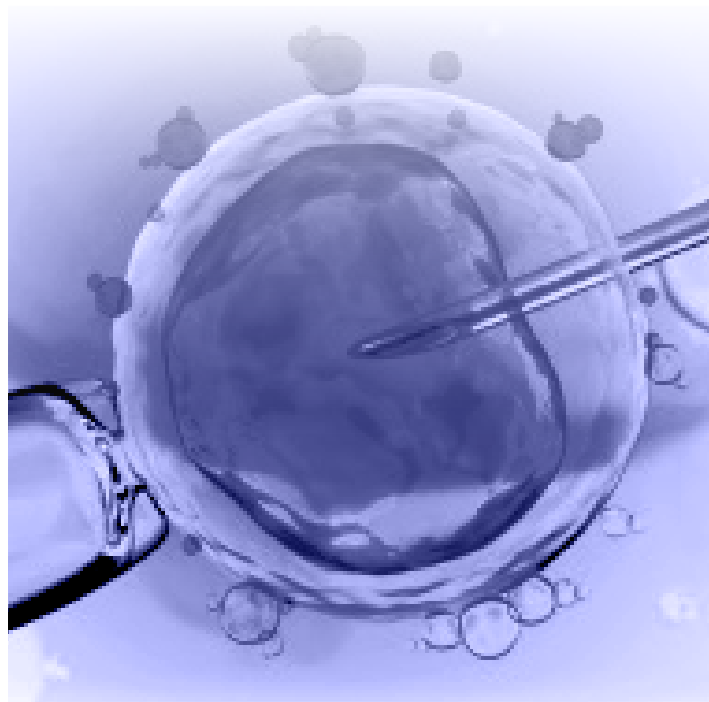

NATIONAL INFERTILITY GROUP REPORT

MARCH 2016



**Healthier
Scotland**
Scottish
Government

NATIONAL INFERTILITY GROUP REPORT

MARCH 2016

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1. FOREWORD

In 2013 the National Infertility Group published its recommendations to the Scottish Government on improving the provision of treatment to infertile couples. It did so at a time where fertility treatment across Scotland varied widely, where access was difficult and long waiting times reduced patients chances of conception.

As well as identifying a clear way forward and defining the funding required to get the service on an even footing, new criteria were brought in to optimise the chances of a live birth whilst improving the safety of both the mother and unborn child. The Scottish Government asked me to reconvene our expert group in 2015 to report on progress and consider the feasibility of introducing measures that we postponed introducing earlier due to competing demands.

I am delighted to say that much has been achieved by NHSScotland in a comparatively short period of time. Waiting times have reduced significantly and treatment is now equitable across Scotland with all couples having the opportunity of 2 cycles if they meet NHS criteria. It remains too early to say just how much of an impact the revised clinical criteria have had on live births but early indications are extremely promising.

What is already very clear however is that the cost of the service to the public purse has increased markedly, not only through the introduction of better equipment and facilities but through far fewer patients self-funding as access has improved. This means that as things stand today only 60% of the service is funded by NHS Boards, the rest is subsidised by Scottish Government funding, originally intended to recover the situation but now being used to maintain an improved status quo. In these times of austerity it is clearly critical that a strategic decision is made on the future funding level of the service, to ensure sustainability prior to any other improvements being introduced.

In our original report we recommended 2 major enhancements when affordable. Firstly removing the unfairness of denying treatment to those couples where one partner already had a child in the home but the other had never had the opportunity to have children. Secondly, in those cases where, in the view of the clinician, a third cycle would be beneficial we were keen to optimise the chances of success. We have laid out in the report a suggested timetable for their introduction which would smooth the impact over a 2 year period. As the likely impact of each measure will be to increase volume by at least 10-15% it is important that the funding issues around the current service are addressed first. We have also suggested a 1 year wait and to discontinue treatment for those over 40 to ensure sufficient capacity, support future service sustainability and reduce waste.

Significant progress has been made around capturing, analysing and interpreting data from the 4 Centres that provide NHS IVF across Scotland. Many of the tables contained in this report are new and represent cutting edge information in this area of medicine. It has taken significant effort from the staff in the 4 Tertiary Centres and those from NHS National Services Scotland to achieve this.

Finally, it has been a pleasure to lead this group. The knowledge of its members is only matched by the depth of their commitment to patients and to continuously improving the services most of them have dedicated their lives to. We live in challenging times and Ministers will have hard decisions to make. I truly hope that the objectivity and evidence contained in this report makes that task easier.

Ian Crichton
Chair, National Infertility Group

Chief Executive NHS National Services
 Scotland 2007 – February 2016

2. INTRODUCTION

The National Infertility Group, chaired by Ian Crichton, Chief Executive of NHS National Services Scotland¹, was set up by Scottish Government Ministers in April 2010 to:

“...bring together service representatives, key national bodies and stakeholder representatives to actively provide expert knowledge and advice to the development of existing and evolving Scottish Government policy on infertility and its implementation within NHS Boards.”

The Group reformed at the end of 2014, as recommended in the 2013 report to consider taking forward a review of specific access criteria. The Group met four times during 2015, and twice during February 2016.

The Group was primarily tasked to review:

- The maximum number of *In vitro* Fertilisation (IVF) cycles offered to eligible NHS patients.
- Current criteria around eligibility for couples who have a child living with them, not biologically related to one partner, under the age of 16

Membership and updated role of the Group during 2015/16 is shown at Annex A.

3. BACKGROUND

The reformed National Infertility Group continued to concentrate on assisted conception techniques involving IVF and when required Intra-Cytoplasmic Sperm Injection (ICSI). Each of the 14 territorial NHS Boards in Scotland commissions cycles of IVF/ICSI from one of the four specialist tertiary referral Centres providing NHS treatment (Aberdeen, Dundee, Edinburgh and Glasgow).

The report refers to other levels of care where appropriate and descriptors of all levels of care are set out below. Patients should follow the pathway of care to ensure referral for IVF/ICSI is appropriate and the patient has had the opportunity to meet the necessary lifestyle criteria.

3.1 Levels of care:

- **Level I:** initial investigation and management provided by the primary care team. This should be couple-based, cover basic history-taking and clinical examination and include laboratory investigations to evaluate the woman's general health status, to confirm ovulation and to assess the quality of the semen of the man. Appropriate diet and lifestyle advice should be given and timely referral to Level II should be arranged.
- **Level II:** further investigation and management provided by a special interest team in a general hospital gynaecology department. The main investigation undertaken in Level II is tubal patency testing and Level II treatments include ovulation induction and occasionally intra-uterine insemination (IUI), with timely referral to Level III.
- **Level III:** specialist care provided in one of Scotland's four tertiary referral Centres (Aberdeen, Dundee, Edinburgh and Glasgow). These Centres also provide Level II care for those couples living within their own catchment areas. Care involves the provision of assisted conception techniques requiring a licence

from the Human Fertilisation and Embryology Authority (HFEA)², including IVF and ICSI.

The activity and success rates of each of the Centres in Scotland, 4 that provide NHS IVF, and 2 completely private clinics are reported to the HFEA³.

IUI became an HFEA licensed treatment in 2007. IUI is undertaken in conjunction with ovulation induction or if IUI is required as well as donor sperm within the Centres. It is also used if there are not enough developing eggs for IVF.

3.2 Arrangement of IVF services in Scotland

Each of the 14 territorial NHS Boards in Scotland commissions cycles of IVF/ICSI from one of the four specialist tertiary referral Centres providing NHS treatment (Aberdeen, Dundee, Edinburgh and Glasgow).

The activity and success rates of each of the Centres in Scotland are reported to the HFEA⁴.

In its 2013 report⁵, the National Infertility Group set updated criteria, which received Ministerial approval, setting out the national criteria which couples must meet to be eligible for referral for NHS treatment.

Each NHS Board has an annual contract with a provider Centre defining the number of cycles of treatment which can be provided to patients in each region. If the demand for treatment is greater than the capacity then waiting times increase. Top up funding from the Scottish Government over the past 4 financial years, from 2012-13 up to 2015 has had a dramatic effect on waiting times across Scotland, with all patients screened for treatment during the quarters ending June, September and December 2015, within 12 months.

Previously, long waiting times were one of the significant reasons why couples chose to fund their own treatment either in an NHS provided service or in the private sector. Now that waiting times are at a maximum of 12 months across Scotland, the main reason couples choose private or self-funded

treatment, is as a result of not meeting the NHS criteria either through having a child in the home (not necessarily the couples' biological child), age or treatment was unsuccessful after two cycles where the prognosis is still good.

3.3 Review of the evidence

As before, both individually and collectively, the Group and its members, sought out relevant and recent research, appraised its relevance and used the results to inform the recommendations. Where it was appropriate and readily available, the Group used Scottish and UK information sources. These include:

- National Institute for Health and Clinical Excellence (NICE) Fertility Guideline⁶
- *Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women.* David J. McLernon, Abha Maheshwari, Amanda J. Lee, and Siladitya Bhattacharya Hum. Reprod. Advance Access published January 18, 2016 Human Reproduction, Vol.0, No.0 pp. 1–10, 2016⁷
- *Live-Birth Rate Associated With Repeat In Vitro Fertilization Treatment Cycles* Andrew D. A. C. Smith, PhD; Kate Tilling, PhD; Scott M. Nelson, PhD; Debbie A. Lawlor, PhD JAMA. 2015;314(24):2654-2662. doi:10.1001/jama.2015.17296⁸

3.4 Reduce inequity and waiting times to 12 months

The original principal issue for the Group was to manage the significant inequity in access to IVF that was prevalent across Scotland as Health Boards made different decisions about the criteria for access to treatment and about the level of investment in treatment. The Group was also acutely aware of the need to solve this issue in the context of increased demand on the NHS in general and the prevailing financial climate.

The Scottish Government acknowledged the inequity that surrounded waiting times for IVF in Scotland, and made the following

manifesto commitment in April 2011: “We will continue to address the variation in waiting times for IVF treatment and during the next Parliament we will work to establish a maximum waiting time of 12 months.”

The Scottish Government announced in September 2012 that an additional £12 million would be made available over 3 financial years to reduce waiting times for IVF treatment across Scotland to 12 months by 31 March 2015.

This funding had already started to reduce the backlog and supported the Scottish Government’s commitment to deliver a maximum waiting time of 12 months for IVF treatment across Scotland by March 2015. Two million pounds was invested in 2012/13, £4 million in 2013/14, and £6 million in 2014/15.

A further £6 million was made available to support IVF waiting times during 2015/16, along with the start of the Gametes project, and other fertility related pieces of work, including a number of projects developed and run by the patient stakeholder group Infertility Network Scotland⁴³, during 2015/16.

3.5 Ensure that the long-term cost of provision is affordable

The National Infertility Group has been cognisant of the tight financial envelope within which NHS Boards must operate and the conflicting demands across many services for resources. NHS Boards have a responsibility to operate within their allocated budgets, and as such to prioritise services to meet the needs of their populations. Given the increasingly challenging financial climate, this continues to put pressure on services such as IVF. However, IVF is a *bona fide* NHS treatment, and the patient stakeholder group and staff in clinics across Scotland, along with the National Infertility Group, have worked hard to normalise fertility treatments, particularly IVF and ICSI. There is a very real capacity for patients to benefit with these treatments.

3.6 Align our recommendations with NHSScotland Quality Strategy⁹

The NHSScotland Quality Strategy aims to deliver the highest quality healthcare to the people of Scotland and ensure that the NHS, Local Authorities and the Third Sector work together, with patients, carers and the public, towards a shared goal of world-leading healthcare.

Three high level Quality Ambitions were developed to reflect the six internationally recognised dimensions of healthcare quality. All healthcare policy development is aligned to drive the delivery of three Quality Ambitions; safe, person-centred and effective, and infertility services are no different. In its considerations, the Group has had to strike a careful balance between the needs of potential parents against the obstetric risks which may be posed as well as the overall effectiveness of treatment and the potential long-term health outcomes for any child born as a result of IVF.

The 20:20 Vision provides the strategic narrative and context for taking forward the implementation of the Healthcare Quality Strategy for NHSScotland⁹, and the required actions to improve efficiency and achieve financial sustainability. The National Infertility Group suggests keeping the initial Vision for all levels of infertility treatment:

“The NHS will provide equitable, timely investigation, intervention and/or support for couples with infertility needs.”

The Group feels that the following further vision for IVF/ICSI treatment remains relevant:

“By 2020, the NHS will meet the needs of all eligible infertile couples within 12 months of being diagnosed as requiring IVF or ICSI treatment.”

3.7 Realistic Medicine

Dr Catherine Calderwood, who was, until February 2015, a member of the National Infertility Group, has recently published her first Annual Report (2014-15)¹⁰, after 9 months, as Chief Medical Officer for Scotland (CMO). The title of the CMOs report is 'Realistic Medicine', and there is much to reflect on in the report.

The CMO has asked clinicians to engage on the following questions:

- How can we further reduce the burden and harm that patients experience from over-investigation and overtreatment?
- How can we reduce unwarranted variation in clinical practice to achieve optimal outcomes for patients?
- How can we ensure value for public money and prevent waste?
- How can people (as patients) and professionals combine their expertise to share clinical decisions that focus on outcomes that matter to individuals?
- How can we work to improve further the patient doctor relationship?
- How can we better identify and manage clinical risk?
- How can all doctors release their creativity and become innovators improving outcomes for people they provide care for?

The Group has incorporated these core values in their discussions since 2010 in developing a streamlined, efficient and effective standard of service available to all infertile couples throughout Scotland.

The Chief Medical Officer asks clinicians working in the NHS to:

- Reduce harm and waste
- Reduce unnecessary variation in practice and outcomes
- Manage risk better
- Become improvers and innovators

One of the key issues the Group has had at the centre of their deliberations is to reduce variation in practices to drive equity of service to all who need it, and to ensure that treatment is only given where it is considered to be clinically effective and safe.

3.8 Definition of infertility

Infertility is recognised across much of Europe as a disease state which, after appropriate investigation, can be treated by appropriate assisted reproductive technology. The World Health Organization (WHO) defines infertility as: "Infertility (clinical definition)¹¹: a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse." The WHO defines health as "... a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity." Infertility, accordingly, is a source of diminished health and social well-being.

3.9 National Institute for Health and Clinical Excellence (NICE)¹²

NICE Clinical Guideline 156⁶: Fertility problems, assessment and treatment, advises that people who experience fertility problems should be treated by a specialist team because this is likely to improve the effectiveness and efficiency of treatment and is known to improve people's satisfaction with treatment. NICE further

advises that over 80% of couples in the general population will conceive in the first year of having regular unprotected sexual intercourse, and over 90% will conceive after 2 years of trying, if the women is aged under 40 years.

TABLE 1.

AGE OF MOTHER	% PREGNANT AFTER 1 YEAR (12 CYCLES)	% PREGNANT AFTER 2 YEARS (24 CYCLES)
19-26	92	98
27-29	87	95
30-34	86	94
35-39	82	90

Data source: NICE Clinical Guideline 156⁶

4. PROGRESS AND IMPROVEMENT

4.1 Aberdeen

Since 2013 the Aberdeen Fertility Centre has invested in training specialist staff to ensure patients receive evidence based treatments and procedures are undertaken by skilled competent staff who can provide appropriate information throughout the patient journey. Due to the specialist nature of this service this takes time to recruit and train to ensure the Centre operates in a safe manner for the number of patients attending the Centre. The sudden increase in patient numbers was challenging however the Centre is now in the position to cope with the numbers being referred. The Centre has also added to the quality of their service by achieving ISO 15189:2012 accreditation for Clinical laboratory testing and *in vitro* diagnostic test systems within the andrology service. The Centre delivers a service which meets ISO 9001:2008 Quality Management Systems. Quality of service is very important to the Aberdeen Fertility Centre.

4.2 Dundee

By employing additional specialist staff the Centre in Dundee has been able to increase the number of treatment cycles, with a subsequent reduction in waiting times for patients from Tayside, Fife and Forth Valley to 6 to 9 months. The Centre was previously criticised for returning patients to the end of the waiting list following unsuccessful treatment; patients requiring a second cycle of treatment are now offered this within 3-4 months, although some patients choose to wait longer. The majority of embryo transfers are carried out at the blastocyst (day 5) stage although day 3 transfers are performed where appropriate. Embryo transfers are now carried out seven days per week to optimise the chance of success for patients. The Centre would have the capacity to deliver more activity provided staffing levels increased. The Centre has ISO 9001:2008 accreditation and is working towards ISO 15189:2012 for the andrology service.

4.3 Edinburgh

From the introduction of the amended criteria for NHS funded IVF treatment in 2013, residents of Lothian and Borders have been treated in line with the criteria. To meet the IVF waiting time of 12 months, Lothian has employed additional administrative and clinical staff. The waiting time for patients in Lothian is now being maintained at 9 – 10 months.

Funding provided by the Scottish Government enabled the Centre to purchase state of the art equipment, which has significantly improved results for patients by increasing the proportion of elective single embryo transfers whilst improving pregnancy rates and decreasing twin rates. Lothian has increased the level of Health Board funded activity to support the Centre in Greater Glasgow and Clyde to successfully achieve the IVF waiting time, by treating patients in Edinburgh who would ordinarily be treated in Glasgow. Quality has always been important to the Centre which has maintained their ISO 9001:2008 and CPA Ltd accreditation whilst also working towards ISO 15189 accreditation.

4.4 Glasgow

The NHS Assisted Conception Service at Glasgow Royal Infirmary (GRI) required major refurbishment during 2012-2014. Whilst out patient services remained on site at GRI, clinical treatments (IVF/ICSI) were transferred to the Glasgow Nuffield Hospitals in line with local contingency plans. At this time there was limited opportunity to increase activity whilst IVF/ICSI was delivered off site. However, during this period, NHS Greater Glasgow and Clyde worked closely with other Boards to access capacity in Tayside and Lothian to successfully reduce waiting times.

The Board spent in excess of £3 million of Capital funding upgrading the clinical environment, including a bespoke embryology/andrology laboratory and purchase of the latest innovative-assisted conception equipment, resulting in a state of the art facility.

Investment in increased staffing and staff training has increased patient throughput and improved waiting times further, with patients from all Boards now waiting less than 9 months. Current IVF success rates at Glasgow Royal Infirmary exceed the national average reported by the HFEA. The Centre has been future proofed in terms of space and equipment and could deliver more activity with increased staffing levels if this was required at a later stage.

4.5 Embryoscopes

Scottish Government funding was used to provide Embryoscopes for all four Assisted Conception Centres. An Embryoscope is a type of specialised incubator with a built in time-lapse video system.

It provides a safe, undisturbed and controlled environment for embryos and allows the scientific staff the opportunity to review embryos at any time and to have a record of their development from the moment the egg fertilises to the moment the embryo is transferred. They can observe the embryo within the incubator using 'real-time' footage, without disturbing them. A large screen provides a continuous overview of all embryos within the incubator. In addition, continuous 4D images are stored automatically with the patient file for review at any time during the embryo's development. More staff are required to provide 7 day cover to ensure optimum time of embryo transfer.

Most importantly, there is evidence to suggest that using an Embryoscope may increase the success of Assisted Conception treatment.

4.6 Scottish Parliament Health and Sport Committee

The Scottish Parliament Health and Sport Committee has taken an interest in the work of the Group, and the Group is confident that all issues raised by the Committee have been discussed and addressed by the Group.

4.7 The role of support organisations

The public needs to be better informed about fertility issues in general and, in particular, what factors might affect fertility, how best to preserve it and what services are available for infertility treatment, support and information.

The Scottish Government is funding Infertility Network Scotland¹³, an organisation which provides help, information and support to patients (both present and past), to assist with this. The National Infertility Group believes that NHS infertility services should be much more person-centred and recognises the varying and sometimes distressing effects patients and their families face in both accessing care and in coming to terms with the consequences of treatment failure.

Infertility Network Scotland's core role is to support patients undergoing treatment, and to work with NHS Boards, Clinics and Health Professionals to ensure a better patient experience. Infertility Network Scotland¹³ liaises regularly with all Health Boards and offer a service to provide patient representation at any Health Board meetings to discuss fertility services. Health Boards should consult with organisations which represent patient views at meetings where provision of secondary and tertiary infertility services are being discussed which may in any way affect patients.

Patients should be made aware of Infertility Network Scotland¹³ and the services that they can provide throughout all levels of the service, from GP to secondary care Centre and through the four IVF/ICSI Centre. Infertility Network Scotland¹³ has vast experience of providing support to all patients and reports that emotional distress caused by infertility is heightened dramatically when patients find themselves unable to access the treatment they need.

Part of Infertility Network Scotland's¹³ service provides targeted help and support on a wide range of issues, to those people who have had successful fertility treatment and to those who found their families through other parenting options, including

adoption. Around one-third of those suffering from infertility will never become parents and the network offers ongoing support to those couples whose treatments have been unsuccessful and are exploring what a life without children will mean for them and the best way of coping with that.

4.8 Education project

Since 2012 Infertility Network Scotland (IN Scotland)¹³ has been funded by the Scottish Government to undertake a Fertility Education project. The aim of the project is to tackle the problem of a lack of awareness of issues surrounding fertility and infertility in Scotland. It was agreed that this would be achieved in a variety of ways, i.e. by working with universities, health professionals; GPs and employers across Scotland to introduce ways of ensuring people are better informed about how their fertility can be conserved. To reduce the instances of infertility through improved outcomes in terms of health and lifestyle both of which can be factors in preserving fertility.

Further adding to the education and information available to fertility sufferers, the project allows the charity to hold regional information events throughout Scotland for people with fertility issues. The overall aim of these events is to provide accurate and up to date information for patients; raise awareness of infertility and the support available and to be educational for patients. Each year dates are arranged to visit universities/colleges/other third sector organisations in Scotland to address the students/young people and give a presentation with interactive tools on facts related to fertility education and preserving fertility. Through this approach we believe we can improve health outcomes for our students/young people.

Another area where better health outcomes may be achieved through education of fertility issues is at GP level and within family planning clinics. Through this project we work to access GPs to encourage them to include a conversation about fertility as part of their general gynaecological checks such as smear tests or when women attend for contraceptive advice and to explain both the

effect of lifestyle factors on their fertility and the decline of female fertility with age. We similarly work with family planning clinics where we encourage them to include these same discussions as part of their system.

Over the course of 2014/15 the need for education surrounding future fertility has been highlighted by Clinical Professionals in the media. Scotland is the only area in the UK to have such a project and is proving through interaction with students/young people and the gathering of statistical data to be needed.

It is widely recognised that there needs to be a change in people's attitude towards the whole area of fertility, career and family. Young people in higher education are the employers and health professionals of the future and through the multi-targeted approach of this project, we believe that we can create a more knowledgeable fertility population and reduce infertility in future years.

4.9 Factors affecting fertility, maternal and infant health

Although the incidence of infertility does not appear to have changed much over the past decade or so, the demand for treatment has grown due to other factors, particularly the age at which couples start trying for a family. Infertility is caused by both male and female factors. The most significant is female age, as after the age of 35 fertility declines steeply. In order to reduce the likelihood of fertility problems, and to have a better chance of successful treatment, women should aim, if possible, to have their first child before age 35.

Several recent reports show that couples are starting their families later and possibly view IVF as a viable treatment option in their late 30s and early 40s. These studies show that public perception of IVF is that it is far more successful than it actually is, particularly in older women. Recent Scottish data shows that success rates are good for women up to and including age 37, with a significant drop off at age 38, and very low success rates from age 40.

Male age has been discussed recently as a factor in couples with fertility problems. The National Infertility Group did not have time to debate this topic properly, consider the evidence and form a view. Therefore, the Group recommends that a future Group discusses and agrees a national age limit for males.

Age-specific Birth rates, per 1,000 female population, Scotland, 1973 to 2014 from National Records Scotland can be viewed at: <http://www.scotlandscensus.gov.uk/NRSinteractivedata/fertility/fertility.html>

The most up to date figures in the link above reinforce the growing trend towards women having children later in life, with the average age of the mother at childbirth in 2014 being 30.

4.10 Reducing risks to mothers and babies

Other factors which influence male or female fertility include a healthy Body Mass Index, minimal alcohol intake, not smoking and avoidance of sexually transmitted infections. These can also significantly influence fertility treatment success. Health promotion messages have increasingly highlighted the impact of these effects, and Infertility Network Scotland¹³ are carrying out work on pre-conception care and fertility risk respectively, which will help highlight these issues. More detail on the work of the charity is set out later in the report.

There is evidence that obesity impacts negatively on almost all aspects of IVF treatment, e.g. a poorer ovarian response, oocyte retrieval is more challenging and fewer oocytes are retrieved. These and other factors combine to make pregnancy rates significantly lower in women with a BMI of >30. Available data suggest that as little as 5-10% weight loss can improve fertility outcomes.

It is vital that primary care services ensure that all women of childbearing age have the opportunity to optimise their weight before pregnancy. Advice on weight and lifestyle factors such as smoking, drinking alcohol and information on their declining fertility should be given during family planning consultations.

Couples presenting with concerns about their fertility should be given advice and support on weight, Body Mass Index and the importance of stopping smoking and drinking if planning a family, prior to being referred for investigation and treatment in secondary care.

MBRRACE-UK¹⁴: Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK, published in 2015 “Saving Lives, Improving Mothers’ Care – Surveillance of maternal deaths in the UK 2011-13 and lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-13”.

The report states that the maternal mortality rate in the UK continues to fall largely as a result of a reduction in deaths from ‘direct’ pregnancy causes. However, the rate of deaths from ‘indirect’ causes has not reduced significantly; these are deaths from conditions not directly due to pregnancy but existing conditions which are exacerbated by pregnancy, for example, women with heart problems.

Clinicians should take care that women who receive medical treatment are medically safe to become pregnant, including taking into account co-morbidities before committing to treatment. Fertility medication should only be prescribed in Clinics where there is access to appropriate monitoring facilities including pelvic ultrasound and biochemical laboratories.

4.11 Pre-implantation genetic diagnosis

The Scottish Pre-implantation Genetic Diagnosis (PGD) service¹⁵ is centrally funded by National Services Division (NSD)¹⁶ and was designated as a national service in 2005. The PGD service carries out genetic testing for fetal chromosome abnormalities at two Centres in Scotland – Glasgow Royal Infirmary, and the Royal Infirmary of Edinburgh. Approximately 30 NHS funded PGD treatment cycles are carried out in both Edinburgh and Glasgow annually.

A short-life working group was convened in 2010 to define more clearly the access criteria for PGD. Members will ensure that NSD is made aware of any decisions on access criteria made by the National Infertility Group.

4.12 Smoking

Smokers may need twice the number of cycles as non-smokers to conceive and the effect is comparable to an increase in female age of 10 years. Female smoking has also been found to double the risk of pregnancy loss in assisted conception pregnancies. Pregnancy complications and outcomes include higher miscarriage rates, placental complications, fetal growth restriction, preterm birth, stillbirth and early neonatal death. Risks can be reversed by smoking cessation.

ASH Scotland¹⁷ – Action on Smoking and Health (Scotland) – is the independent Scottish charity taking action to reduce the harm caused by tobacco. ASH Scotland’s vision is of a healthier Scotland, free from the harm and inequality caused by tobacco. ASH believe that every baby should be born free from the harmful effects of tobacco.

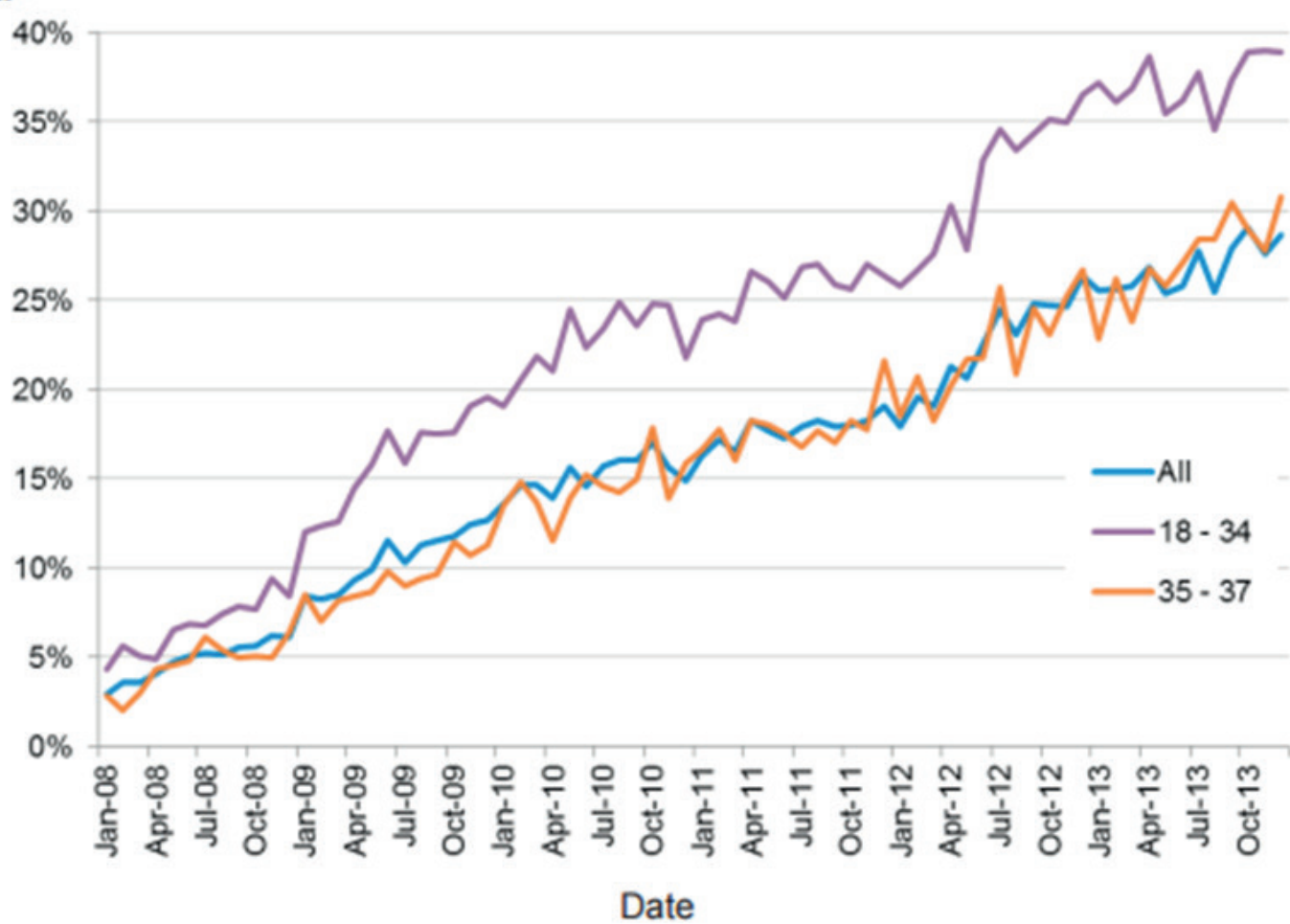
Secondary Centres and the four tertiary Centres are supporting the aims of ASH Scotland – through monitoring and encouraging couples to stop smoking before trying to become pregnant.

4.13 The important implications of single embryo transfer and the increase in frozen embryo transfers

The aim for all couples that require IVF/ICSI treatment is to have a healthy child. However, there is a higher incidence of multiple pregnancies even for those that have only one embryo transferred.

Elective single embryo transfer (eSET) undoubtedly reduces the incidence of twin pregnancy, and Scottish clinics are doing very well with their eSET policies which has given an overall reduction in multiple births which is better than in the rest of the UK.

FIGURE 1.
Percentage of eSETS (2008-2013)



There were concerns in the past that eSET would reduce pregnancy rates, however that does not seem to be the case in Scotland. There is recent robust evidence (BMJ 2010; 341:c6945)¹⁸ that the pregnancy rate over two cycles (fresh plus frozen embryo transfer) using single embryo transfer is as good as with a single cycle where two embryos are transferred with minimal risk of twin pregnancy.

The four Centres providing NHS IVF have worked extremely hard to reduce long waiting times over the past few years. Safety and improvement have been key features of practice, in Centres in recent years. In particular the increased and increasing use of single embryo transfer, along with ensuring that only patients who would benefit from further treatment are offered additional cycles, has become the norm. This should be strengthened going forward, with

clinicians taking notice of the Chief Medical Officer’s 2015/16 report about wasteful and harmful medicine, and be clear that treatment is not given to patients who have a poor chance of success, or for whom it would not be safe to treat.

The four tertiary Centres in Scotland are supportive of the need to address the public health concerns of multiple pregnancies, and believe that a common approach will help reduce the number of multiple pregnancies in Scotland.

Infertility Network Scotland¹³ developed a patient factsheet¹⁹ on Single Embryo Transfer which is supplied to all four NHS IVF Centres in Scotland and given out to patients in the majority of Centres, along with individual Centres’ own leaflets and information, for example the Centre’s pregnancy rates resulting from single embryo transfer.

4.14 Improving the pathway of care

An Infertility Referral Pathway and explanatory notes have been updated showing the expected pathway from primary to secondary care, with a further pathway outlining secondary to tertiary care. The aim of both Pathway documents is to guide timely, appropriate investigations and referral whilst providing consistent advice, from primary care through to tertiary care, which can improve fertility, enable couples to access treatment (where appropriate), optimise the success rates of treatment and reduce pregnancy risk.

As in 2013, further discussions should take place within NHS Boards to ensure that GPs and secondary care services are made aware of forthcoming changes to access criteria.

These reflect updated access criteria as agreed by the Group, and will be available online once any changes to access criteria have been implemented. The initial pathway was amended to reflect comments from BMA Scotland²⁰, and a number of GP representatives. Whilst the Group is happy for the mode of referral to be left to individual NHS Boards as not all areas use the same referral systems, the Pathway must be followed in the timeframe indicated.

NHS Boards, and in particular, the four NHS Centres providing treatment, should work with the patient stakeholder group, Infertility Network Scotland¹³, to ensure that patients are kept informed of changes to treatment pathways.

4.15 Counselling

All Centres in Scotland have their own independent counsellor linked to the tertiary Centre, which is more than the HFEA²¹ legally require of each Centre.

The Group is satisfied with counselling services that are provided in licensed clinics providing NHS treatment in Scotland on a regular 9-5 basis. Infertility Network Scotland¹³ raised concerns about the availability of crisis counselling. The Group agreed that patients should be signposted to out of hours crisis counselling already available, including NHS 24²² which provides advice for patients who feel anxious or depressed.

Additionally, consideration should be given to developing specific information to give to NHS 24²² to help staff provide assistance to patients undergoing assisted conception treatment, who require help out of hours.

4.16 Communication with patients

Where appropriate, Secondary and Tertiary Centres should ensure the use of positive terminology in all correspondence with patients undergoing treatment in Assisted Conception Centres. Infertility Network Scotland¹³ could assist with this, for example Centres could share all new template letters and information to be shared with patients.

5. DATA

Most effective number of cycles

The main results from the paper published in Human Reproduction in January 2016⁷ notes that: “After the third complete IVF cycle (defined as three fresh IVF treatments – including replacement of any surplus frozen-thawed embryos), the conservative cumulative live birth rate (CLBR) in women who commenced IVF during 1992-98 was 30.8% increasing to 42.3% during 1999-2007.” The optimal CLBR were 44.6% and 57.1% respectively. After eight complete cycles the optimal CLBR was 82.4%. This data also reflects improvements in technology and a more conservative embryo transfer policy.(Cumulative live birth rates after one or more cycles of IVF:a population based study of linked cycle data from 178,898 women: Human Reproduction Jan 16) (Recently published paper)⁷.

live birth rate after six cycles was 65.3% with variations by age and treatment type. Within the paper the live birth rates within initiated treatment cycle and cumulative live birth rates across all cycles show that after three cycles the conservative live birth rate is 44.6% and optimal estimate is 59%. (Live birth rate associated with repeat IVF treatment cycles: JAMA 2015.)⁸

These papers were published in reputable medical journals that select high impact research papers for publication both show that cumulatively three cycles could result in an increase from 45% after two cycles to 57% after three cycles.

The findings in the paper published in JAMA⁸ state that the cumulative prognosis-adjusted

FIGURE 2.

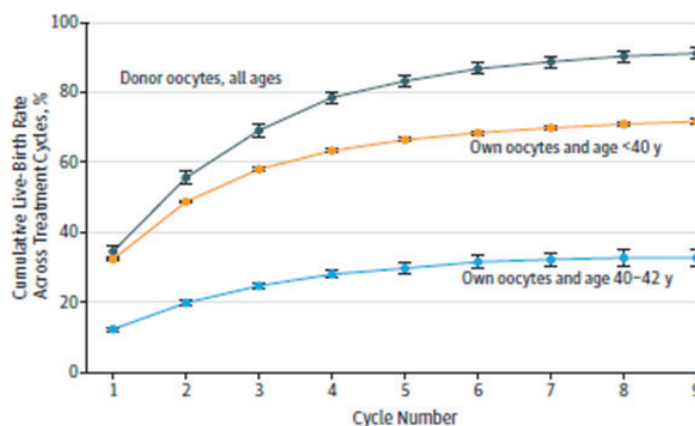
Live birth rates per complete cycle and cumulate live birth rates per woman by period

Period	Complete cycle	No. women	No. women with at least one live birth	Conditional live birth rate	Conservative cumulative live birth rate	Optimal cumulative live birth rate
1992–1998	1	71 551	13 697	19.1 (18.85, 19.43)	19.1 (18.85, 19.43)	19.1 (18.86, 19.43)
	2	33 155	5960	18.0 (17.56, 18.39)	27.5 (27.15, 27.80)	33.7 (33.27, 34.09)
	3	14 288	2356	16.5 (15.88, 17.10)	30.8 (30.43, 31.10)	44.6 (44.09, 45.145)
	4	5649	905	16.0 (15.06, 16.98)	32.0 (31.69, 32.37)	53.5 (52.80, 54.18)
	5	2135	333	15.6 (14.06, 17.14)	32.5 (32.15, 32.84)	60.7 (59.82, 61.67)
	6	878	117	13.3 (11.08, 15.57)	32.7 (32.32, 33.00)	66.0 (64.78, 67.16)
	7	372	51	13.7 (10.21, 17.20)	32.7 (32.39, 33.07)	70.6 (69.06, 72.20)
	8	147	14	9.5 (4.78, 14.27)	32.8 (32.41, 33.09)	73.4 (71.43, 75.41)
1999–2007	1	107 347	30 546	28.5 (28.19, 28.73)	28.5 (28.19, 28.73)	28.5 (28.19, 28.73)
	2	46 439	11 116	23.9 (23.55, 24.32)	38.8 (38.52, 39.10)	45.6 (45.24, 45.93)
	3	17 913	3791	21.2 (20.57, 21.76)	42.3 (42.05, 42.64)	57.1 (56.67, 57.52)
	4	6253	1189	19.0 (18.04, 19.99)	43.5 (43.15, 43.75)	65.3 (64.71, 65.80)
	5	2175	365	16.8 (15.21, 18.35)	43.8 (43.49, 44.09)	71.1 (70.38, 71.79)
	6	793	121	15.3 (12.76, 17.76)	43.9 (43.61, 44.20)	75.5 (74.55, 76.43)
	7	292	44	15.1 (10.97, 19.17)	43.9 (43.65, 44.24)	79.2 (77.89, 80.46)
	8	110	17	15.5 (8.70, 22.21)	44.0 (43.66, 44.26)	82.4 (80.59, 84.14)

Cumulative live birth rates after one or more complete cycles of IVF: a population-based study of linked cycle data from 178 898 women: David J. McLernon, Abha Maheshwari, Amanda J. Lee, and Siladitya Bhattacharya, 2016. Published by Oxford University Press on behalf of the European Society of Human Reproduction and Embryology⁷.

FIGURE 3.

Cumulative live-birth rate across all initiated IVF cycles by age and oocyte source



No. of women	1	2	3	4	5	6	7	8	9
Donor oocytes, all ages	3587	1636	939	554	287	126	53	27	8
Own oocytes and age <40 y	133379	53568	19719	6641	2357	882	335	131	51
Own oocytes and age 40-42 y	15561	6671	2579	884	301	130	60	36	20
Own oocytes and age >42 y	4420	1578	509	160	67	24	10	5	4

The prognosis-adjusted estimate of cumulative live-birth rate (ie, the rate shown on the y-axis is the likelihood of a live birth across all initiated cycles up to and including the numbers on the x-axis), with 95% confidence intervals (error bars). These are presented for women in 2 different age categories at the start of their first in vitro fertilization (IVF) treatment cycle (<40 years and 40-42 years; women in both of these categories used their own oocytes) and also in women who used donor oocytes (these women cover the full age range). Data for women older than 42 years at their first treatment cycle are not shown

because rates were so low it would have been difficult to represent them on this same graph (full results for these women are shown in Table 3). The prognostic-adjusted estimate assumes that 30% of those who discontinued IVF did so because of poor prognosis and that the live-birth rate in that 30% would have been 0 had they continued. Analyses were completed for 156 947 women undergoing 257 398 cycles. Log-rank tests indicated a difference between the cumulative live-birth rates for all groups ($P < .001$ for all comparisons).

Live-Birth Rate Associated With Repeat In Vitro Fertilization Treatment Cycles Andrew D. A. C. Smith, PhD; Kate Tilling, PhD; Scott M. Nelson, PhD; Debbie A. Lawlor, PhD JAMA. 2015;314(24):2654-2662. doi:10.1001/jama.2015.17296⁸.

The use of IVF as fertility treatment should not be regarded as a single cycle opportunity for conception. Effective fertility treatment requires repeated exposure to the opportunity to conceive. This principle applies to the treatment of anovulatory infertility or the use of donor insemination and should therefore apply to IVF. To return a woman to the end of a queue for treatment between cycles only serves to increase her age at the time of exposure. The link between increased female age and reduced chance of success is well recognised. In clinical effectiveness terms it is better for NHS entitlement to be realised in the shortest time frame possible. Couples should therefore be returned to the top of the queue if repeat cycles are required.

5.1 Data collection

Data are required to understand the present situation and to predict the likely future workload, costs and waiting times. The Group

has carried out work on the following topics: ways of obtaining standard data; how waiting times should be defined; the development of an economic model, and the commissioning of a model to simulate the effect on numbers and waiting times of various changes in criteria for treatment.

Although Scotland has good quality national data relating to hospital inpatients and day cases, there are specific issues relating to infertility. The Human Fertilisation and Embryology legislation dictates that the only national organisation which is permitted to receive identifiable data is the Human Fertilisation and Embryology Authority²³ (HFEA). Although the HFEA publishes information describing the performance of the various Centres in Scotland, it has no information on waiting times or costs.

5.2 Local Delivery Plan (LDP) Standards formerly (HEAT Standard) for IVF

The Scottish Government requires NHSScotland to measure the time people wait for treatment; this includes people waiting for IVF. The Scottish Government has set a target for NHSScotland, that eligible patients will commence IVF treatment within 12 months by 31 March 2015. In practice, this will be the percentage of patients who were screened at an IVF Centre within 12 months of a referral from secondary to tertiary care. The Scottish Government has determined that the LDP Standard for IVF waiting times should be delivered for at least 90% of patients, as for some patients it may not be clinically appropriate for treatment to begin within the target’s time.

In terms of reporting information to monitor progress towards this target, the National Infertility Group recommended that the screening appointment should be the point signalling the start of treatment. This was in part due to the fact that data cannot be reported to ISD beyond this point in an IVF journey without breaching the Human Fertilisation and Embryology (HFE) Act²³. However, there was also agreement that it was at this point patients feel that their IVF treatment journey has begun.

The data are collected by the IVF Centre Boards (NHS Lothian, NHS Grampian, NHS Greater Glasgow & Clyde, and NHS Tayside) for all patients who have been referred into their IVF Centre; these four Boards then submit the data to ISD³⁶. The statistics, on first cycles, are presented in two ways: firstly, by the four IVF Centres, and secondly, by the 14 referring/commissioning Boards. The Scottish Government has agreed that the 14 referring Boards are responsible for meeting the target in partnership with the four tertiary Centres.

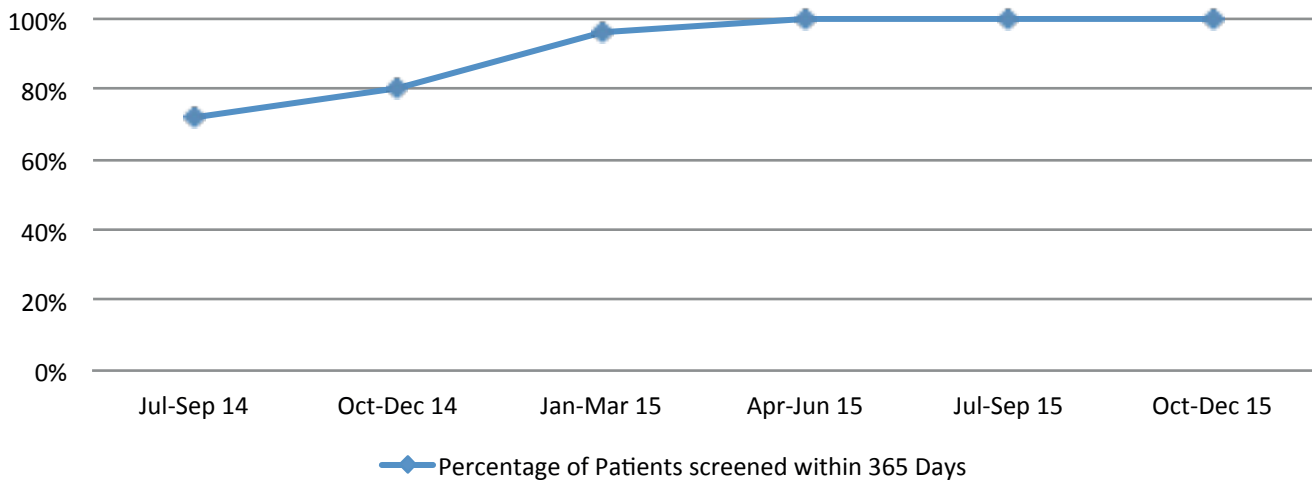
Waiting Times data for IVF are developmental. NHS Boards are working with ISD and the Scottish Government to improve the completeness and consistency of the information. The Scottish Government has set a target that at least 90% of eligible patients will commence IVF treatment within 12 months. This was due for delivery by 31 March 2015.

During the quarter ending December 2015:

- 397 eligible patients were screened at an IVF centre in Scotland. This compares to 332 in the quarter ending September 2015.
- 100% of eligible patients were screened for IVF treatment within 365 days (12 months).’

FIGURE 4.

Percentage of eligible patients who were screened for IVF treatment within 365 days, during the last six quarters, across Scotland



Data source: Information Services Division

5.3 ISD³⁶ Data Collection for the 2015 review

The process of collecting and analysing the data collected by ISD has been very time consuming and challenging. Due to the HFE Act²³, ISD analysts had to go to the IVF Centres to collect and analyse the data and only send back aggregate level tables to ISD. Extracting the data for the different systems, quality assuring the data and ensuring that data was collected consistently across the four Centres required a lot of manual work by both ISD and the IVF Centres' staff.

TABLE 2.

Charges for NHS funded infertility care

CHARGES USED FOR NHS FUNDED CYCLES COMMISSIONED FROM NHS BOARDS			
	2012/13	2013/14	2014/15
ABERDEEN	3,370	3,760	4,375
DUNDEE	3,567	3,665	3,764
EDINBURGH	4,031	4,201	3,967
GLASGOW - IVF	3,936	4,045	4,153
GLASGOW - ICSI	4,245	4,362	4,480

The information in the above table was provided by Centres to ISD.

These charges were used by Centres for service level agreements with commissioning NHS Boards.

They are standard charges covering a complete cycle as per the National Infertility Group definition (i.e. an initial fresh and all subsequent frozen embryo replacements).

Centres were asked to provide information on their charges for a self funded IVF cycle. Centres were asked to provide charges for defined elements of care: initial consultation; an IVF cycle involving one fresh embryo replacement episode; and a subsequent frozen embryo replacement episode. It is recognised that patients undergoing full self-funded care may incur additional charges, e.g. for investigations, additional drugs, embryo storage, US scans, etc. In addition, charges for ICSI cycles would be expected to be higher than those for IVF cycles. The information provided suggests that in 2014/15 the cost would be between £4,700-£5,200.

Self-funded IVF care in Glasgow is provided through the University with the support of the NHS Centre. Income from self-funded cycles goes directly to the University then the University pays a lump sum to the Glasgow Centre as specified in an annual service level agreement. Despite requests for figures, no information on income received from provision of self-funded IVF care has been provided to ISD by the University.

The Group received some information on both income and costs from the 4 Centres providing NHS IVF. Overall, the figures reported by the Centres suggest that the total reported income supporting provision of level III infertility treatment by NHSScotland has increased from £10.5 million in 2012/13 to £13.5 million in 2014/15. In general, income from commissioning Boards has been fairly consistent over time, top up funding from the Scottish Government has increased from £2 million in 2012/13 to £6 million in 2014/15, and income from self-funded treatment has reduced. The level of top up funding from provider Boards varies considerably between the 4 Centres.

TABLE 3.

NHS funded first and subsequent cycles initiated

CENTRE PATIENT TREATED BY	NUMBER OF NHS FUNDED FIRST AND SUBSEQUENT CYCLES INITIATED						
	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	59	50	84	59	68	70	88
DUNDEE	79	81	123	87	100	75	135
EDINBURGH	72	73	73	75	107	95	113
GLASGOW	N/A	N/A	147	174	197	140	209
TOTAL	N/A	N/A	427	395	472	380	545

A cycle is fresh plus any subsequent frozen transfers

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

First fresh and subsequent cycles provided to the same couples that were initiated from July 2013 onwards have been included in the data.

Note that the Glasgow Centre was closed from 9 November 2012 to 15 September 2014 and treatment cycles were provided on behalf of GG&C by Nuffield Glasgow Fertility Services during that time. NHS funded cycles involving a woman's own eggs and partner's sperm to create embryos using IVF and/or ICSI are included.

Information is available from Glasgow from January 2014 patients starting their first cycle at this point would meet national access criteria.

TABLE 4A.

Embryo replacement episodes provided

NUMBER OF NHS FUNDED FIRST AND SUBSEQUENT CYCLES INITIATED THAT RESULTED IN AT LEAST ONE EMBRYO REPLACEMENT EPISODE							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	48	46	75	52	58	60	69
DUNDEE	62	65	88	66	75	53	99
EDINBURGH	69	69	62	68	92	85	99
GLASGOW	N/A	N/A	125	154	163	120	156
TOTAL	N/A	N/A	350	340	388	318	423

% OF CYCLES INITIATED THAT RESULTED IN AT LEAST ONE EMBRYO REPLACEMENT EPISODE							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	81.4	92.0	89.3	88.1	85.3	85.7	78.4
DUNDEE	78.5	80.2	71.5	75.9	75.0	70.7	73.3
EDINBURGH	95.8	94.5	84.9	90.7	86.0	89.5	87.6
GLASGOW	N/A	N/A	85.0	88.5	82.7	85.7	74.6
TOTAL	N/A	N/A	82.0	86.1	82.2	83.7	77.6

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

An embryo replacement episode is defined as the transfer of one or more fresh or frozen embryos into a woman at any one time.

Information is available on cycles provided up to end March 2015. Cycles initiated in the last quarter (January to March 2015) may not have had time to have any embryo replacement episodes before end March 2015, hence results for that quarter are likely to be an underestimate.

Overall, 83% of cycles initiated in Scotland in 2014 resulted in at least one embryo replacement episode.

TABLE 4B.

NUMBER OF EMBRYO REPLACEMENT EPISODES RESULTING FROM NHS FUNDED FIRST AND SUBSEQUENT CYCLES INITIATED IN THE PERIOD SPECIFIED

CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	61	57	95	67	68	66	69
DUNDEE	72	80	114	80	82	52	99
EDINBURGH	106	92	89	90	111	87	101
GLASGOW	N/A	N/A	143	186	180	124	156
TOTAL	N/A	N/A	441	423	441	329	425

MEAN NUMBER OF EMBRYO REPLACEMENT EPISODES PER CYCLE THAT RESULTED IN AT LEAST ONE REPLACEMENT EPISODE

CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	1.27	1.24	1.27	1.29	1.17	1.10	1.00
DUNDEE	1.16	1.23	1.30	1.21	1.09	0.98	1.00
EDINBURGH	1.54	1.33	1.44	1.32	1.21	1.02	1.02
GLASGOW	N/A	N/A	1.14	1.21	1.10	1.03	1.00
TOTAL	N/A	N/A	1.26	1.24	1.14	1.03	1.00

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

Any fresh cycle can result in none, one, or multiple embryo replacement episodes. Cycles initiated in (at least) the last three quarters (July 2014 to March 2015) may not have had time to complete all possible

embryo replacement episodes related to that cycle prior to end March 2015 hence results for those periods are likely to be underestimates.

Cycles initiated in January to June 2014 that resulted in any embryo replacement involved on average 1.25 replacement episodes per cycle.

TABLE 4C.

NUMBER OF EMBRYO REPLACEMENT EPISODES INVOLVING ANY FRESH EMBRYO(S)							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	41	46	72	44	51	59	69
DUNDEE	59	60	80	63	67	49	99
EDINBURGH	67	67	58	64	92	84	99
GLASGOW	N/A	N/A	117	141	151	117	155
TOTAL	N/A	N/A	327	312	361	309	422

MEAN NUMBER OF FRESH EMBRYO REPLACEMENT EPISODES PER CYCLE THAT RESULTED IN AT LEAST ONE REPLACEMENT EPISODE							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	0.9	1.0	1.0	0.8	0.9	1.0	1.0
DUNDEE	1.0	0.9	0.9	1.0	0.9	0.9	1.0
EDINBURGH	1.0	1.0	0.9	0.9	1.0	1.0	1.0
GLASGOW	N/A	N/A	0.9	0.9	0.9	1.0	1.0
TOTAL	N/A	N/A	0.9	0.9	0.9	1.0	1.0

TABLE 4C. (CONTINUED)

NUMBER OF EMBRYO REPLACEMENT EPISODES INVOLVING ONLY FROZEN EMBRYO(S)							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	20	11	23	23	17	7	0
DUNDEE	13	20	34	17	15	3	0
EDINBURGH	39	25	31	26	19	3	2
GLASGOW	N/A	N/A	26	45	29	7	1
TOTAL	N/A	N/A	114	111	80	20	3

MEAN NUMBER OF FROZEN EMBRYO REPLACEMENT EPISODES PER CYCLE THAT RESULTED IN AT LEAST ONE REPLACEMENT EPISODE							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	0.4	0.2	0.3	0.4	0.3	0.1	0.0
DUNDEE	0.2	0.3	0.4	0.3	0.2	0.1	0.0
EDINBURGH	0.6	0.4	0.5	0.4	0.2	0.0	0.0
GLASGOW	N/A	N/A	0.2	0.3	0.2	0.1	0.0
TOTAL	N/A	N/A	0.3	0.3	0.2	0.1	0.0

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

Usually the first embryo replacement episode in any one cycle involves replacement of fresh embryo(s), and surplus embryos created as part of that cycle are frozen and stored. If the first embryo replacement episode does not result in a pregnancy/birth, the frozen embryos can be thawed and replaced in subsequent replacement episode(s) as part of the overall cycle of care.

It is possible for a cycle to result in only replacement of frozen embryos, for example, if a woman is unwell after egg collection, or is at risk of ovarian hyperstimulation, all available embryos may be frozen then replacement episodes undertaken when the woman is well enough.

For cycles initiated in January to June 2014 (i.e. those likely to have had time to complete all possible embryo replacement episodes), almost all cycles resulting in an embryo replacement episode had a replacement episode involving fresh embryo(s). An additional 0.3 frozen embryo replacement episodes per cycle that resulted in any replacements were also provided.

The proportion of cycles involving frozen (but not fresh) embryo replacements clearly declines over the last three quarters examined. This reflects the fact that frozen replacements usually happen after fresh replacements hence more time is required to get a complete picture of all frozen replacements associated with any particular cycle.

TABLE 5A.
Single embryo transfer

NUMBER OF EMBRYO REPLACEMENT EPISODES INVOLVING A SINGLE EMBRYO							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	38	37	70	36	40	39	34
DUNDEE	48	61	89	63	58	33	62
EDINBURGH	86	69	70	67	87	53	75
GLASGOW	N/A	N/A	39	56	79	61	80
TOTAL	N/A	N/A	268	222	264	186	251

% OF EMBRYO REPLACEMENT EPISODES INVOLVING A SINGLE EMBRYO							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	62.3	64.9	73.7	53.7	58.8	59.1	49.3
DUNDEE	66.7	76.3	78.1	78.8	70.7	63.5	62.6
EDINBURGH	81.1	75.0	78.7	74.4	78.4	60.9	74.3
GLASGOW	N/A	N/A	27.3	30.1	43.9	49.2	51.3
TOTAL	N/A	N/A	60.8	52.5	59.9	56.5	59.1

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

Each embryo replacement episode can involve the replacement of one or more embryos. Overall, for the cycles studied, around 60% of embryo replacement episodes involved only one embryo. All embryo replacement episodes involved one or two embryos only: no replacement episodes involved three or more embryos.

TABLE 5B.
Single embryo transfer

NUMBER OF EMBRYO REPLACEMENT EPISODES INVOLVING ELECTIVE SINGLE EMBRYO REPLACEMENT							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	30	33	56	32	33	31	28
DUNDEE	29	26	27	29	30	18	28
EDINBURGH	80	64	61	65	69	44	62
GLASGOW	N/A	N/A	N/A	N/A	N/A	N/A	N/A
TOTAL	139	123	144	126	132	93	118

% OF SINGLE EMBRYO REPLACEMENT EPISODES THAT WERE ELECTIVE							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	78.9	89.2	80.0	88.9	82.5	79.5	82.4
DUNDEE	60.4	42.6	30.3	46.0	51.7	54.5	45.2
EDINBURGH	93.0	92.8	87.1	97.0	79.3	83.0	82.7
GLASGOW	N/A	N/A	N/A	N/A	N/A	N/A	N/A
TOTAL	80.8	73.7	62.9	75.9	71.4	74.4	69.0

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

Replacement of a single embryo can be elective, i.e. through choice (more embryos are available but only one is replaced to minimise the risk of multiple pregnancy) or inevitable (only one embryo is available). Overall, for the cycles studied, around 72% of single embryo replacement episodes performed in the three Centres that were in a position to provide information to ISD (Aberdeen, Dundee and Edinburgh) were elective.

TABLE 6.
Pregnancy rates achieved for cycles initiated following implementation of national access criteria

NUMBER OF NHS FUNDED FIRST AND SUBSEQUENT CYCLES WITH VIABLE PREGNANCY RECORDED AFTER ANY EMBRYO REPLACEMENT EPISODE							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	25	18	32	24	19	18	26
DUNDEE	28	27	44	30	35	21	32
EDINBURGH	36	34	22	35	39	33	29
GLASGOW	N/A	N/A	43	57	60	47	65
TOTAL	N/A	N/A	141	146	153	119	152

% OF ALL CYCLES INITIATED WITH VIABLE PREGNANCY RECORDED							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	42.4	36.0	38.1	40.7	27.9	25.7	29.5
DUNDEE	35.4	33.3	35.8	34.5	35.0	28.0	23.7
EDINBURGH	50.0	46.6	30.1	46.7	36.4	34.7	25.7
GLASGOW	N/A	N/A	29.3	32.8	30.5	33.6	31.1
TOTAL	N/A	N/A	33.0	37.0	32.4	31.3	27.9

% OF CYCLES RESULTING IN AT LEAST ONE EMBRYO REPLACEMENT EPISODE WITH VIABLE PREGNANCY RECORDED							
CENTRE PATIENT TREATED BY	QUARTER CYCLE INITIATED						
	JUL-SEP 2013	OCT-DEC 2013	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
ABERDEEN	52.1	39.1	42.7	46.2	32.8	30.0	37.7
DUNDEE	45.2	41.5	50.0	45.5	46.7	39.6	32.3
EDINBURGH	52.2	49.3	35.5	51.5	42.4	38.8	29.3
GLASGOW	N/A	N/A	34.4	37.0	36.8	39.2	41.7
TOTAL	N/A	N/A	40.3	42.9	39.4	37.4	35.9

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

Viable pregnancy is defined as 'Intrauterine fetal pulsation seen'. Cycles initiated in (at least) the last three quarters (July 2014 to March 2015) may not have had time to complete all possible embryo replacement

episodes, and/or have early outcomes for their embryo replacement episodes recorded prior to end March 2015, hence results for this period are likely to be underestimates.

The viable pregnancy rate following first and subsequent NHS funded cycles initiated across Scotland in January to June 2014 was 35%.

TABLE 7.
Outcome by Cycle type

PREGNANCY AND LIVE BIRTH RATE BY CYCLE TYPE					
NHS FUNDED FIRST CYCLES INITIATED JUL-DEC 2013: OUTCOMES BY CYCLE TYPE					
TOTAL (3 CENTRES)	1 FRESH (ONLY)	1 FRESH + ≥1 FROZEN	≥1 FROZEN ONLY	NO EMBRYO REPLACEMENT EPISODES	TOTAL
NUMBER OF FIRST CYCLES INITIATED	264	71	19	54	408
NUMBER WITH VIABLE PREGNANCY RECORDED	125	30	10	0	165
% OF ALL FIRST CYCLES RESULTING IN VIABLE PREGNANCY	47.3	42.3	52.6	N/A	40.4
NUMBER WITH LIVE BIRTH RECORDED	123	16	7	0	146
% OF ALL FIRST CYCLES RESULTING IN LIVE BIRTH	46.6	22.5	36.8	N/A	35.8

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

For this analysis only first cycles initiated in the period July to December 2013 have been considered. Embryo replacement episodes and associated early outcomes (viable pregnancies) known by end March 2015 have been included. It is possible that a small number of viable pregnancies resulting from cycles initiated in July to December 2013 may not have been known about by that time, hence observed pregnancy rates may be a slight underestimate of final achieved pregnancy rates.

For the pregnancies known about by end March 2015, final outcomes known by end December 2015 have been ascertained and included in the table above. It is possible that there was a small number of ongoing pregnancies (i.e. without final outcome known) at that stage hence the observed live birth rates may be a slight underestimate of final achieved live birth rates.

The viable pregnancy rate following all NHS funded first cycles initiated in Aberdeen, Dundee, and Edinburgh in the period July to December 2013 was 40% (95% CI 36-45%). The live birth rate following these cycles was 36% (95% CI 31-41%).

TABLE 8.
Outcome by Maternal Age

PREGNANCY AND LIVE BIRTH RATE BY MATERNAL AGE NHS FUNDED FIRST CYCLES INITIATED JUL-DEC 2013: OUTCOMES BY MATERNAL AGE				
TOTAL (3 CENTRES)	MATERNAL AGE AT START OF CYCLE			TOTAL
	<35	35-37	38-42	
NUMBER OF FIRST CYCLES INITIATED	254	90	64	408
NUMBER RESULTING IN AT LEAST ONE EMBRYO REPLACEMENT EPISODE	218	78	58	354
NUMBER WITH VIABLE PREGNANCY RECORDED	115	39	11	165
% OF ALL FIRST CYCLES RESULTING IN VIABLE PREGNANCY	45.3	43.3	17.2	40.4
NUMBER WITH LIVE BIRTH RECORDED	104	35	7	146
% OF ALL FIRST CYCLES RESULTING IN LIVE BIRTH	40.9	38.9	10.9	35.8

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

The observed pregnancy and live birth rates (for all maternal age groups) may be a slight underestimate of final achieved outcomes as described in 'Outcomes by cycle type'.

Maternal age at start of cycle is defined as age at the start date of stimulation as recorded on the HFEA Intention to Treat (ITT) form.

Current national access criteria state that cycles must be initiated before a woman's 40th birthday and all embryo replacement episodes must be complete by her 41st birthday (although women aged 40 or 41 may initiate one cycle if they have had no previous infertility treatment). No NHS funded first cycles were provided to women aged >42 years in the period examined.

The viable pregnancy rate following all NHS funded first cycles initiated in Aberdeen, Dundee, and Edinburgh in the period July-December 2013 was 40% (95% CI 36-45%). The live birth rate following these cycles was 36% (95% CI 31-41%).

Due to small numbers, patients aged 40 - 42 have been included in the column 38 -42.

TABLE 9.
Multiple pregnancy rate

TOTAL (4 CENTRES)	QUARTER CYCLE INITIATED				
	JAN-MAR 2014	APR-JUN 2014	JUL-SEP 2014	OCT-DEC 2014	JAN-MAR 2015
NUMBER OF NHS FUNDED FIRST AND SUBSEQUENT CYCLES INITIATED	427	395	472	380	545
NUMBER WITH VIABLE PREGNANCY RECORDED AFTER ANY EMBRYO REPLACEMENT EPISODE	141	146	153	119	152
NUMBER WITH VIABLE MULTIPLE PREGNANCY RECORDED AFTER ANY EMBRYO REPLACEMENT EPISODE	13	22	13	14	12
% OF ALL CYCLES INITIATED WITH VIABLE MULTIPLE PREGNANCY RECORDED	3.0	5.6	2.8	3.7	2.2
% OF ALL CYCLES RESULTING IN A VIABLE PREGNANCY THAT RESULTED IN A VIABLE MULTIPLE PREGNANCY	9.2	15.1	8.5	11.8	7.9

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

Viable pregnancy is defined as beating fetal heart ('Intrauterine fetal pulsation seen') recorded on the early outcome form. Viable multiple pregnancy is defined as >1 fetal hearts recorded on the early outcome form. Cycles initiated in (at least) the last three quarters (July 2014 to March 2015) may not have had time to complete all possible embryo replacement episodes and/or have

early outcomes for their embryo replacement episodes recorded prior to end March 2015 hence results for this period are likely to be underestimates.

Overall, 4% of first and subsequent NHS funded cycles initiated in the period January-June 2014 resulted in a viable multiple pregnancy. Viable multiple pregnancies accounted for 12% of all viable pregnancies resulting from cycles initiated January-June 2014.

TABLE 10.
Estimated demand for third NHS funded cycles

POTENTIAL IMPACT ON DEMAND OF OFFERING THREE RATHER THAN TWO CYCLES ESTIMATED DEMAND FOR THIRD NHS FUNDED CYCLES	
TOTAL (4 CENTRES)	
NUMBER OF NHS FUNDED SECOND CYCLES INITIATED JUL-DEC 2013	249
NUMBER THAT DID NOT RESULT IN A LIVE BIRTH IE POTENTIALLY ELIGIBLE FOR THIRD CYCLE	151
NUMBER WITH WOMAN AGED <39 YEARS AND 6 MONTHS AT DATE OF LAST OUTCOME FORM RELATING TO SECOND CYCLE IE LIKELY TO STILL MEET AGE RELATED ACCESS CRITERION FOR THIRD CYCLE	118
NUMBER WHO HAD ≥3 EGGS COLLECTED DURING THEIR SECOND CYCLE (AS RECORDED ON RELEVANT IVF TREATMENT AND EMBRYO CREATION/USE FORM) IE LIKELY TO BE CLINICALLY SUITABLE FOR A THIRD CYCLE	110

The information above has been obtained directly from Centres' information systems by ISD staff with support from the Centres.

The table above is based on second cycles provided July-December 2013 as broadly speaking outcomes should have been known for this group by end March 2015, hence the number/proportion eligible to progress to a third cycle can be assessed.

Embryo replacement episodes and associated early outcomes (viable pregnancies) known by end March 2015 have been included.

For the pregnancies known about by end March 2015, final outcomes known by end December 2015 have been ascertained and included in the table above. It is possible that a small number of viable pregnancies or final outcomes relating to these cycles were not known within the timescales available hence the number of women with no live birth may be a slight overestimate.

Note that the substantial majority of couples undergoing second cycles during this period will have started their IVF prior to July 2013 and therefore will not have been required to meet national access criteria.

Current national access criteria state that cycles must be initiated before a woman's 40th birthday and all embryo replacement episodes must be complete by her 41st birthday (although women aged 40 or 41 may initiate one cycle if they have had no previous infertility treatment).

It has been assumed that it can take up to 6 months after knowing that the second cycle had failed to instigate a third cycle. Women aged up to 39.5 years at the time their second cycle is known to have failed have therefore been included as those that would have time to instigate a third cycle if that became available.

The Group is considering extending the offer of NHS funded care from two to three cycles 'where there is a good prognosis of pregnancy'. Only women who have had a good response to their second cycle (defined here as at least three eggs collected) are likely to be considered as having good prognosis. Patients who have had a failed fertilisation or who did not develop viable embryos suitable for transfer would not be offered a further treatment cycle.

The increase in demand to sustain this criterion is estimated to be approximately 10%.

Note that couples with two failed cycles who meet age and clinical suitability criteria for a third cycle may not wish to attempt a third cycle and/or may not continue to meet other access criteria.

5.4 Child in the home

Current national access criteria for NHS funded level 3 infertility care state that the couple must have no child living in their home. The Group is considering amending this to a requirement that at least one partner within the couple has no biological child. This would mean that couples where one partner has a biological child from a previous relationship living in the couple's home would become eligible for NHS funded infertility care.

To quantify the likely increase in demand, ISD asked a number of Centres/hospitals providing level II infertility services to estimate the following information:

- 1 The number of couples discharged from NHS Level 2 infertility service July to December 2013 who had been found to be potentially suitable for IVF treatment, i.e. had:
 - Infertility with an appropriate cause, of any duration – all couples
 - Unexplained infertility of 2 years – heterosexual couples
 - Unexplained infertility following six to eight cycles of donor insemination – same sex couples
- 2 The number referred on to NHS Level 3 care
- 3 The number not referred on to NHS Level 3 care due to one partner having a biological child living in the couple's home
- 4 The number of those referred on where both partners had at least one biological child (although none living in the couple's home)

None of the Centres/hospitals approached was able to provide the detailed information required to accurately estimate the impact of changing the access criterion, although some Centres did carry out an audit and were able to provide some aspects of the information requested.

The information provided is relatively difficult to interpret, however, it suggests that changing the access criterion as proposed may increase demand for IVF by around 10-15% once steady state is reached. Concern remains amongst some members however, that 15% is too low a figure, and referrals if this criterion changes may well be considerably higher than 15%.

Couples who have a child each with another partner will not be eligible for treatment together. Couples who have a biological child together regardless of age will also not be eligible for treatment. This criterion is about ensuring each partner within a couple has an opportunity to be a parent.

5.5 Variation in demand across Scotland

The variation in demand for IVF treatment continues to increase across Scotland. The Centres in Aberdeen, Edinburgh and Glasgow have seen an increase in demand for IVF, although Glasgow referrals have recently started to stabilise. Referrals to the Centre in Dundee have remained fairly stable.

5.6 Commissioning by Health Boards, criteria and waiting times

Whilst there are now nationally set and adhered to criteria across Scotland, not all NHS Boards provide the appropriate level of IVF funding for their patients. Without the Scottish Government 'top up' funding, waiting times in certain NHS Boards would have almost certainly remained high. If the Scottish Government 'top up' funding were to cease, waiting times would immediately start to increase.

The Group's priority remains equitable, fair and timely access; however, local Board investment continues to be a crucial factor in IVF funding, and could be a barrier to widening access criteria.

The table below shows the number of NHS funded cycles paid for by each Board and the number of Scottish Government funded cycles required to top up NHS Board funding in 2015/16.

TABLE 11.
Number of NHS and Scottish Government funded cycles

NHS BOARD	NUMBER OF NHS FUNDED CYCLES 2015/16	NUMBER OF SG FUNDED CYCLES 2015/16
AYRSHIRE & ARRAN	118	0
BORDERS	30	0
DUMFRIES & GALLOWAY	33	0
FIFE	56	49
FORTH VALLEY	86	54
GRAMPIAN	73	181
GREATER GLASGOW & CLYDE	388	222
HIGHLAND	63	25
LANARKSHIRE	184	6
LOTHIAN	195	170
ORKNEY	8	0
SHETLAND	7	0
TAYSIDE	85	51
WESTERN ISLES	NO LIMIT SET	N/A

Data source: Tertiary Centres, 2016

SG funded figures for NHS Lothian include 34 cycles for NHS Greater Glasgow and Clyde, NHS Ayrshire & Arran and NHS Lanarkshire patients.

Table above suggests that SG funding provided supported NHS Greater Glasgow and Clyde predominately, however, this reflects the higher population and consequential higher demand for treatment.

Waiting times when the National Infertility Group was set up in 2010 were more than 3 years in some areas, and almost 4 years in certain Boards before the Scottish Government 'top up' funding was allocated. The funding began to have a positive impact on waiting times in some areas very quickly. The table below shows waiting times in December 2012, a few months prior to the National Infertility Group finalising its work in early 2013, alongside waiting times in December 2015, following 4 years of investment by the Scottish Government.

TABLE 12.
Comparison of waiting times

NHS BOARD	WAITING TIME DECEMBER 2012	WAITING TIME DECEMBER 2015
AYRSHIRE & ARRAN	1 YEAR, 10 MONTHS	9 MONTHS
BORDERS	NO WAIT	NO WAIT
DUMFRIES & GALLOWAY	1 YEAR	9 MONTHS
FIFE	1 YEAR, 6 MONTHS	6 MONTHS
FORTH VALLEY	1 YEAR, 6 MONTHS	6 MONTHS
GRAMPIAN	3 YEARS, 8 MONTHS	6-9 MONTHS
GREATER GLASGOW & CLYDE	1 YEAR, 11 MONTHS	9 MONTHS
HIGHLAND	1 YEAR, 10 MONTHS	4-6 MONTHS
LANARKSHIRE	1 YEAR	9 MONTHS
LOTHIAN	1 YEAR	9-10 MONTHS
ORKNEY	3-6 MONTHS	2 MONTHS
SHETLAND	3-6 MONTHS	2 MONTHS
TAYSIDE	1 YEAR, 6 MONTHS	6 MONTHS
WESTERN ISLES	3 MONTHS	3 MONTHS

Data source: Tertiary Centres, 2016

It is to be welcomed that all patients, regardless of where they live in Scotland are being screened for treatment within 12 months. However, variation does still exist, with small numbers of patients from the island Boards, and Borders having no wait or being seen within 3 months, and patients from the largest Boards, Lothian and Glasgow being seen for screening appointment within 10 months.

The time from date of referral from secondary to tertiary care to date of the IVF screening appointment is being routinely monitored by ISD to measure progress against the LDP Standard on IVF waiting times due to HFEA restrictions on sharing of data relating to IVF treatment. To produce information for the National Infertility Group's review, ISD staff were added to each of the 4 Centres' HFEA licences and directly analysed information on site in the Centres. This provided an opportunity to collect and analyse additional patient level information on the time interval between patients' screening appointment and definitive

treatment (ovarian stimulation) commencing – i.e. the portion of the patient wait that is not routinely monitored.

The information showed that, for patients starting their first cycle in January to March 2015, in all Centres at least 70% of patients started treatment within 4 months of their screening appointment, more than 90% of patients started treatment within 6 months and all patients started within 12 months. The interval between screening and starting treatment can be influenced by a number of factors including a woman's menstrual cycle, time required for additional investigations, patient choice or unavailability e.g. due to holidays, etc. Patients starting treatment in January may wait slightly longer following their screening appointment than patients starting treatment at other times of the year, due to centre closures over the Christmas period.

6. FUNDING AND ACTIVITY

We know that where patients do not meet the access criteria for IVF they can opt to 'self-fund' in an NHS or University managed facility or in the private healthcare sector. Generally, self-funding in an NHS/University facility is cheaper than treatment in a private clinic.

Reliance on self-funding is a core element of three of the four NHS Centres, where income from patients self-funding has, for many years, helped to subsidise the provision of NHS treatment.

TABLE 13.
Numbers of NHS/SG funded and self funded IVF treatment cycles by NHS Board of residence of patient, 2015/16.

NHS BOARD	NUMBER OF FULL NHS- AND SG FUNDED CYCLES IN 2015/16	NUMBER OF SELF FUNDED CYCLES IN 2015/16	TOTAL NUMBER OF CYCLES IN 2015/16
GREATER GLASGOW & CLYDE	610	N/A	610
LANARKSHIRE	190	N/A	190
AYRSHIRE & ARRAN	118	N/A	118
DUMFRIES & GALLOWAY	33	N/A	33
TERTIARY CENTRE (GLASGOW)			
LOTHIAN	298	155	453
BORDERS	26	N/A	26
TERTIARY CENTRE (EDINBURGH)			
GRAMPIAN	254	117	371
HIGHLAND	88	38	126
ORKNEY	8	4	12
SHETLAND	7	3	10
TERTIARY CENTRE (ABERDEEN)			
FIFE	105	31	136
FORTH VALLEY	140	19	159
TAYSIDE	136	41	177
WESTERN ISLES	2	1	3
TERTIARY CENTRE (DUNDEE)			
SCOTLAND			

Data source: Tertiary Centres, 2016

Self-funding relates to patients paying for treatment, usually due to not meeting NHS criteria, in Centres providing NHS treatment (Dundee, Edinburgh, Glasgow), or University Centres (Aberdeen). These figures do not include treatment undertaken in the private sector.

6.1 The activity in each Centre and the capacity

Table 14 shows the current level of activity in each of the provider Centres, along with the actual capacity – if funded and appropriately staffed.

Although all four Centres have the capacity to increase activity, there needs to be further investment in staff and equipment, to enable this. Staffing in such a specialist area has been problematic in the past, particularly in relation to Laboratory staff. These issues continue to impact on Centres. NHS Boards should continue to utilise the risk target in their Local Delivery Plans (LDPs), in respect of the waiting time for IVF. Provider Centres should continue to support commissioning Boards with this task.

TABLE 14.
Capacity in provider Centres

PROVIDER CENTRE	CYCLES CARRIED OUT 2014/15	ACTUAL CAPACITY	POTENTIAL CAPACITY
NHS GRAMPIAN	489	At capacity	720
NHS GREATER GLASGOW & CLYDE	992	At capacity	1,250
NHS LOTHIAN	566	At capacity	650
NHS TAYSIDE	557	At capacity	800
SCOTLAND	2,604	At capacity	3,420

Data source: Tertiary Centres, 2016

If funding is made available to increase access, as before the four Centres should continue to share capacity, although it is possible that traffic flows may be different. Changes in practice within the Centres, e.g. the move to blastocyst transfers requiring 7-day transfers, has increased workloads.

6.2 IVF Funding

Some NHS Boards are not investing appropriate amounts in this service, and they will have to increase this in the future and continue to do so annually, to ensure that the service remains equitable across Scotland.

Working out the current cost per cycle across the four tertiary Centres is not particularly straightforward. There is the cost commissioning Boards pay the tertiary Centres for a cycle of treatment, there is the cost patients who are self-funding in the four Centres pay, and there is the charge the Scottish Government has paid per cycle for additional treatment. The previous Group was always clear that commissioning Boards were not paying enough for IVF, and even the current figure does not take into account certain costs and neither does it take account of the capital costs of running a tertiary service, these costs therefore all fall on the provider Boards of the four tertiary Centres.

The Group considers that the four tertiary Centres should increase the charge of a self-funded cycle. Clearly this should still represent better value for money to the self-funded patient than using the private sector.

6.3 Definitions of a cycle of treatment and when waiting time clock starts and stops

6.3.1 Definition of 'one cycle of IVF'

The National Infertility Group agreed that the definition of 'one full cycle of IVF' should be: "One fresh cycle includes ovulation induction, egg retrieval, fertilisation, transfer of fresh embryos followed by freezing of suitable embryos and subsequent replacement of these, provided the couple still fulfil access criteria. Self-funding for replacement will be required if the couple no longer fulfil access criteria. If suitable embryos are frozen then these should be transferred before the next stimulated treatment cycle as this will avoid ovulation induction and egg collection, both of which carry risks for the woman."

Whilst this definition is now standard practice across Scotland, the Group is clear this is not the case elsewhere. Definitions vary not just across England, but Europe and the rest of the world have different definitions when talking about IVF cycles. As such, caution should be taken when comparing cycles available in Scotland to other countries as they may not be the same. This makes comparisons with published studies difficult. A recent study⁸ carried out by the University of Glasgow and the University of Bristol has defined the definition of a cycle as the same as the National Infertility Group and understands it is possibly the first published study to define cycles in this way.

Centres need to be explicit at the outset of NHS treatment around charges for embryo storage that apply following a successful pregnancy, or when patients no longer meet NHS criteria for other reasons. This should be the same for all patients regardless of where they receive treatment. The four Centres should develop a national protocol for this, to be discussed at the first meeting of the proposed new Expert Fertility Group.

If embryos are created in a self funded/private cycle, and the couple reach the top of the NHS waiting list, they could then have the frozen embryo transfer funded by the NHS. However, this would count as their first full cycle. Patients wishing to use this protocol would have to agree this in writing prior to starting treatment.

If a couple initiate a cycle that does not result in an embryo transfer this should not count as a full cycle. However, a further cycle should only be initiated if, in the treating clinician's view it is in the patients' best interests. Health Boards will be charged a fee for the failed cycle.

Currently across the four Centres, patients wait around 2-3 months for a frozen transfer following an unsuccessful fresh cycle, and anywhere between 3 and 11 months for a 2nd fresh cycle. This is usually patient driven, and can take place as and when patients wish, depending on the capacity of the Centre.

6.3.2 Definition of waiting time

Within NHSScotland the definition of the waiting time for IVF treatment is as follows:

- Clock starts when all access criteria are fulfilled, and secondary care referred letter is received in tertiary care Centre.
- Clock stops when the couple is screened for treatment. Time between clock starting and stopping should be a maximum of 12 months and is the 'Waiting time'.

Couples must fulfil **all** of the access criteria before referral from secondary Centres or primary care teams to one of the four tertiary Centres, including recommended BMI and non-smoking criteria. Smoking status should not rely on patient report but should be assessed using carbon monoxide testing, with cut off of 7ppm (parts per million). Patients must also be nicotine free before referral, i.e. patients should no longer be addicted and using patches or any other form of replacement therapy. Repeat BMI checks and carbon monoxide testing will be carried out before each treatment cycle.

It is important that couples do not reach tertiary services unless they meet all access criteria, and are ready for treatment. Patients who are undergoing treatment in secondary services should not be referred for IVF until they have completed treatment. As already mentioned, access criteria will be reapplied before each treatment cycle.

6.4 Existing access criteria for all couples – implemented on 1 July 2013

Infertility with an appropriate cause, of any duration – all couples

or

Unexplained infertility of 2 years – heterosexual couples

Unexplained infertility following six to eight cycles of donor insemination – same sex couples

- Eligible patients may be offered up to two cycles of IVF/ICSI where there is a reasonable expectation of a live birth.
- Both partners must be nicotine free and

non-smoking for at least 3 months before referral for treatment and continue to be nicotine free and non-smoking during treatment.

- Both partners must abstain from illegal and abusive substances.
- Both partners must be Methadone free for at least one year prior to referral for treatment and continue to be Methadone free during treatment.
- Couples must have no child under the age of 16 living with them in their home.
- Neither partner should drink alcohol prior to or during the period of treatment.
- BMI of female partner must be above 18.5 and below 30.
- Neither partner to have undergone voluntary sterilisation, even if sterilisation reversal has been self-funded.
- NHS funding will not be provided to couples where either partner has already received the number of NHS funded IVF treatment cycles supported by NHSScotland regardless of where in the UK they received treatment.
- No individual (male or female) can access more than the number of NHS funded IVF treatment cycles supported by NHSScotland under any circumstances, even if they are in a new relationship.
- Fresh cycles of treatment must be initiated by the date of the female partner's 40th birthday, and all subsequent frozen transfers must be complete before the woman's 41st birthday.
- Couples must have been co-habiting, at the same address, in a stable relationship for a minimum of 2 years.
- NHS funding may be given to those patients who have previously paid for IVF treatment, if in the treating clinician's view, the individual clinical circumstances warrant further treatment.
- Patients should not be placed at the end of the waiting list following an unsuccessful treatment cycle.

Normally, there would be a gap of 11 months between cycles of IVF, for patients who remain eligible.

It is essential that patient consent is sought for the freezing of embryos and, if given, couples are informed at the outset that once they have exhausted their NHS quota of IVF, or have a successful live birth, or no longer meet any of the eligibility criteria, self-funding for any future transfers will be required.

Patients should also be advised at the outset of any constraints to storage time and costs that may apply.

Welfare of the child

The HFE Act²³ extract relevant to the welfare of the child provision is set out as follows:

“No treatment services regulated by the HFEA may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth.”

Other medical conditions

GPs, referring and treating clinicians must take into account other serious medical conditions, such as (but not limited to) diabetes, epilepsy, congenital heart disease, chronic renal failure and rheumatoid arthritis and clinicians should take care that women who receive medical treatment are medically safe to become pregnant, before committing to treatment. Pre-conception counselling with an appropriate specialist should be offered if appropriate.

Equality Act 2010²⁴

NHS Boards should be reminded that there should be no discrimination in the provision of infertility services on the grounds of race, faith, gender identity, sexual orientation or disability. The requirement of the Act has to be balanced against the duty of licensed provider Centres under the HFE Act²³. An extract from the welfare of the child provision is set out below.

7. 2016 CONCLUSIONS AND RECOMMENDATIONS

7.1 Conclusions

In 2013, the Group recommended a short focused review starting in 2015 to reflect on the implementation of the access criteria changes from 1 July 2013, and emerging clinical evidence in light of new treatment pathways, and also to consider the recurring service cost before any further criteria, were considered.

The Group was keen for the following criteria to be introduced when affordable:

- Eligible patients may be offered up to three cycles of IVF/ICSI where there is a reasonable expectation of a live birth
- One partner has no biological child – as long as all further criteria are met by both partners without exception

The Group is still of the view that the current criterion that there should be no child in the home, as outlined in EAGISS²⁵, and in place across England, but not Northern Ireland or Wales, is unfair, and should be changed as set out in the recommendations below. The Group is also of the view that three full cycles of IVF gives patients the optimum chance of a live birth, and the maximum number of cycles should be increased from 2 to 3, as set out in the recommendations below. This is in line with recommendations in the most up-to-date NICE Guidelines, and research papers published in 2016.

However, Scottish Government Ministers and NHSScotland will need to be satisfied that the four NHS Centres have the appropriate support, funding and capacity beyond current Health Board funding and recurrent Scottish Government funding to implement further changes.

The long-term sustainability of both the LDP Standard for IVF waiting times, and any changes to criteria, require recurring funds, and the Group would like to see a commitment from the Scottish Government and all Health Boards to recurring funds for sustaining the service to the current level to ensure that no matter where couples live in Scotland, they will continue to be able to access the same level of service.

A new expert group will help with this, and implementation of the recommendations if accepted by Ministers, will ensure that no matter where couples live in Scotland, they will continue to be able to access the same excellent level of service currently available to NHS patients.

7.2 2016 Recommendations

The Group makes the following recommendations to Scottish Government Ministers:

1. Funding of IVF – a mainstream treatment – must be sustainable.
 - a) Scottish Government Ministers should provide reassurances that the current ‘top up’ funding of 40% is recurring. It is not normal practice for a mainstream medical treatment to require such a high level of additional Government funding.
 - b) Three out of four of the Centres providing NHS IVF receive income from patients who choose to self-fund IVF. As expected, self-funding has reduced over the past 4 years as waiting times have fallen, and may well continue to reduce further over the coming years particularly if new criteria are implemented. Provider Boards should plan for this possible reduction.

- c) All Health Boards, not just provider Boards, need to reassure the Scottish Government that they are committed to providing the current level of IVF funding, and where it is underfunded, Boards need to work towards a proportional approach. Provider Boards should work with all Boards using their Centres to this end.
- d) Scottish Government Ministers will need to put monitoring in place to ensure that Boards continue to fund IVF at least at the current level in the short term, as well as – in certain Boards that are currently underfunding – increase funding levels once new criteria are implemented.
- e) Monitoring should include the 12 month waiting time for IVF treatment.

If the Scottish Government is content that IVF funding is sustainable then the Group makes the following further recommendations to Scottish Government Ministers:

- 2. The Group recommends that the current ‘child in the home criterion’, should be replaced with the following: ‘One partner has no biological child’. All other criteria, without exception must be met by both partners.
 - a) Changing this criterion will amend the inequity that currently exists when couples need IVF, but cannot access as one partner has a biological child living with the couple. Only couples where one partner has never been a biological parent will qualify for treatment. All other access criteria will apply.
 - b) Once fully implemented and any initial backlog dealt with, the increase in demand to sustain this criterion is estimated to be approximately 15%. A suggested timetable for implementation is set out at 4 below.
- 3. The Group recommends increasing to a maximum of 3 full cycles of IVF for new eligible patients, where it is likely

to be clinically effective.

- a) The increase in demand to sustain this criterion is estimated to be approximately 10%. A suggested timetable for implementation is set out at 4 below.
 - b) A third cycle may be offered to patients who have a good prognosis of pregnancy. As with a second cycle, patients who have had less than 3 eggs collected or who have had failed fertilisation or poor embryo development and it is not clinically appropriate, would not be offered a further treatment cycle.
4. The Group recommends implementation of the change to couples where ‘one partner has no biological child’, which could be introduced on 1 September 2016 for all new patients referred for the first time from secondary care, and then from 1 April 2017 introduce a maximum of 3 cycles for all new patients referred from secondary care from this date. The third cycle would not be available retrospectively to those patients in the system, or those who have had treatment at any point in the past. This is also the case for ‘one partner has no biological child’.

- a) There is time for crucial capacity planning and discussions between provider and referring Boards prior to the introduction of new criteria, and provider Boards should urgently start these discussions.

Risks

- b) There are risks associated with implementing new criteria too soon and too close together. A gap of 7 months given the time patients will take to come through for treatment, seems to be achievable under the watchful eye of a new Expert Group (recommendation 5 below).
- c) Introduce treatment available to couples where one partner has never had a child and meet all other criteria,

for new referrals from 1 September 2016. This is likely to result in patients receiving treatment from around 1 March – 1 June 2017 if waits are between 6 and 9 months.

- d)** Introduce third cycle for all new couples referred from secondary care who meet the criteria as of 1 April 2017.
If 6-9 month waiting time first couples starting first cycles would be seen in Centres between 1 October 2017 and 1 January 2018.
If 3-4 months between cycles second cycle would be 1/2/18 – if 9-month wait 1/5/18
If 3-4 months between cycles third cycle would be 1/6/18 – if 9-month wait 1/9/18
- 5.** The Group recommends a new Expert Group should be set up to assist with the implementation of new criteria. The Group will be tasked with monitoring referral numbers to the 4 Centres to ensure that the service can cope with the increased number of referrals, and problem solve any issues that may arise. The Group should ensure that all Centres are implementing on the same basis, share capacity where available and discuss and resolve any issues nationally.
- a)** The Group will have a slightly different make up from the soon to be disbanded National Infertility Group. A Director of Planning and Director of Finance should be included in the membership of the new Group.
- b)** However, service providers and the patient stakeholder group Infertility Network Scotland¹³ will be key members of the new Group, which should also consider a number of other outstanding issues set out in this report, including storage charges and specific access criteria for the male partner on BMI and age.
- 6.** The Group recommends that couples where the women is aged from 40-42

should no longer be eligible for NHS treatment. Data collection has shown that the outcomes in Scottish clinics for this age group in NHS patients are very poor, and not clinically effective. Currently, this group of patients can access one cycle of treatment, if the couple fulfill certain additional criteria. This original Group recommended treatment up to the age of the 40th birthday would be clinically effective, and this has been backed up by recent data analysis showing a lack of effectiveness in age 40-42.

- a)** The Group recommends that referrals from secondary care under this criterion should stop on 31 August 2016. Patients already referred to this date should continue to receive treatment where clinically appropriate.
- 7.** The Group recommends that patients undergoing assisted conception who require crisis counselling should be signposted to out of hours crisis counselling already available. Additionally, the new Expert Group should consider developing specific information to give to NHS 24²² to help staff provide assistance to patients undergoing assisted conception treatment, who require help out of hours.
- 8.** The Group recommends that the new Expert Group consider a national protocol around charges for embryo storage that apply following a successful pregnancy, or when patients no longer meet NHS criteria for other reasons. This will address the differences in practice for patients receiving treatment in the four Centres currently.
- 9.** The Group recommends that, where appropriate, Secondary and Tertiary Centres should ensure the use of positive terminology in correspondence with patients.
- 10.** The new Group should consider ways to have robust, safe and

straightforward data reporting for this service, in line with the HFE Act.²³

11. The Group recommends that Health Board Chief Executives be informed of access criteria changes by way of a Chief Executives Letter (CEL).
12. The Group recommends that an updated Pathway should issue to all Primary Care providers and Secondary Care Centres. The Pathway should be signed off by the new Expert Group.
13. Finally, the Group considers that a 12 month waiting time for IVF is not unreasonable, and is far longer than other waiting time standards. If all Boards provided additional funding at the level required to meet the 12 month waiting time for their own patients, the additional Scottish Government funding could be used to increase capacity over the next 2 years for the recommendations set out above.

7.3 Proposed access criteria

Definition of infertility (no change)

Infertility with an appropriate cause, of any duration – all couples

or

Unexplained infertility of 2 years – heterosexual couples

Unexplained infertility following six to eight cycles of donor insemination – same sex couples

Updated access criteria for all couples

- Couples can access treatment if one partner has no living biological child

NEW – suggest implementation for all new referrals from 1 September 2016

- Eligible patients may be offered up to three cycles of IVF/ICSI where it is likely to be clinically effective*

NEW – suggest implementation for all new referrals from 1 May 2017

- Fresh cycles of treatment must be initiated by the date of the female

partner's 40th birthday, and all subsequent frozen transfers must be complete before the woman's 41st birthday.

- Couples where the female partner is aged 40-42 will no longer be eligible for one cycle of IVF due to a lack of clinical effectiveness in this age range.

NEW – suggest stopping referrals in this age range from 31 August 2016.

- Both partners must be nicotine free and non-smoking for at least 3 months before referral for treatment and continue to be nicotine free and non-smoking during treatment.
- Both partners must abstain from illegal and abusive substances.
- Both partners must be Methadone free for at least one year prior to referral for treatment and continue to be Methadone free during treatment.
- Neither partner should drink alcohol prior to or during the period of treatment.
- BMI of female partner must be above 18.5 and below 30.
- Neither partner to have undergone voluntary sterilisation, even if sterilisation reversal has been self-funded.
- NHS funding will not be provided to couples where either partner has already received the number of NHS funded IVF treatment cycles supported by NHSScotland regardless of where in the UK they received treatment.
- No individual (male or female) can access more than the number of NHS funded IVF treatment cycles supported by NHSScotland under any circumstances, even if they are in a new relationship.
- Couples must have been co-habiting in a stable relationship for a minimum of 2 years.
- NHS funding may be given to those patients who have previously paid for

IVF treatment, if in the treating clinician's view, the individual clinical circumstances warrant further treatment.

- Patients should not be placed at the end of the waiting list following an unsuccessful treatment cycle.

Normally, there would be a gap of 3–11 months between cycles of IVF, for patients who remain eligible. Where possible, this should be patient led.

It is essential that patient consent is sought for the freezing of embryos and, if given, couples are informed at the outset that once they have exhausted their NHS quota of IVF, or have a successful live birth, or no longer meet any of the eligibility criteria, self-funding for any future transfers will be required.

Patients should also be advised at the outset of any constraints to storage time and costs that may apply.

**A third cycle may be offered to patients who have a good prognosis of pregnancy. As with a second cycle, patients who have had less than three eggs collected or who have had failed fertilisation or poor embryo development and it is not clinically appropriate, would not be offered a further treatment cycle.*

New criteria will not be applied retrospectively.

8. ONGOING WORK

8.1 Gametes Group

A Gametes Group was set up in 2014 to assess the situation across Scotland with many aspects of Gamete Donation, as well as fertility preservation.

8.1.2 Fertility preservation

Patients who are to receive oncology treatments which are likely to compromise their fertility are potentially clinically eligible for fertility preservation treatment, although referring Clinicians should ensure patients are well enough and understand the implications of treatment before referral. Additionally, there are treatments outwith oncology which impact on a patient's future fertility which will further increase the demand on this service.

The British Fertility Society²⁶, which is a multidisciplinary society, has developed an Oncofertility network due to the increased number of referrals to Centres for fertility preservation for women diagnosed with cancer. This initiative has been supported by the Royal College of Nursing²⁷ and the patient support group Infertility Network UK²⁸. The Gametes Group will be following the progress of the Oncofertility network.

It is important that the Gametes Group follows progress in both oncofertility and other clinical treatments that impact on patient fertility, to ensure that any proposed treatments may be applied fairly to these patient groups.

There is a joint collegiate document 'The effects of cancer treatment on reproductive function. Guidance on management.' Royal College of Physicians²⁹, Royal College of Radiologists³⁰, Royal College of Obstetricians and Gynaecologists³¹. London: Royal College of Physicians, 2007 which is in the process of being updated. Within the report there is a recommendation on funding stating that 'NHS funding bodies are strongly encouraged to develop equitable funding protocols for

patients in this field, if necessary with national guidance. Access to fertility services is often urgently required when there is a need to proceed quickly with treatment for threatening cancer.'

In the 2007 report, egg freezing was relatively new and the success rates were low however with developments in egg freezing this is now a more realistic option and there is a growing need. Services for men are generally well established but availability and access to services for women varies widely depending on the oncology network and IVF funding streams. The report also states that 'Embryo storage prior to treatment is possible for the minority of patients with a partner and sufficient time for IVF and should be offered.' The UK is lagging behind in this rapidly growing subspecialty of 'oncofertility'. Currently this service is being provided within the four tertiary Centres in Scotland but is being funded from the IVF budget thus increasing the waiting time and diminishing the funding available to the infertile population.

SIGN Clinical Guideline 132: Long term follow up of survivors of childhood cancer³², was updated in March 2013. The section on 'Fertility Issues' was completely updated and will be considered when the Gametes Group make formal recommendations in this important area.

Despite numerous business cases in some areas, none of the four clinics providing NHS IVF receives dedicated funding for fertility preservation patients. This has a negative impact on both IVF waiting times and budgets, and can mean that IVF patients are delayed due to the high priority status of fertility preservation patients. Oncologists continue to refer patients with a poor prognosis as well as those who are too unwell for fertility preservation. Conversely, it is likely that patients in some areas and certain specialties are not being offered the option of fertility preservation.

There are real concerns in the Centres about future funding of fertility preservation, and the increasing numbers of Gametes being

held in storage for, in some cases, decades. Protocols need to be drawn up with criteria for access to fertility preservation and the Gametes Group has drawn up draft criteria which has been approved by the National Infertility Group. Further discussions with experts and stakeholders are needed, particularly on which specialties, drugs, medical treatments, and likely numbers should be considered for fertility preservation. It will be important to understand the future workload impact on Centres.

It is important to note that access criteria will still apply for such patients seeking infertility treatment. At the present time most treatment Centres have the ability to offer fertility preservation options to this group of patients where clinically feasible. A difficulty relates to the funding of such care since this falls outwith the remit of normal contractual arrangements for the provision of fertility care. This issue should be considered by the group tasked with the future provision of gamete donation.

8.1.3 Donated Gametes

Patients who require access to donated gametes (sperm or eggs) are still receiving patchy access across Scotland to this service.

Some provider Centres have continued to find it difficult to manage recruitment of egg and/ or sperm donors. Advantage may be gained by structuring planning and funding for such activities on a national basis, thereby achieving a more unified service option. Planning continues to create centralised, national storage for gametes within the Scottish National Blood Transfusion Service (SNBTS)³³, new national centre at the Heriot Watt campus in Edinburgh.

Four meetings of an operational subgroup of the National Gametes Group have been held to discuss the feasibility, possible structure and content of the proposed storage. Ratification is required by the National Gametes Group on the agreement reached to store donor sperm centrally, with the principle for egg storage also agreed. Gamete

storage related to fertility preservation in patients is still under discussion, and will be discussed further once a strategy has been agreed.

In addition, it is felt that there would be significant advantage in having a single, national approach to ensure compliance with the new EU Directive³⁴ on coding for tissues and cells and this is being addressed by the sub-group.

Two meetings have been held with SNBTS senior management to progress the planning required to enable the storage and logistics of these processes to be put in place. Funding to enable the initial phase of storage for sperm has now been provided by the Scottish Government to ensure this can be progressed.

A detailed paper describing the activities and proposals will be prepared for discussion at the next National Gametes Group in early spring 2016.

The Human Fertilisation and Embryology Authority (HFEA), sets the levels of compensation for sperm and egg donation services³⁵. These are, for sperm donors, a fixed sum of £35 per visit including expenses, and for egg donors, a fixed sum of £750 per cycle of donation including expenses.

ANNEX A

Membership and updated remit

Membership of the National Infertility Group during 2015/16

NHS BOARD	ROLE	ORGANISATION
IAN CRICHTON (CHAIR)	CHIEF EXECUTIVE	NHS NATIONAL SERVICES SCOTLAND
GWENDA BURNS	SCOTTISH BRANCH CO-ORDINATOR	INFERTILITY NETWORK SCOTLAND
DR CATHERINE CALDERWOOD (TO FEBRUARY 2015)	SENIOR MEDICAL OFFICER (WOMEN AND CHILDREN'S HEALTH)	SCOTTISH GOVERNMENT
JUDE CHALMERS (TO SEPTEMBER 2015)	INFORMATION ANALYST	NHS NATIONAL SERVICES SCOTLAND
SARAH CORCORAN	SENIOR POLICY MANAGER, MATERNAL AND INFANT HEALTH BRANCH	SCOTTISH GOVERNMENT
LAURA DOBBIE (FROM SEPTEMBER 2015)	SENIOR INFORMATION ANALYST	NHS NATIONAL SERVICES SCOTLAND
ELLEN DREW	CLINICAL EMBRYOLOGIST, NINEWELLS HOSPITAL DUNDEE	NHS TAYSIDE
JOHN FROGGATT	DEPUTY DIRECTOR, CHILD AND MATERNAL HEALTH	SCOTTISH GOVERNMENT
DR MARK HAMILTON	CONSULTANT GYNAECOLOGIST, ABERDEEN CENTRE FOR REPRODUCTIVE MEDICINE, ABERDEEN MATERNITY HOSPITAL	NHS GRAMPIAN
ANDREW JACKSON	ASSOCIATE DIRECTOR IN STRATEGIC PLANNING	NHS Lothian
DR VANESSA KAY	CONSULTANT GYNAECOLOGIST, ASSISTED CONCEPTION UNIT, NINEWELLS HOSPITAL	NHS TAYSIDE
DR HELEN LYALL	SUB-SPECIALIST CONSULTANT IN INFERTILITY AND REPRODUCTIVE MEDICINE	NHS GREATER GLASGOW AND CLYDE
ANNE MCCONNELL	BUSINESS/QUALITY MANAGER, ASSISTED CONCEPTION UNIT, NINEWELLS HOSPITAL	NHS TAYSIDE
MICHELLE MCLAUCHLAN	GENERAL MANAGER, OBSTETRICS AND GYNAECOLOGY	NHS GREATER GLASGOW AND CLYDE
AMY MCKEON	PRINCIPAL INFORMATION ANALYST	NHS NATIONAL SERVICES SCOTLAND
DR DAVID MCQUEEN	CONSULTANT GYNAECOLOGIST & DIRECTOR OF MEDICAL EDUCATION, FORTH VALLEY ROYAL HOSPITAL	NHS FORTH VALLEY
ALISON MCTAVISH	UNIT MANAGER, ABERDEEN CENTRE FOR REPRODUCTIVE MEDICINE, ABERDEEN MATERNITY HOSPITAL	NHS GRAMPIAN

FIONA SCHOFIELD (FROM OCTOBER 2015)	SERVICE MANAGER WOMEN'S SERVICES, EDINBURGH FERTILITY & REPRODUCTIVE ENDOCRINE CENTRE	NHS Lothian
SUSAN SEENAN	CHIEF EXECUTIVE	INFERTILITY NETWORK UK
ANTHEA TAYLOR	POLICY OFFICER, CHILD AND MATERNAL HEALTH	SCOTTISH GOVERNMENT
DR JOO THONG	CONSULTANT IN CHARGE OF ASSISTED CONCEPTION UNIT, ROYAL INFIRMARY OF EDINBURGH	NHS Lothian
ISABEL TRAYNOR	ASSISTED CONCEPTION SERVICE NURSE MANAGER, GLASGOW ROYAL INFIRMARY	NHS Greater Glasgow and Clyde
DR LORNA WATSON	CONSULTANT IN PUBLIC HEALTH MEDICINE, NHS FIFE, HONORARY SENIOR LECTURER, UNIVERSITY OF ST ANDREWS	NHS Fife
DR RACHAEL WOOD	CONSULTANT IN PUBLIC HEALTH MEDICINE	NHS National Services Scotland
SHEENA YOUNG	HEAD OF BUSINESS DEVELOPMENT	INFERTILITY NETWORK

Role and Remit of National Infertility Group - 2015/16

The Group, Chaired by Ian Crichton, Chief Executive of NHS National Services Scotland¹, is a national one, convened by the Scottish Government, bringing together service representatives, key national bodies and stakeholder groups.

Members will actively provide expert knowledge and advice to the development of existing and evolving Scottish Government policy on infertility and its implementation within NHS Boards.

Members will provide two way communication and liaison between the constituent bodies they represent and the National Infertility Group.

Ministerial advice and support

The Group will provide Ministers with an update by March 2016.

Issues for the Group to consider and make recommendations to Scottish Government Ministers include:

- Continuation of standardisation of access criteria to ensure high quality and equitable care across Scotland. This includes consideration of increasing the number of full cycles of IVF to 3, and the child in the home criteria.
- Data collection - to be led by colleagues in Information Services Division³⁶ in collaboration with the four Centres providing NHS IVF.

ANNEX B

Total number of NHS and self/privately funded IVF cycles in Scotland

TABLE A.

Fresh own egg cycles (HFEA definition)

	2010	2011	2012	2013	2014 (TO 30.6.14)
NHS FUNDED					
ABERDEEN	298	144	126	342	160
DUNDEE	206	195	270	481	259
EDINBURGH	222	228	314	368	202
GLASGOW	757	697	622	40	32
GLASGOW NUFFIELD	-	-	96	824	457
GCRM	<10	-	-	-	-
IVF SCOTLAND	<10	-	-	-	-
TOTAL NHS FUNDED	1,482	1,261	1,424	2,055	1,105
SELF FUNDED					
ABERDEEN	192	232	270	196	76
DUNDEE	219	187	258	138	38
EDINBURGH	299	189	167	168	39
GLASGOW	162	135	111	7	-
GLASGOW NUFFIELD	202	170	179	218	61
GCRM	780	791	626	699	277
IVF SCOTLAND	71	187	209	184	85
TOTAL SELF FUNDED	1,925	1,891	1,826	1,611	580
TOTAL	3,407	3,152	3,250	3,666	1,685

Fresh IVF & ICSI cycles using own eggs (as defined by HFEA) initiated in Scotland by funding type (data provided by HFEA) Note that the HFEA uses a different definition of a 'cycle' of IVF/ICSI to the National Infertility Group.

TABLE B.
Frozen own egg cycles (HFEA definition)

	2010	2011	2012	2013	2014 (TO 30.6.14)
NHS FUNDED					
ABERDEEN	62	41	25	40	33
DUNDEE	54	42	65	114	66
EDINBURGH	25	78	141	132	94
GLASGOW	206	235	186	-	-
GLASGOW NUFFIELD	-	-	<10	189	100
GCRM	<10	-	-	-	-
IVF SCOTLAND	-	-	<10	-	-
TOTAL NHS FUNDED	348	396	418	475	292
SELF FUNDED					
ABERDEEN	71	30	59	83	52
DUNDEE	70	78	85	89	36
EDINBURGH	105	97	83	120	42
GLASGOW	44	36	39	-	-
GLASGOW NUFFIELD	139	128	122	86	32
GCRM	158	217	184	258	131
IVF SCOTLAND	<10	22	21	37	19
TOTAL SELF FUNDED	593	608	593	673	312
TOTAL	941	1,004	1,011	1,148	604

The information above was provided by the HFEA to ISD in Oct 2015 (FOI request numbers 2015 - 00310 and 00348).

The Glasgow Centre was closed from 9 November 2012 to 15 September 2014 and treatment cycles were provided on behalf of NHS GG&C by the Glasgow Nuffield. IVF Scotland closed on 28 February 2015 after around 5 years' operation. There should therefore be no activity assigned to Glasgow in 2013 or the first half of 2014 - although the HFEA figures do show low cycle numbers assigned to Glasgow in that period. This suggests there was some error in the treatment Centre variable assigned to those cycles.

Note that the funding type variable (NHS/self) is not validated by the HFEA hence its accuracy is unknown.

The HFEA figures assign cycles to the Centre in which they were provided hence Glasgow activity in 2012-14 that was actually provided from the Glasgow Nuffield has been assigned to the Nuffield.

Overall therefore, it seems reasonable to use the HFEA figures to give a broad overview of trends in NHS and self-funded IVF activity over time at all Scotland level - but data for individual Centres should be interpreted with caution.

In general when reporting headline figures on the total number of IVF/ICSI cycles provided, the HFEA count both fresh cycles and, in addition, any frozen embryo replacements.

ANNEX C

Pathway Subfertility referral

Information for you:

PRIMARY CARE

Initial investigations for any couple experiencing infertility are inexpensive, non-invasive and likely to yield useful information prior to onward referral. Couples who experience problems conceiving should ideally be seen together although this may not be possible if registered with different practices.

Full history and examination of both partners if appropriate

Information to give to patient(s):

COUPLE PRESENT WITH INFERTILITY – UNLESS INDICATED AS IN EARLY REFERRAL, DO NOT REFER, BUT DO:

Reassure—84% of couples will conceive in 1st year of having unprotected sexual intercourse and 92% will conceive by first the 2nd year (NICE)

Advise sexual intercourse every 2-3 days rather than timing intercourse with the menstrual cycle

Consider underlying psychosexual problems

GPs, referring and treating clinicians must take into account other serious medical conditions and should take care that women who receive medical treatment are medically safe to become pregnant, before committing to treatment. Pre-conception counselling with an appropriate specialist should be offered if appropriate.

Offer lifestyle advice and support to couples to meet lifestyle changes

Smoking cessation – both partners must be non-smoking

Alcohol guidance – **advise that there is no known safe level of alcohol for pre-conception or during pregnancy – Government advice.** Neither partner should drink alcohol prior to or during the period of treatment.

BMI for female partner to be above 18.5 and below 30, though ideally should be <25 for both partners. If BMI outwith this range, couple can still be referred to secondary care though will not be able to access assisted conception

Recreational drug cessation for both partners – both partners must abstain from illegal and abusive substances

Methadone – both partners must be methadone free

Stable relationship – couples must have been co-habiting in a stable relationship for a minimum of 2 years

Caffeine only to be taken in moderation by both partners

Folic acid 5mg per day should be prescribed in women who have had previous pregnancy affected by NTD, or who have diabetes or epilepsy. Otherwise recommend 0.4mg daily

Arrange routine investigations:

If history, examination and routine investigation of both partners normal, no indications for early referral exist, and the period of infertility is less than 12 months, referral can be deferred until the couple have been trying for 12 months.

FEMALE	
	Rubella status
	Thyroid function
	Chlamydia screen
	Mid-luteal progesterone adjusted for cycle length (day 21 in a 28 day cycle)
	Ensure cervical smear up to date
In addition, if cycle longer than 42 days or periods are absent:	
	Prolactin
	Testosterone
	FSH/LH

MALE
Semen analysis—arranged with local Fertility Clinic. If sample normal, then does not need to be repeated. If abnormal, repeat usually requested (Here the option of adding in local details of how to arrange would be helpful).

CONSIDERATIONS FOR EARLY REFERRAL	
FEMALE	MALE
Age >35	Abnormal results on semen analysis x2 (WHO levels to be used)
Amenorrhoea	
Oligomenorrhoea	
Previous ectopic pregnancy	
Previous proven PID/STI	
Previous pelvic surgery	
Any significant relevant abnormality on history, examination or investigations	
Previous investigations have revealed a problem	

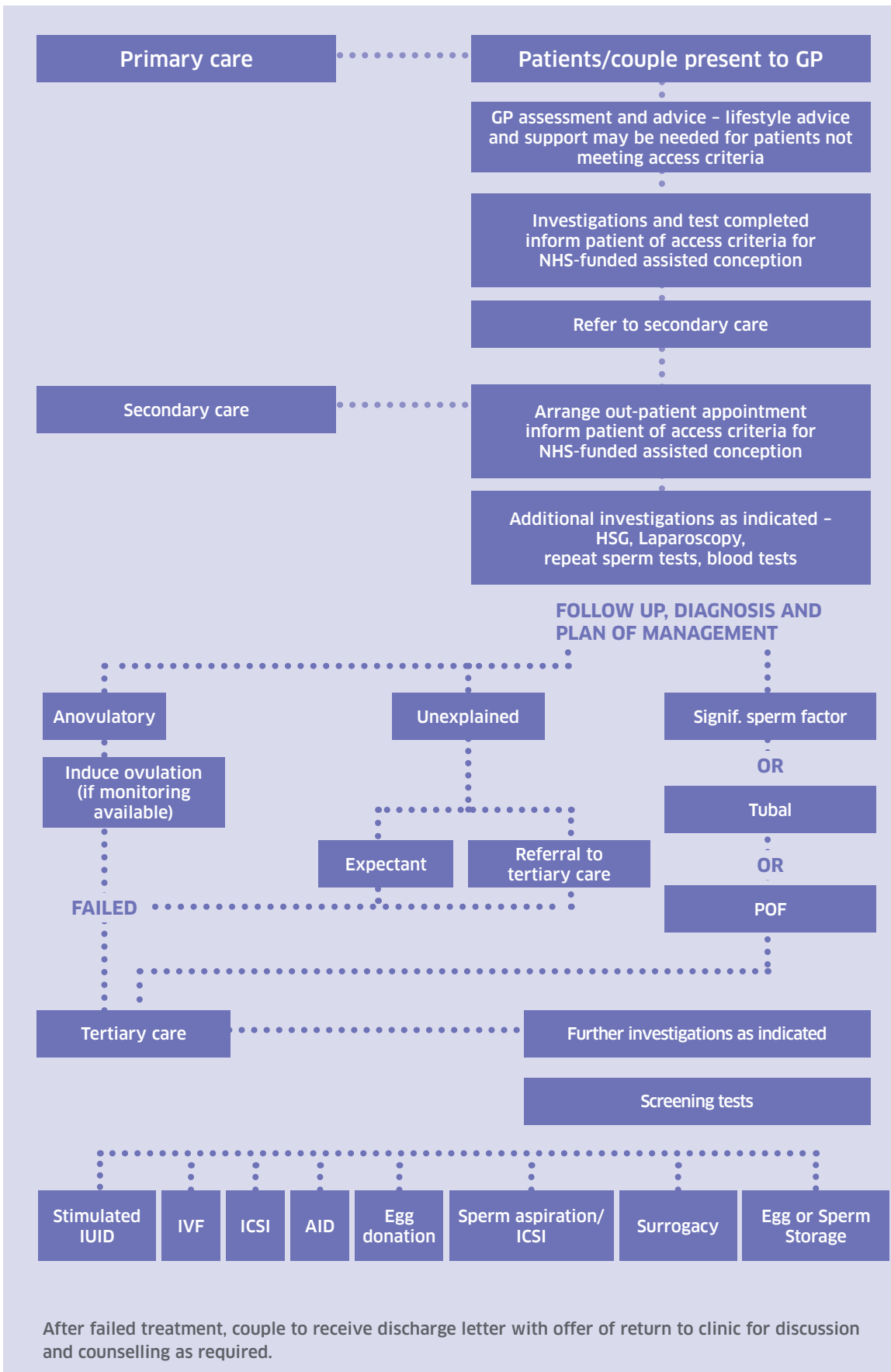
Referral Form

FEMALE PARTNER			
<input type="radio"/> Mrs <input type="radio"/> Miss <input type="radio"/> Ms Other			
First name		Middle name	Surname
Date of birth		CHI	
d	d	m	m
y	y	y	y
Address		Preferred tel no	
GP Information		Referring Consultant Information	
Duration if Infertility (Primary)		(Secondary - details)	
Relevant PMH		BMI	
Menstrual cycle		Smoking	
Cervical smear history		Alcohol	
Contraceptive history		(Recreational drugs)	
Sexual history (frequency/problems)		Relevant family history	
Drugs		Folic acid advice	
Allergies		Relevant findings on examination	
		Previous fertility treatment	
Investigation	Date	Result	
Chlamydia			
Rubella			
Mid-luteal progesterone			
Cervical smear			
If indicated:			
TSH			
Prolactin			
Testosterone			
FSH & LH			

Referral Form

MALE PARTNER			
<input type="radio"/> Mr <input type="radio"/> Other			
First name	Middle name	Surname	
Date of birth	CHI		
d d m m y y y y			
Address		Preferred tel no	
GP Information		Referring Consultant Information	
Duration if Infertility (Primary)		(Secondary - details)	
Relevant PMH	Smoking		
Sexual history (frequency/problems)	Alcohol		
Drugs	(Recreational drugs and/or body-building supplements)		
Allergies	Relevant family history		
BMI	Relevant findings on examination		
	Previous fertility treatment		
Semen analysis	Sample 1	Sample 2	Lower reference limits
Date			
Semen volume (ml)			1.5 (1.4-1.7)
Total sperm number (10 ⁶ per ejaculate)			39 (33-46)
Sperm concentration (10 ⁶ per ml)			15 (12-16)
Total motility (PR+NP, %)			40 (38-42)
Progressive motility (PR %)			32 (31-34)
Vitality (live spermatozoa, %)			58 (55-63)
Sperm morphology (normal forms, %)			4 (3.0-4.0)

Flow Chart



Pathway of care explanatory notes

DIET AND LIFESTYLE

An important part of management of couples who experience subfertility is provision of appropriate, consistent and timely advice on diet and lifestyle issues so as to optimise chances of conception, be able to access assisted conception when needed, and to reduce pregnancy-related risks.

Couples should therefore be supported to:

- Stop smoking (both partners)
- Achieve BMI between 18.5 and less than 30, but normal BMI is healthiest
- Reduce/stop alcohol intake
- Take caffeine containing drinks in moderation only
- Stop recreational drugs
- Stop taking methodone

ACCESS CRITERIA FOR ASSISTED CONCEPTION

When assisted conception is required, all of the following criteria must be met before referral:

- Age – Fresh cycles of treatment must be initiated by the woman's 40th birthday and therefore consideration should be given to current waiting times. All subsequent frozen transfers must be complete before the woman's 41st birthday
- Sterilisation – Neither partner to have undergone voluntary sterilisation, even if sterilisation reversal has been self-funded
- BMI for female partner should be above 18.5 and below 30 before referral
- Smoking – Both partners must be non-smoking and nicotine free for at least 3 months prior to referral for treatment and continue to be non-smoking during treatment this includes any nicotine replacements or vaporised cigarettes
- Previous children – No child living in the home
- Number of cycles – Eligible couple may have up to 2 cycles, but should be aware that if response and ovarian reserve is assessed to be poor, further treatment will not be given.
- Methadone – both partners must be methadone free for at least one year prior to referral and during treatment
- Alcohol – Neither partner should drink alcohol prior to referral and during treatment
- Both partners must abstain from illegal and abusive substances prior to referral
- Stable relationship – Couples must have been co-habiting in a stable relationship for a minimum of 2 years
- NHS funding will not be provided to couples where either partner has already received 2 NHS-funded IVF treatment cycles regardless of where in the UK they received treatment.
- No individual (male or female) can access more than 2 cycles of NHS-funded IVF treatment cycles under any circumstances, even if they are in a new relationship

WAITING TIMES

Couples should ideally be seen in secondary care within 12 weeks from referral from GP. Baseline investigations should be completed and simple treatment in secondary care ideally commenced, (eg ovulation induction for ovulatory problem, ideally within 18 weeks.

Examples of when the clock should be stopped include:

- Diagnosis of Unexplained Infertility when treatment may be deferred until duration of infertility 2 years
- When access criteria not met
- When referred to tertiary care

SECONDARY TO TERTIARY CARE REFERRAL

Information for you:

SECONDARY CARE

When referring from secondary to tertiary care, duplication of tests can be avoided with clear pathway and documentation.

Investigation in secondary care, when applicable (i.e. investigations not already carried out and recorded in process from primary to secondary care).

FEMALE

Tubal patency testing:

HSG/HyCoSy Date Result

Laparoscopy and dye test Date Result

Diagnostic Date Result

Rubella Date Result

Chlamydia Date Result

Infection screen

AMH

Further blood results as indicated

SECONDARY TO TERTIARY CARE REFERRAL - continued

MALE	
SA and concentration	<input type="checkbox"/> if required
FSH, LH	<input type="checkbox"/> if required
Testosterone	<input type="checkbox"/> if required
Cystic Fibrosis screen	<input type="checkbox"/> if required
Karyotype	<input type="checkbox"/> if required
Infection screen	<input type="checkbox"/> if required
Further blood results as indicated	<input type="text"/>

DIAGNOSIS	
Unexplained	<input type="checkbox"/>
Tubal	<input type="checkbox"/>
Male factor	<input type="checkbox"/>
Ovulatory	<input type="checkbox"/>
Other	<input type="text"/>

SUMMARY OF PREVIOUS TREATMENTS
<input type="text"/>

CONFIRMATION OF ELIGIBILITY FOR NHS TREATMENT	
Female Age <input type="text"/>	BMI <input type="text"/>
Neither partner smoking <input type="checkbox"/>	Previous children male <input type="checkbox"/> female <input type="checkbox"/>
Ovulatory <input type="checkbox"/>	Previous NHS cycles <input type="checkbox"/>
Sterilisation <input type="checkbox"/>	Co-habiting <input type="checkbox"/>

ANNEX D

IVF provision in the rest of the UK

England

Provision in England varies depending on where patients live. In April 2013 responsibility for the commissioning of fertility services was handed to local GP-led Clinical Commissioning Groups (CCGs). It seems clear that the reorganisation of commissioning arrangements in England has not addressed the inequity of access to treatment across the country, and in some parts of England, access has reduced over the past 2 years, or is no longer available on the NHS.

In 2015 Fertility Fairness³⁷ conducted an audit of every Clinical Commissioning Group (CCG) in England. This found that just 18% of CCGs provide the NICE recommended three cycles, with 24% offering two cycles and 57% offering one cycle. When compared with data from 2014, these numbers reveal a 7% fall in CCGs offering two cycles of IVF, and a corresponding rise in the number of one cycle providers. Additionally, at least 44% of CCGs do not offer a 'full cycle' as defined by NICE, and in place for all NHS patients in Scotland.

There are, however, areas of good practice within England, including the North East, where all eligible couples can access three full cycles of IVF.

Wales

Provision in Wales is for 2 full cycles of IVF for eligible couples, waiting times are similar to Scotland, with patients being seen within 12 months. Criteria in Wales is similar to Scotland, although couples with a child in the home not biologically related to one partner can access treatment.

Northern Ireland

Provision in Northern Ireland is for all couples, regardless of whether they have children, to access one fresh cycle of IVF, with a limit of one frozen transfer. Waiting times remain longer than in Scotland and Wales.

ANNEX E

GLOSSARY

Aggregated data	<p>Aggregated data is the consolidation of data relating to multiple patients, and therefore cannot be traced back to a specific patient – they are merely counts.</p> <p>Aggregate data cannot provide the type of detailed information which patient level data can, but is crucial for planning and guidance of the performance of health systems.</p>
Anovulatory infertility	Anovulation means lack of ovulation and is associated with either absent or irregular menstrual periods. The World Health Organization (WHO) classification of anovulation is based on measurements of the reproductive hormones in blood i.e. follicle stimulating hormone (FSH), luteinizing hormone (LH) and oestradiol (oestrogen).
ART	Assisted Reproductive Technology
Assisted conception treatment (ACT)	The name for treatments that enable people to conceive by means other than sexual intercourse. Assisted conception treatments include intrauterine insemination (IUI), <i>in vitro</i> fertilisation (IVF), intracytoplasmic sperm injection (ICSI), donor insemination and IVF with donated eggs.
Blastocyst transfers	Embryos are cultured in the laboratory incubator to the blastocyst stage before they are transferred to the womb. At this time, one or two of the best quality blastocysts are selected and then implanted into the woman's womb.
Body Mass Index (BMI)	The measurement used to define the range of healthy weight. BMI is calculated by dividing weight in kilograms by height in metres squared (that is, height in metres multiplied by itself).
Chief Executive Letter (CEL)	These letters provide direction from DG Health and Social Care and Chief Executive, NHSScotland on the implementation of Scottish Government policies.
Clinical Commissioning Group (CCG)	Clinical commissioning groups (CCGs) are NHS organisations set up by the Health and Social Care Act 2012 to organise the delivery of NHS services in England.
Co-morbidities	Co-morbidity is the presence of one or more additional disorders (or diseases) co-occurring with a primary disease or disorder and is associated with worse health outcomes, more complex clinical management, and increased health care costs.

CO testing	A carbon monoxide (CO) breath test shows the amount of carbon monoxide in the breath – the test is quick to carry out, non-invasive and provides a cost effective means of validating a person’s smoking status.
Cryopreservation	The freezing of eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.
Cumulative live birth rate (CLBR)	Cumulative rates are calculated as the delivery rate following repeated cycles of treatment. Cumulative rates usually include a defined number of attempts or a specific time period in which live birth delivery is attempted.
Cycle of IVF	The National Infertility Group agreed that the definition of one full cycle of IVF should be – “One fresh cycle includes ovulation induction, egg retrieval, fertilisation, transfer of fresh embryos, followed by freezing of suitable embryos and subsequent replacement of these, provided the couple still fulfil access criteria.”
Donor insemination	The placing of donor sperm into a woman’s womb.
Expert Advisory Group on Infertility Services in Scotland (EAGISS)	The Expert Advisory Group on Infertility Services in Scotland (EAGISS) was set up in 1988.
Egg	The female reproductive cell. A woman usually produces one egg in a normal monthly cycle.
Egg collection	A procedure by which a woman’s eggs are collected. Also known as egg retrieval or oocyte retrieval.
Egg donation	The process by which a fertile woman donates her eggs for use in the treatment of other women or for use in research.
Embryoscope incubator	Embryoscope is an incubator that maintains the necessary physiological conditions required by a living embryo while they are in the IVF laboratory. It has an incorporated time lapse system that has a camera that continuously captures images and records them as a video of the embryonic development.
Embryo	A fertilised egg.
Embryo transfer	Transfer of an embryo into the womb as part of IVF.
eSET	Elective single embryo transfer
Fertility Fairness	Fertility Fairness (previously the National Infertility Awareness Campaign) has campaigned for people to have comprehensive and equal access to a full range of appropriate NHS investigations and treatments for infertility.

Fertility preservation	Patients who are to receive oncology treatments or other treatments which are likely to compromise their fertility are clinically eligible for fertility preservation treatment.
Gametes	A mature sexual reproductive cell, a sperm or egg.
Human Fertilisation and Embryology Authority (HFEA)	The Human Fertilisation and Embryology Authority is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research.
<i>In vitro</i> diagnostic testing	<i>In vitro</i> diagnostics are tests that can detect diseases, conditions, or infections. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.
<i>In vitro</i> fertilisation (IVF)	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.
Insemination	A technique to place sperm into a woman's vagina or womb.
Intracytoplasmic sperm injection (ICSI)	A variation of IVF in which a single sperm is injected into an egg.
Intra-uterine insemination (IUI)	A technique to place sperm into a woman's womb through the cervix.
ISO accreditation	There are different ISO standards - ISO 9001 covers the quality management system for the Unit and ISO 15189 covers e.g. andrology laboratories.
Macrosomia	Macrosomia is the medical term used to describe newborns that are large for gestational age e.g. an usually high birth weight.
Multiple pregnancy	When a woman is pregnant with more than one baby at a time.
National Institute for Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance in England and Wales on promoting good health and preventing and treating ill health.
Oncology	Oncology is a branch of medicine that deals with the prevention, diagnosis and treatment of cancer.
Oocyte retrieval	A technique used in <i>in vitro</i> fertilisation (IVF) in order to remove oocytes from the ovary of the female, enabling fertilisation outside the body.

Ovulation induction	Ovulation induction is the stimulation of ovulation by medication. It is usually used in the sense of stimulation of the development of ovarian follicles to reverse anovulation or oligoovulation, but can also be used in the sense of triggering oocyte release from relatively mature ovarian follicles.
Puerperium	The puerperium covers the 6-week period following birth.
Pre-implantation genetic diagnosis (PGD)	PGD is a procedure which allows the testing of embryos at an early stage of development to identify if they are affected by genetic disorder/ chromosome abnormality.
Service Level Agreement (SLA)	Service level agreement between the provider and the client.
Scottish Intercollegiate Guidelines Network (SIGN)	SIGN was established in 1993 by the Scottish Medical Royal Colleges. Its aim is to improve the effectiveness of clinical care for patients in Scotland by developing, publishing and disseminating evidence-based guidelines that identify and promote good clinical practice.
Scottish Parliament Health & Sport Committee	The Health and Sport Committee examines the Scottish Government’s health policy, the NHS in Scotland, sport and other matters within its remit.
Information Services Division (ISD)	ISD is a division of National Services Scotland, part of NHS Scotland. ISD provides health information, health intelligence, statistical services and advice that support the NHS in progressing quality improvement in health and care and facilitates robust planning and decision making.
Sperm	The male reproductive cell produced by men, which fertilises a woman’s eggs.
Tubal patency testing	Scan examination of the fallopian tubes or laparoscopy.
US scan	Ultrasound scan
Viable pregnancy	Defined as beating fetal heart “intrauterine fetal pulsation seen” recorded on the early outcome form.
World Health Organization (WHO)	WHO is a specialised agency of the United Nations concerned with international public health.

ANNEX F

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