



NATIONAL INFERTILITY GROUP REPORT January 2013

national infertility group report

January 2013

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1. Introduction

1. 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.”

2. The full role and remit of the Group is shown in Appendix C.

2. The aim:

2.1 Reduce inequity and waiting time to 12 months

3. The principal issue for the Group was to manage the significant inequity in access to IVF that has arisen across Scotland as Health Boards have 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 Group notes that the Scottish Government has acknowledged the inequity that surrounds waiting times for IVF in Scotland, and that the Government 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.”**

2.2 Achieve this by using short-term money to target waiting times

4. The Scottish Government announced in September 2012 that an additional £12 million would be made available over the next 3 years to reduce waiting times for IVF treatment across Scotland to 12 months by 31 March 2015.
5. This funding has already started to reduce the backlog and will support 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 is being invested in 2012/13, with a further £4 million in 2013/14, and £6 million in 2014/15.

2.3 Ensure that the long-term cost of provision is similar to current cost

6. The National Infertility Group has been very cognisant of the tight financial envelope within which NHS Boards must operate and the conflicting demands across many services for resources.
7. 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 has, over time – particularly in bigger Boards – put pressure on services such as IVF.

2.4 Align our recommendations with 20:20 Vision

8. The NHSScotland Quality Strategy² 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.
9. Three high level Quality Ambitions were developed to reflect the six internationally recognised dimensions of healthcare quality. All healthcare policy development is being aligned to drive the delivery of these three Quality Ambitions:
 - Safe** – There will be no avoidable injury or harm to people from healthcare, and an appropriate, clean and safe environment will be provided for the delivery of healthcare services at all times.
 - Person-centred** – Mutually beneficial partnerships between patients, their families and those delivering healthcare services which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision-making.
 - Effective** – The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated.
10. In its considerations, the Group has had to strike a careful balance between the needs of potential parents against not only the obstetric risks which may be posed but also the overall effectiveness of treatment and the potential long-term health outcomes for any child born as a result of IVF.

3. What are we talking about?

3.1 Definition of infertility

11. Infertility is recognised across much of Europe as a disease state which can be treated by appropriate assisted reproductive technology. The World Health Organization (WHO)³ defines infertility as: “Infertility (clinical definition): 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.
12. NICE advises in its 2012 consultation document⁴ 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. The chances of conceiving naturally in the first 2 years of trying far outweigh the overall likelihood of successful IVF treatment. The table below sets out the pregnancy rate over 2 years, by age.

Table 1. Cumulative probability of conceiving a clinical pregnancy by the number of menstrual cycles attempting to conceive in different age categories (assuming vaginal intercourse occurs twice per week).

Adapted in NICE Fertility Guideline consultation 2012⁴, from Dunson et al, 2004.

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

Table 2. Research undertaken in the North East of Scotland⁵, showed that with regular unprotected sexual intercourse, 94% of women aged 35 years, and 77% of those aged 38 years, will conceive after 3 years of trying (2009).

Age of mother	% Pregnant after 3 years
35	94
38	77

3.2 Three levels of care

- 13.** Previous working groups on infertility in Scotland – the Expert Advisory Group on Infertility Services in Scotland⁶ and its predecessor ‘Infertility Services in Scotland’⁷ (1993) – used a model of services within a framework of three levels of care that is still generally used. These are:
- **Level I:** initial investigation and management provided by the primary care team.
 - **Level II:** further investigation and management provided by a special interest team in a general hospital gynaecology department.
 - **Level III:** specialist care provided in one of Scotland’s four tertiary referral centres (Aberdeen, Dundee, Edinburgh and Glasgow). These centres will also provide Level II care for those couples living within their own catchment areas.
- 14.** Level I care 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 care involves further management of couples referred following completion of basic assessment in Level I. 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 care involves the provision of assisted conception techniques requiring a licence

from the Human Fertilisation and Embryology Authority (HFEA)⁸, including *in vitro* fertilisation (IVF) and intra-cytoplasmic sperm injection (ICSI). IUI became an HFEA licensed treatment in 2007 and is now mostly carried out in level III centres.

3.3 The main issue is IVF/ICSI

- 15.** In practice, this report concentrates on Level III treatments; assisted conception techniques involving IVF. The report refers to other levels of care where appropriate.

3.4 How are IVF services arranged in Scotland?

- 16.** For Level III services, each of the 14 territorial NHS Boards in Scotland commissions cycles of IVF/ICSI from one of the four specialist tertiary referral centres in the NHS (Aberdeen, Dundee, Edinburgh and Glasgow).
- 17.** The activity and success rates of each of the units in Scotland are reported to the HFEA¹⁶ and the latest published data are shown in Appendix D.
- 18.** Each NHS Board sets out the criteria which couples must meet to be accepted for treatment and has a contract with the provider unit which agrees the number of cycles of treatment which will be carried out on the Board's patients in any given year. The number of cycles is effectively the supply of treatment provided by a Board. If the demand for treatment is greater than this supply then waiting times increase. Long waiting times are one significant reason why couples choose to fund their own treatment either in an NHS provided service or in the private sector.
- 19.** Provider units hold separate waiting times for each of the Health Boards, so the waiting time of a couple is not necessarily the result of the capacity of the provider unit but is a result of the commissioning arrangements of the Health Board in which they reside.
- 20.** There are wide variations in the provision of infertility services amongst NHS Boards, including waiting times, the number of cycles of IVF offered, the definition of a cycle and eligibility criteria. Table 4 on page 15 sets out some of this variation.
- 21.** Table 3 sets out numbers of NHS and self-funded IVF treatment cycles by NHS Board during 2011/12.

Table 3. Numbers of NHS-funded and self-funded IVF treatment cycles by NHS Board of residence of patient.

NHS Board	Number of fresh cycles in 2011/12 NHS-funded	Number of fresh cycles in 2011/12 Self-funded	Number of fresh cycles in 2011/12 Total
Greater Glasgow & Clyde	388	81	469
Lanarkshire	185	38	223
Ayrshire & Arran	118	24	142
Dumfries & Galloway	33	7	40
Tertiary centre (Glasgow)	724	150	874
Lothian	195	159	354
Borders	33	27	60
Tertiary centre (Edinburgh)	228	186	414
Grampian	120	120	240
Highland	70	69	139
Orkney	12	6	18
Shetland	10	5	15
Tertiary centre (Aberdeen)	212	200	412
Fife	55	57	112
Forth Valley	54	43	97
Tayside	85	65	150
Western Isles	10	2	12
Tertiary centre (Dundee)	204	167	371
Scotland	1368	703	2071

Self-funding is patients paying for treatment in NHS centres (Dundee, Edinburgh, Glasgow), or University centres (Aberdeen). These figures do not include treatment undertaken in the private sector.

3.4.1 The financial arrangements for IVF are different to other NHS services

22. 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. Furthermore, a proportion of patients who do meet the NHS access criteria and who want to avoid long NHS waiting times choose to self-fund.
23. 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.
24. Not all the patients included in the activity shown in the four NHS centres are fully funded by the NHS. Indeed, 34% of fresh cycles are paid for by patients treated in NHS units. The reasons behind this lie in the way in which these units were initially developed.

25. In Aberdeen the IVF Unit is administered by the University of Aberdeen, which employs the staff and owns the equipment. The NHS contracts with the University for an agreed number of cycles on an annual basis. The remaining activity within the Unit is funded by patients themselves. Often patients self-fund because of prolonged waiting times but in many instances it is because the patients do not meet NHS eligibility criteria.
26. The Unit in Dundee has been providing IVF treatment since the early 1980s and started offering self-funded treatment in 1994. This was around the time Health Boards started contracts with Units and it was realised that there was a market for those who would not be eligible for NHS-funded treatment and who could not afford or did not wish to access treatment at a private Unit. Since that time, the tariff has been set based on the number of cycles the unit can provide per year and takes into account all expenditure including staffing, overheads, equipment, and consumables. The unit is non profit making; the self-funded income supplements the income from NHS contracts and keeps the Unit viable.
27. NHS Boards have occasionally made contracts with private fertility units to provide cycles of IVF to reduce waiting times.

3.5 Why do we have a problem of inequity and long waits?

28. The National Infertility Group acknowledges that, although the EAGISS report⁶ was a well-evidenced piece of work, the implementation of its recommendations has varied in NHS Boards across Scotland. EAGISS recommended that a Health Board with a population of 250,000 would need to commission 154 cycles of IVF per annum. This would mean a total of 3,080 cycles for a Scottish population of 5 million. Yet today NHS Boards are only commissioning 1368 cycles. The cost per cycle has doubled since EAGISS made its recommendations.
29. There are several reasons why the EAGISS guidelines have not been uniformly implemented:
 - NHS Boards have a responsibility to spend the funds they receive from the government in a way that maximises the health of their population. The benefit of infertility treatment, in spite of the emotional stress associated with it, is seen as a low priority compared with the treatment of other conditions with more evident consequences in terms of premature death, disease and disability.
 - The improvement of effective and efficient treatment services has been the major focus of the NHS in Scotland in the last decade. Targets have been put in place for a wide range of healthcare activities, yet none of these has required NHS Boards to improve access to IVF treatment.
 - Targets for treatment waiting times have been put in place nationally. The exclusion of IVF from these has meant that large differences between NHS Boards have been able to persist and develop.
 - Although the incidence of infertility has not changed, the demand for treatment has grown due to other factors such as the choice couples make to delay starting a family.

- IVF and ICSI have become increasingly the treatment of first choice for infertility – particularly male factor infertility – in preference to other modes of treatment.
- 30.** The Group recognises that the Scottish Government and NHS Boards will be faced with many difficult choices around healthcare priorities, but sees no good reason why infertility services across Scotland cannot be better aligned and provided more equitably in future.

3.6 What has been done in the past to manage the problem?

- 31.** The Expert Advisory Group on Infertility Services in Scotland (EAGISS) recorded in its report⁶, published in 2000, that: “The NHS Executive and its Scottish counterpart have acknowledged that infertility management represents a healthcare need.” The report noted the wide variations in provision among Scottish Health Boards. The National Infertility Group notes that, 11 years after the publication of EAGISS, equity of access has yet to be achieved across Scotland.
- 32.** The Scottish Executive published the EAGISS report in February 2000 to inform NHS Boards’ planning and provision of infertility services in Scotland. These guidelines, which remain extant, recommend that those who are eligible for NHS funded *in vitro* fertilisation (IVF) treatment should be entitled to a maximum of three NHS funded cycles of assisted conception. This includes a minimum of two transfers of fresh embryos obtained following a full cycle of down-regulation, ovarian stimulation and egg recovery. Where frozen embryos are available, the third NHS-funded cycle should involve transfer of stored embryos.
- 33.** EAGISS further recommends that once accepted onto an assisted conception programme, eligible couples should be permitted to undergo successive cycles within a time frame of their own choosing. They should not return to the end of a waiting list following an unsuccessful cycle of treatment.
- 34.** EAGISS also recommends that NHS-funded assisted conception should be offered to couples who meet the following eligibility criteria:
- Infertility with an appropriate diagnosed cause, of any duration
 - or
 - Unexplained infertility of at least 3 years duration
 - Female partner aged <38 years at the time of treatment
 - Neither partner previously sterilised
 - No child living with the couple in their home
 - Less than three previous embryo transfers funded from any source
- 35.** In 2007, the Government conducted a stakeholder consultation on views about access to Level III infertility services, with the aim of producing recommendations on access for NHS Boards across Scotland. The report of the review was published¹⁰ in March 2007, and recommendations for access to services were sent to NHS Board Chief Executives.

- 36.** The 2007 recommendations were:
- The upper age limit for access to NHS-funded Level III assisted conception treatments (ACT) should be 39 years inclusive, i.e. the woman should be before her 40th birthday at the time of treatment.
 - In addition, the upper age limit should not apply for replacement of frozen embryos which were created from previous treatments occurring before the patient's 40th birthday, i.e. if a woman is in the middle of eligible cycles of treatment, then the frozen embryo can still be used after the 40th birthday.
 - Timing – once accepted onto an ACT programme patients should be allowed to undergo successive cycles of Level III ACT within a reasonable timescale agreed between themselves and the clinicians providing the treatment.
- 37.** The NICE Guideline on Fertility was first published in 2004¹¹ and is currently undergoing a partial review. A consultation was launched in 2012⁴, and publication of the updated guideline is planned for 20 February 2013. The NICE Guideline on Fertility is being developed for use in England, Wales and Northern Ireland. The guideline is not mandatory.

4. What did we do?

4.1 Main Group

- 38.** The National Infertility Group was set up, in spring 2010, at the request of Scottish Government Ministers, to help consider ways to best ensure equity and consistency of NHS infertility services across Scotland. The Group, chaired by Ian Crichton, Chief Executive of NHS National Services Scotland, met for the first time in April 2010, and thereafter met approximately every 2 months to the date of the final meeting in January 2013.
- 39.** Membership of the Group during 2012, along with the Group's initial role and remit, is at Appendix C. The Group has made use of its members' extended clinical and patient networks as well as taking input from NHS Boards.

4.2 Working Groups

- 40.** The Group was supported by working sub-groups which undertook more detailed research and provided expert advice on:
- (1) Communication,
 - (2) Data Sets and Modelling,
 - (3) Pathways of Care,
 - (4) Standardisation of Access Criteria, and
 - (5) Single embryo transfer principles.

4.3 Review of the evidence

- 41.** Both individual members of the Group and the five working groups 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.

4.4 Gathering information (from units, HFEA etc)

4.4.1 Data collection

- 42.** 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.
- 43.** Throughout the collection of data the Group has been conscious that under the confidentiality provisions of the Human Fertilisation and Embryology Act 2008¹² (HFE Act 2008), when a couple is undergoing licensed treatment, patient identifiable information from licensed centres to any person or organisation for whatever purpose, without specific consent of each patient concerned, would be a breach of the Act.

4.4.2 Obtaining routine data

- 44.** 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 Authority¹⁶ (HFEA). Data relating to infertility, even when obvious identifiers have been removed, may still be considered a disclosure, and it is therefore not permissible for individual records to be passed to the Information Services Division (ISD) of NHS National Services Scotland¹. Although the HFEA publishes information describing the performance of the various centres in Scotland, it has no information on waiting times or costs and no plans to produce such data.
- 45.** Data collection has been a difficult part of the process. Each of the four units collects its own data. Although the methods of data collection are not identical, they are very similar and the data group has worked to harmonise the definitions used. Based on the data needs of the economic model and the simulation model it has been possible to devise an inventory of aggregated data such that each unit has been able to contribute comparable key data. In some cases this has required a small amount of funding to assist in data collection or collation. In the future we expect better information capture within the confidentiality rules of the HFEA, and it is evident that some degree of funding will be required in future for the capture of information to assist with the 2015 review, and the Scottish Government's HEAT target. Data needs should be identified by a short life data group no later than April 2013 to enable the four centres providing NHS IVF to start capturing this information.

4.5 Modelling

- 46.** Merck Serono Ltd¹³, a pharmaceutical company, has developed an infertility service costing model. The Infertility Network Scotland¹⁴ managed to gain ownership of this model so that it could be shared with the National Infertility Group and adapted to reflect the Scottish picture. The model is built on a decision tree process which relies on an initial feed of information on:

- Rates of arrival from GP referrals
 - Proportions of cases funded by NHS, self or private funding
 - Proportion of cases with good prognosis, based on age of patient
 - Costs of appointments and stays in hospital.
- 47.** Using data derived from the individual units, augmented where necessary by adapting data from England, it has been possible to create a number of scenarios and examine the cost implications over a defined period of time.
- 48.** This approach has been helpful in examining the constituents of existing costs but less useful in predicting future costs. This reflects the limited capability of this sort of model to deal with the complexity of the overall system.

4.6 Discrete events simulation modelling

- 49.** During the course of the work of the National Infertility Group, it became apparent that, although the economic model was important and individual NHS Boards (notably Fife) had made some useful attempts to model various scenarios using advanced spreadsheet-based work, there was a need for a deeper understanding of the relationship between changes in access criteria, waiting times and throughput. Researchers from Health Economics and Health Technology Assessment at Glasgow University¹⁵ were therefore commissioned to produce a 'discrete events simulation model' of Scottish infertility services.
- 50.** Such a model, based on 'stocks and flows', can describe a dynamic system and allow various 'what if' scenarios to be considered and the outcomes studied. The infertility services model has been designed to undertake the following investigations:
- The evolution of the IVF/ICSI waiting list (in terms of waiting time and queue length).
 - How each of the following eligibility criteria affect the waiting times associated with patients pending treatment:
 - Age
 - BMI
 - Smoking status
 - One partner has no genetic child
 - How each of the following service configurations affect the waiting times associated with patients pending treatment:
 - The maximum number of allowed treatment cycles
 - The queuing method for repeat cycles
- 51.** In particular, it was possible to use the model to work out whether it would be possible to achieve a maximum waiting time of less than one year by March 2015, and what throughput of patients would be required to achieve this target. From this, an approximate cost could be calculated on a cost per case basis.
- 52.** The model structure was designed for each of the four NHS Level III centres in Scotland. Historical data and queue history took into account differences in criteria for each Board feeding into these centres.

53. Although this modelling is very sophisticated compared to much of the planning which is done within the NHS in Scotland, it can only ever be a relatively crude representation of reality, and like all attempts to foresee future trends, may give predictions which turn out to be inaccurate. Nevertheless, it is possible to examine some aspects of the model's strengths and weaknesses in order to gain a better understanding of the probability of its predictions coming true.
- a. **Structure of model.** The four clinics function in very similar ways with the same basic elements (e.g. waiting times, clinics, investigations, admissions, egg harvesting, etc), and the flow of patients between the elements follows similar, and relatively straightforward, patterns. Considerable effort was made to gain sufficient understanding of the way that the system works in real life. This allowed a fairly robust model to be constructed.
 - b. **Input data.** This area caused considerable difficulty as various different types of data were needed. These are described below:
 - **Initial numerical data.** These included such things as the number of patients likely to present for treatment and the number of patients who could be treated in a given amount of time. The data were collected directly from the units and also from the returns issued to the HFEA¹⁶. These parameters were difficult to establish for some of the units. The model itself allowed some triangulation because the known waiting time could be used to derive plausible inputs which could then be compared to the raw data and also clarified with the data providers. We are therefore reasonably confident about these data. Where possible, 'worst case' assumptions have been made.
 - **Process data.** It was important to try to estimate the proportion of patients who would have opted for completely private care or self-funding within an NHS facility whilst waiting times were long, but who would opt to be treated within the NHS if they knew that waiting times would be less than a year. Similarly, it was important to estimate the proportion of patients who would leave a waiting list, perhaps by achieving natural pregnancy or by moving location. In the absence of good quality data, a conservative best-guess approach had to be taken. These numbers are, however, likely to be relatively small, and so a fair amount of inaccuracy would have a relatively small effect on the outputs.
 - **Behavioural parameters.** In particular, the smoking status and the body mass index (BMI) of patients likely to require treatment were very important because the access criteria stipulated that people had to be non-smokers and of normal BMI. Such data were not reliably known for all clinics and had to be extrapolated from one clinic to another. Any available smoking data were usually based on self-report by women, but the access criteria suggest that there should be the option of cotinine testing for both partners. This is likely to increase the number of ineligible couples compared to self-reported data.

54. It was particularly difficult to estimate the likely proportion of people who would be able to change their habits if they were smokers or were outside the BMI parameters. The data are poorly recorded and a review of available literature was unhelpful. We have tried to always err towards estimates which were likely to increase rather than decrease waiting times. Nevertheless, the BMI and smoking parameters have an important impact on the model and if the levels of these parameters are actually lower than we have estimated, or there turns out to be a greater ability to change, then there will be a noticeable increase in resource need and cost.
- c. **Inherent probabilistic uncertainties.** The models have a probabilistic element such that the same parameters loaded into the same model and then run are likely to give slightly different results. This, of course, reflects reality; even simple structures like outpatient clinics held on different days with identical numbers of patients may take wildly differing times to complete. The models are therefore run approximately 1,000 times with exactly the same parameters and the outputs compared. The resulting waiting times form a statistical distribution from which it is possible to look at the range of variation. These ranges are presented as 95% intervals so that the most likely result is in the middle of this interval and any simulation has a one in 20 chance of being outwith the interval. For most of the simulations, in terms of waiting times, the width of this 95% range is less than 6 months. Planning has been done based on the upper limit of this range. This means that if the model projects that a one year waiting time can just be achieved, then there is only a 5% chance that this will be exceeded and it is very likely that the waiting time will be noticeably less than a year (assuming all the other model parameters and functioning is correct).
55. Where possible, the results of the Discrete Events Simulation Model were compared with the Merck Serono Economic Model. Baseline results and input parameters were broadly in line. Comparison of resulting costs between the two models for future years was difficult due to the different ways in which the models work. The Discrete Events Model gives the cost for the number of cycles that would need to be performed in order to maintain a specific waiting time and simulates individuals going through treatment under set configurations. The Merck Serono Economic model is based on a decision tree process and provides the costs for the number of cycles required if all IVF referrals were to be treated. It is unsuitable for estimating the costs of clearing the backlog of referrals but gives an estimate of costing once a steady state is achieved. This cost seems to be higher than that derived by the Discrete Events Simulation Model and this probably relates to the fact that the model does not adequately address the complexity of the system. This is borne out by the fact that the Merck Serono model suggests a considerably greater throughput once steady state is achieved. Such a throughput would suggest that there is greater unmet need at present than is observed and does not explain the relatively stable waiting times.

56. The model will be passed to Information Services Division¹ at the end of the project, allowing further simulations to be run in future using different parameters and modifications to the model. In particular, further use will be made of the model in the run up to the review in 2015 to assess timing and pace of further service improvements.
57. Further details of the outcomes of various scenarios for the Discrete Events Simulation model can be found in Appendix A, including Scenarios 2 and 8 which most closely reflect the pathway recommended by the Group.

5. What did we find?

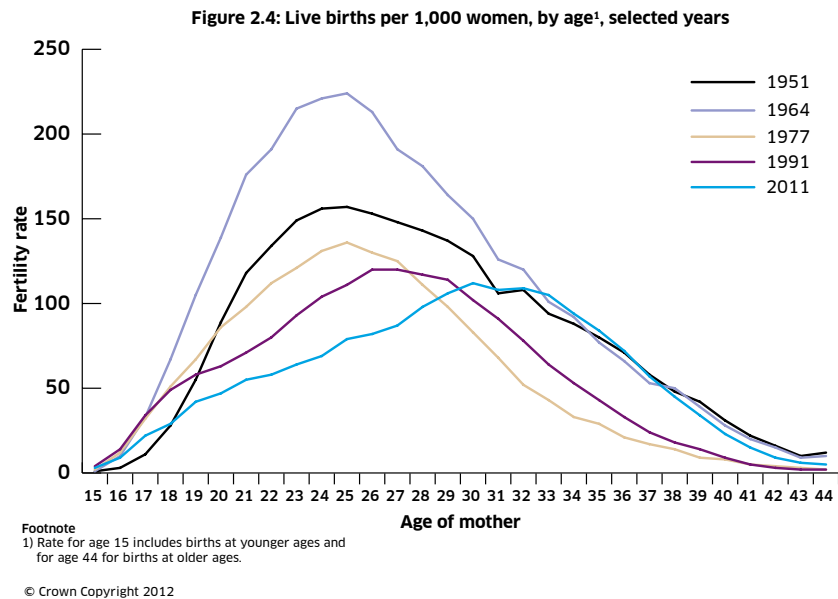
5.1 Overall activity in Scotland

58. The overall IVF activity in Scotland, the number of resulting births and the success rates for individual units can be accessed from the HFEA website¹⁶. The most up to date data on the HFEA website dates from 2010, and we have used these figures as they have been validated. These have been collated in Appendix D. Overall 4,332 cycles (this figure includes both fresh and frozen cycles) of treatment were given in 2010, of which 3,031 were given in the four NHS units. This resulted in 1,043 live births of which 735 were from NHS units.
59. Around 3.5% of all first births in Scotland are as a result of IVF treatment. One in seven of first births in women aged 35 to 39 is aided by assisted conception techniques.
60. At the current average working estimate of £3,600 per cycle of IVF/ICSI, the average cost per live birth is £12,325 for women below the age of 35, rising to £19,360 for women aged 38 to 39. In the few women treated over the age of 40 the cost per live birth is considerably more.

5.2 Trend over time: the reason for the increase in demand

61. The HFEA's report¹⁷ *Fertility Treatment in 2010*, shows there was a 6% rise in 2010 in the number of fertility treatments carried out in the UK, and that the average age of women undergoing IVF in 2010 was 35.1 years, up from 33.6 in 1991. This reflects the wider trend seen in Scotland and across the UK for women to have their children later. In Scotland, the average age of mothers has increased from 27.4 in 1991 to 29.6 in 2010.
62. The figure below illustrates the trend to increasing age of women giving birth in Scotland – drawn from *Scotland's Population 2011 – The Registrar General's Annual Review of Demographic Trends*¹⁸ According to this review, though the levels differed considerably, the age patterns of fertility for 1951, 1964 and 1977 were roughly the same. However, the age distributions for 1991 onwards show distinctly older peaks and that for 2011 reveals a further reduction in fertility of women in their twenties, mirrored by an increase for women in their thirties, compared with 1977 and 1991.
63. The trend towards later childbearing is underlined by changes in the average age of all women giving birth. This was 29.7 in 2011, compared to 27.4 in 1991, 26.1 in 1977, and 27.4 in 1964.

Figure 1. Scotland's Population 2011 - The Registrar General's Annual Review of Demographic Trends



64. Some variation in demand for IVF treatment has been seen across Scotland. Certain areas, including Fife, have seen an increase in demand for IVF, whilst referrals have reduced elsewhere. However, overall demand has increased due to couples deferring the decision to have children until later in their reproductive life.

5.3 Numbers being commissioned by Health Boards, criteria and waiting times

65. Not all NHS Boards offer patients access to funding for the same number of cycles, with NHS Borders, NHS Dumfries & Galloway, NHS Fife, NHS Forth Valley, NHS Greater Glasgow & Clyde, NHS Lanarkshire and NHS Lothian funding up to two cycles of treatment to patients. Eligible patients in NHS Ayrshire & Arran, NHS Grampian, NHS Highland, NHS Tayside and all three of the island Boards can access funding for up to three cycles of treatment. During the lifetime of this Group, several NHS Boards reduced provision from three to two cycles, however, the situation at the end of December 2012 is that around 20% of eligible patients in Scotland can potentially access three cycles of treatment, with the remaining 80% able to access two.
66. At present some NHS Boards take into account self-funded cycles and deduct these from the number of NHS-funded cycles. In addition, long waiting times often mean that although a patient is theoretically entitled to a number of cycles, in practice, time runs out for them and their actual entitlement is less. This was particularly the case in NHS Boards which have now officially reduced the number of available cycles. Furthermore, as this group of patients is older when treated their outcomes are adversely affected, which is why reducing waiting times across Scotland is so important.
67. In addition, there is wide variation in the per capita number of cycles commissioned by each Board. NHS Fife Health Board commissions 2.57 cycles per 1,000 women aged 30 to 39, whereas NHS Ayrshire and Arran commissions 5.85 - twice the rate.

68. Waiting times during 2012 varied from no wait in NHS Borders, to 3 years and 8 months in NHS Grampian. In addition, patients in NHS Fife, NHS Forth Valley and NHS Tayside are moved to the bottom of the waiting list after an unsuccessful treatment cycle.
69. As already noted, the Group's priority is equity; however, local Board investment is a crucial factor and it is clear that Board funding decisions and not capacity in the treatment centres, is generating this variation.
70. The tables that follow set out further details of IVF provision. Table 4 shows current provision by NHS Boards during December 2012, whilst Table 5 compares the picture at the end of 2012 with waiting times in December 2010. Table 6 sets out details of capacity in the provider units for the quarter ending September 2012.

Table 4. Situation in NHS Boards during December 2012 for first cycle of treatment

Boards are listed under their provider Board

NHS Board	Number of NHS-funded cycles per annum	Numbers waiting	Number of cycles	Waiting time (December 2012)	Eligible Population (women aged 30-39)	Cycles per 1,000 eligible women
Greater Glasgow & Clyde (Provider)	338	296	2	1 year, 11 months	80,161	4.22
Ayrshire & Arran	118	113	3	1 year, 10 months	20,171	5.85
Dumfries & Galloway	33	18	2	1 year	7,206	4.58
Lanarkshire	185	59	2	1 year	35,044	5.28
Grampian (Provider)	120	264	3	3 years, 8 months	33,300	3.60
Highland	70	80	3	1 year, 10 months	16,598	4.22
Orkney	12	0	3	3-6 months	1,109	10.82
Shetland	10	0	3	3-6 months	1,403	7.13
Lothian (Provider)	195	309	2	1 year	61,617	3.16
Borders	30	0	2	No wait	5,769	5.20
Tayside (Provider)	86	221	3	1 year, 6 months	22,100	3.89
Fife	55	129	2	1 year, 6 months	21,420	2.57
Forth Valley	83	183	2	1 year, 6 months	18,093	4.59
Western Isles	No limit set	0	3	3 months	1,456	

All NHS Boards currently include the replacement of any frozen embryos resulting from a fresh treatment cycle, within one full cycle of IVF treatment.

Table 5. Comparison of waiting times

NHS Board	Waiting time December 2010	Waiting time December 2012
Ayrshire & Arran	1 year, 10 months	1 year, 10 months
Borders	No wait	No wait
Dumfries & Galloway	1 year	1 year
Fife	3 years, 3 months	1 year, 6 months
Forth Valley	3 years, 3 months	1 year, 6 months
Grampian	2 years	3 years, 8 months
Greater Glasgow & Clyde	2 years	1 year, 11 months
Highland	1 year, 6 months	1 year, 10 months
Lanarkshire	1 year	1 year
Lothian	2 years	1 year
Orkney	3-6 months	3-6 months
Shetland	3-6 months	3-6 months
Tayside	1 year, 3 months	1 year, 6 months
Western Isles	2-3 months	3 months

5.4 IVF in Scotland compared to the rest of the UK

- 71.** Provision in England varies depending on where patients live and a June 2011 report¹⁹ by the Westminster All Party Parliamentary Group on Infertility found that 39% of PCTs offered one cycle of treatment, 26% offered two and 27% offered three cycles. From April 2013 responsibility for the commissioning of fertility services will be handed to local GP-led Clinical Commissioning Groups.
- 72.** There remain considerable concerns amongst providers and patient groups that the reorganisation of commissioning arrangements in England will not address current inequalities in access to treatment across the country.
- 73.** Waiting times in Northern Ireland exceed 12 months, and eligible couples receive one cycle of fresh IVF along with one frozen transfer (where available). All eligible couples with children can access treatment.
- 74.** Eligible patients in Wales can access up to two cycles of IVF, and wait a maximum of 18 months for treatment.
- 75.** A table at Appendix E, compares the amount of IVF being delivered regionally across the UK. Scotland is currently delivering more IVF treatment *pro rata* than other areas of the United Kingdom.
- 76.** A recent study²⁰ shows that Government funded IVF provision in the UK is amongst the lowest in Europe.

5.5 The activity in each unit and the capacity

- 77.** Table 6 shows the current level of activity in each of the provider units, along with the actual capacity – if funded and appropriately staffed.

78. Although Centres may have the capacity to increase activity there would need to be investment in equipment and, possibly, staff. Staffing in such a specialist area has been problematic in the past, particularly in relation to Embryology Laboratories. These issues will have an impact on the budget setting for each Centre. We would expect NHS Boards to utilise the risk target in their Local Delivery Plans (LDPs), in respect of the IVF HEAT target. Provider units will have to support commissioning Boards with this task.

Table 6. Capacity in provider units for quarter ending September 2012

Provider unit	Current cycles carried out	Actual capacity	Potential capacity
NHS Grampian	412	500	768
NHS Greater Glasgow & Clyde	874	874	874
NHS Lothian	480	530	600
NHS Tayside	465	650	900

79. Whilst a lack of funding has been the main reason for high waiting times in the past, there will be capacity issues in the short term as NHS Boards seek to drive down their waiting times to reach a waiting time of 12 months by 31 March 2015, in some instances effectively almost doubling demand against the centres current capacity. It will be important for the four NHS Centres to discuss and share available capacity.

5.6 Numbers/proportions self-funding and why people self-fund

80. From data available from the HFEA for 2010, 30% of IVF cycles (own eggs, fresh cycles) are provided in Scotland by private healthcare providers. This figure will include a fair proportion of patients who do not meet NHS eligibility criteria. This figure is almost certainly substantially higher in England.
81. Using data available from NHS centres for 2011/12 (see Table 3), 1368 cycles were NHS-funded with 703 cycles self-funded. Assuming the proportion of patients using private clinics has not changed since 2010 the percentages of all fresh IVF cycles carried out in Scotland by the different funding sources are approximately 46% NHS-funded, 24% self-funded at NHS centres and 30% self-funded at private clinics.
82. The high proportion of couples currently funding their own treatment is a cause for concern if a high proportion of them are doing so only to avoid long NHS waiting times. Group members, however, were of the opinion that more patients self-funded because they did not meet their NHS Board's criteria for access, though particularly in NHS Grampian excess waiting times have also contributed to this figure. Reducing the NHS waiting times without taking action to standardise eligibility criteria and provision across Scotland may lead to a very significant increase in demand for NHS treatment and thus increase waiting times again.

5.7 Cost of IVF

83. Figure 2, taken from the discrete events simulation modelling shows the current baseline cost of NHS IVF in Scotland.

Figure 2. Current baseline cost of NHS IVF in Scotland

Base case – National

Provider unit	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20
NHS Grampian	210 (204,212)	210 (203,212)	210 (203,212)	210 (204,212)	210 (204,212)	210 (204,212)	210 (204,212)	210 (204,212)
NHS Tayside	261 (255,270)	235 (228,243)	235 (227,243)	235 (228,243)	235 (228,243)	235 (228,243)	235 (228,243)	235 (228,243)
NHS Lothian	225 (216,228)	225 (215,228)	225 (215,228)	225 (215,228)	225 (216,228)	225 (216,228)	225 (216,228)	225 (216,228)
NHS Greater Glasgow & Clyde	724 (724,724)	724 (724,724)	724 (724,724)	724 (724,724)	724 (724,724)	724 (724,724)	724 (724,724)	724 (724,724)
National	1419 (1407,1431)	1393 (1379,1405)	1393 (1379,1405)	1394 (1380,1405)	1394 (1381,1405)	1394 (1381,1405)	1394 (1381,1405)	1394 (1381,1405)
Preg/cycle	0.26	0.26	0.26	0.26	0.26	0.26	0.26	0.26

Mean number of cycles performed (with 95% confidence interval) and success rate

Board	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20	Total
NHS Grampian	754,204	754,456	755,143	755,784	756,320	756,896	757,073	757,148	
NHS Tayside	940,453	845,564	845,356	845,046	845,687	844,978	845,701	845,525	
NHS Lothian	808,682	808,358	808,301	809,773	809,849	810,706	809,294	810,000	
NHS Greater Glasgow & Clyde	2,606,400	2,606,400	2,606,400	2,606,400	2,606,400	2,606,400	2,606,396	2,606,400	
National	5,109,739	5,014,778	5,015,200	5,017,003	5,018,256	5,018,980	5,018,465	5,019,073	40,231,494

Mean cost (£), assuming £3,600 per treatment cycle

84. A number of NHS Boards have, over the past few years, made significant changes to address long waiting times in their areas. This has included increased investment, changes to eligibility criteria and treatment pathways, including a reduction, in the number of cycles of IVF provided. As a result waiting times have reduced, sometimes dramatically, in these areas.
85. 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. Appendix F sets out the number of cycles per 1,000 eligible women each Board currently commissions.
86. Based on figures provided by the four tertiary centres, the average tariff or working estimate for a cycle of IVF/ICSI treatment is £3,600. Modelling work has been developed to determine what level of funding would be required, first, to reduce waiting times to 12 months and, secondly to keep the service in a steady state.

6. Clinical effectiveness of IVF

87. Overall, 24% of IVF cycles in Scotland result in the birth of a live baby. The success rate of treatment is, however, significantly affected by maternal age and health behaviours.
88. Infertility is caused by both male and female factors. Many causes of infertility are not preventable, but there are known factors which contribute to a proportion of cases. The most significant is age, and female fertility declines steeply after the age of 35. 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.
89. Other factors which may 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 may need to increase awareness of these effects, and both NHS Health Scotland and Infertility Network Scotland are carrying out work on pre-conception care and fertility risk respectively, which will help highlight these issues. More detail on these factors is set out below.

6.1 Factors affecting fertility, maternal and infant health

6.1.1 Obesity

90. The increasing prevalence of obesity is a major health problem. A recent Health Survey for England²¹ found that one-quarter of both men (23.6%) and women (23.8%) are obese, with a body mass index (BMI) of ≥ 30 kg/m². In total, 50% of women of childbearing age are either overweight (BMI 25–29.9 kg/m²) or obese and 18% are obese at the start of pregnancy.
91. This 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.
92. Maternal obesity has become one of the most commonly occurring risk factors in obstetric practice. Obesity in pregnancy is usually defined as a Body Mass Index (BMI) of 30 kg/m² or more at the first antenatal consultation. BMI is a simple index of weight-for-height and is calculated by dividing a person's weight in kilograms by the square of their height in metres (kg/m²). Currently, 20–40% of women gain more than the recommended weight during pregnancy, resulting in an increased risk of maternal and fetal complications.
93. More than half of women who die during pregnancy, childbirth or the puerperium are either obese or overweight. The maternal complications associated with obesity also include miscarriage, hypertensive disorders such as pre-eclampsia, gestational diabetes mellitus, infection, thromboembolism, caesarean section, instrumental and traumatic deliveries, wound infection and endometritis.

- 94.** The fetal risks associated with obesity include stillbirths and neonatal deaths, macrosomia, neonatal unit admission, preterm births, congenital abnormalities and childhood obesity with associated long-term risks. Excessive weight gain in pregnancy is also associated with persistent retention of the weight gained beyond pregnancy in the mother and an increase in obesity in children at 2–4 years. The health risks to the mother and baby of obesity and excessive weight gain pose significant demands on the healthcare system, with an increased need for additional care and resources in both primary and secondary care settings.
- 95.** The joint Royal College of Obstetricians and Gynaecologists (RCOG)²² and Centre for Maternal and Child Enquiries²³ (CMACE, formerly CEMACH) guidelines and the National Institute for Health and Clinical Excellence (NICE) guidance recommend that women with a BMI of ≥ 30 kg/m² should have consultant care rather than midwifery-led care, which places a massive burden on maternity unit resources. Obese women spend an average of 4.83 more days in hospital, resulting in a fivefold increase in the cost of antenatal care. The costs associated with newborns are also increased, as babies born to obese mothers have a 3.5-fold increased risk of admission to the neonatal intensive care unit (NICU). Obesity now costs the NHS around £1 billion a year and the UK economy a further £2.3 billion of indirect costs. Reducing maternal and childhood obesity, through effective obesity treatment programmes, could result in significant advantages for the NHS and society.

6.1.2 Smoking

- 96.** Smoking is associated with reduced fertility, although this has not always been widely recognised. The evidence is consistent, through a range of pathways affecting both male sperm production and many female aspects including hormone levels and egg development. Female smokers are more likely to have infertility, and delayed conception is more common with female exposure to active or passive smoking.
- 97.** There is compelling evidence of a negative effect of smoking on IVF outcome, which has been shown to apply to females in relation to active and passive smoking, and in addition there is evidence of reduced success with male smoking. The impact of passive smoking is only slightly less than active smoking and effects are reversed after about one year.
- 98.** 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.

6.1.3 Substance misuse

99. Any substance misuse during pregnancy will reach the developing baby and may cause harm.

6.1.4 Alcohol

100. Every pregnant woman in Scotland is given a copy of the NHS Health Scotland and Scottish Government publication *Ready, Steady, Baby*²⁴ which states that there is no 'safe' time for drinking alcohol during pregnancy and no 'safe' amount. Drinking no alcohol in pregnancy is the best and safest choice.

6.1.5 Maternal age

101. A woman's ability to conceive a child reduces with age – the younger she is the higher the chance of success. In the year from 01/01/2010 to 31/12/2010, for women having IVF using fresh embryos created with their own fresh eggs, the percentage of cycles started that resulted in a live birth (national averages) was:

- 32.2% for women aged under 35
- 27.8% for women aged between 35–37
- 21% for women aged between 38–39
- 13.7% for women aged between 40–42
- 5.3% for women aged between 43–44
- 2% for women aged 45 and over

102. These figures show clearly that IVF is most successful in women aged under 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. Women need to be made more aware of the steady decline in their fertility from age 30, and especially in the steep decline from age 35. Appendix G sets out the cost effectiveness of IVF by age.

103. The tables at Appendix H set out the proportion of births due to IVF or ICSI, and show that these treatments account for 3.55% of all first births in Scotland. 433 out of 3181 (13.6%) of first babies born to women between the ages of 35 and 39 are due to IVF or ICSI and 64 out of 634 births (10.1%) in women over the age of 40¹⁶. Treatment results in a live birth in approximately 25% of those undergoing the first fresh embryo transfer, but this is significantly higher in younger women and significantly lower in older women. The success of treatment reduces with a second fresh cycle, and continues to reduce with subsequent treatments.

6.2 How many cycles should be provided?

- 104.** The New England Journal of Medicine published an article in 2009, *Cumulative live-birth rates after in vitro fertilization*²⁵ based on couples accessing six cycles of IVF treatment. It demonstrated the live birth rates in relation to each cycle based on an optimistic cumulative live birth rate assuming that patients who did not return for treatment had the same chance of a pregnancy resulting in a live birth as those who remained in treatment. The conservative birth rate assumes that patients who did not return for treatment did not have a pregnancy resulting in a live birth.
- 105.** Six thousand, one-hundred-and-sixty-four women undergoing 14,248 cycles were included in the study which showed the live birth rates in the table below:

Table 7. Cumulative live birth rate after successive treatment cycles

No of cycles	Conservative live birth rate	Optimistic live birth rate
1	25	25
2	37	40
3	45	53
4	49	62
5	50	68
6	51	72

- 106.** These data would indicate that providing three cycles of IVF should result in a 45-53% chance of a live birth rate. Since the publication of this study in 2009, national UK data have shown a continued trend upwards in success rates after IVF and thus one would expect that cumulative live birth rates will continue to rise.
- 107.** Definitions used in these data are historical and not necessarily indicative of improvements which may be seen in the future based on the new definition of a cycle of IVF as outlined in this report. However, the Group was of the view these data remain helpful. As mentioned later in the report, NHS Boards are advised to keep a careful eye on the increasing numbers of patients who have multiple frozen embryo transfers and the subsequent cost.

6.3 Should we treat couples with existing children?

- 108.** To ensure a fully equitable service for infertility patients throughout Scotland, anyone with a fertility problem who could benefit from treatment and who fit the criteria based on medical evidence, should be treated, including those whose partner has had a child from a previous relationship. The NHS in Scotland should aim to ensure that all inequities relating to infertility treatment are removed and set a deadline for achieving this.

6.4 Waiting list management

- 109.** To manage the waiting list most efficiently patients should be allowed to continue with treatment once they have reached the top of the waiting list.

- 110.** The use of IVF as a 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.
- 111.** The Group recommends that patients currently on the waiting list who will no longer meet the new criteria from 1 April 2013, be kept on a 'holding list' for a period of (at least) one year and, during that time, be supported by their NHS Board to make lifestyle changes that will, ultimately enable them to receive treatment.
- 112.** All new patients from 1 April 2013, without exception, must meet new access criteria recommendations.
- 113.** NHS Boards, and in particular, the four NHS Centres providing treatment, should work with the patient stakeholder group, Infertility Network Scotland¹⁴, to ensure that patients are kept informed of changes to treatment pathways.
- 114.** In 2010, NHS Lothian altered its treatment pathway and eligibility criteria for IVF patients. Some of these changes anticipated recommendations outlined in this report.
- 115.** As it was recognised that some couples undergoing or waiting for treatment could be affected by these changes, thought was given on how to handle the transition. In a manner similar to that proposed in this report, it was decided that those already undergoing treatment would be not affected, while those waiting for treatment were advised of the change and, where appropriate, directed to support to address their smoking or BMI status. As these lifestyle changes can be difficult, couples were not removed from the waiting list but retained their 'place in the queue' in the expectation that these changes would have been successfully made by the time treatment was offered. Extra time was allowed for patients to make the change had they not successfully done so by the time they reached the front of the queue.
- 116.** Infertility Network Scotland¹⁴ had kept abreast of the changes in NHS Lothian and, further to the support provided by the service, were able to help couples work through why these changes had been introduced, how these changes affected them and what options were available. It is believed that the communication with patients by both the service and Infertility Network Scotland made the transition to the new pathway and criteria more understandable than it may have otherwise been.

6.5 The role of support organisations

117. 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.
118. The Scottish Government is funding Infertility Network Scotland¹⁴, 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.
119. Infertility Network Scotland's core role is to support patients undergoing treatment, and to work with NHS Boards to ensure a better patient experience.
120. Health Boards were surveyed in September 2009²⁶ to establish details of their provision of infertility services and what eligibility criteria were being used in each Health Board area. Following this, Infertility Network Scotland met with all Health Boards who were not meeting the current Government recommendations for patients needing to access fertility services with a view to establishing what plans they had to meet these recommendations. Staff from Infertility Network Scotland offered to provide patient representation at any Health Board meetings to discuss fertility services. Health Boards were surveyed recently, to establish what positive changes there had been for patients since the first survey, and Infertility Network Scotland is in the process of collecting these responses.
121. Health Boards should consult with organisations which represent patient views at meetings where provision of IVF services is being materially reviewed or changed.
122. There can be many hurdles to overcome before reaching the stage of having infertility treatment, as well as during and after treatment, whatever the outcome. Infertility Network has much experience of giving support to this group of patients and reports that emotional distress caused by infertility is heightened dramatically when patients find themselves unable to access the treatment they need, and find that access criteria and waiting times differ depending on where they live in Scotland.
123. Part of Infertility Network UK, the AceBabes network¹⁴ provides targeted help and support on a wide range of issues, not only to those people who have had successful fertility treatment, but also to those who found their families through other parenting options, including adoption.
124. Around one-third of those suffering from infertility will never become parents and More To Life, another part of the charity, 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.

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

125. There are 'hidden' costs associated with IVF. For example, in women who conceive twins (or more), the need for hospital based antenatal care, complicated vaginal deliveries and caesarean sections is higher and is associated with more frequent and longer maternal and neonatal hospital admissions. This can result in higher costs to the NHS with the 'care' cost of a twin pregnancy estimated at approximately three times the cost of a singleton pregnancy. Singletons born as a result of IVF are also more likely to require neonatal care. The average cost of caring for a baby in neonatal intensive care in the UK is around £1,000 a day²⁷.
126. There is strong evidence that the rise in recent years in the prevalence of twin births in the UK is related to fertility treatment, particularly IVF, in addition to an independent effect of rising maternal age. Data from the Human Fertilisation and Embryology Authority (HFEA)²⁸ shows in 2009 the multiple IVF birth rate following fresh embryo transfer in the UK was 22.4%. In comparison, one in eighty women who conceive naturally has a multiple birth.
127. The direct link between the number of embryos transferred to the uterus during IVF treatment and the chance of twin pregnancy is beyond dispute. An analysis of the factors contributing to high multiple pregnancy rates after IVF acknowledged that contracting arrangements for NHS-funded care influenced uptake of single embryo transfer policies within clinics.
128. The Human Fertilisation and Embryology Authority (HFEA) has introduced a graduated policy²⁸ insisting on all clinics in the UK achieving a reduction in multiple pregnancy rates to 10% of all births following IVF over a 3-year period. The final target which came into effect from October 2012 is 10%.
129. Elective single embryo transfer will undoubtedly reduce the incidence of twin pregnancy. However, there are concerns amongst providers that this will reduce pregnancy rates and potentially result in patients deciding to move to centres abroad who do not operate such a policy in the hope of improving their chances of pregnancy. All centres in the UK have to meet the HFEA target regardless of whether they are NHS or private centres. There is recent robust evidence (BMJ 2010; 341:c6945)⁹ 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. This concern will therefore be reduced if the definition of a cycle is recognised as set out above.
130. The four tertiary units 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. The principles at Appendix I underpin the advice which patients should receive about the appropriate number of embryos to transfer in a treatment cycle.

131. Recognising the importance of reducing risk to both mothers and children and requirements on reducing multiple births from the Human Fertilisation and Embryology Authority, NHS Lothian changed its treatment pathway for infertility in 2010.
132. This approach was drawn from the recommendations of a UK-wide expert group in 2006. This group, chaired by Professor Peter Braude, recommended that single embryo transfer should become the norm. The case for a transfer of a single blastocyst, in good prognosis patients, on day five or six is overwhelming, and frozen cycles should be used after each fresh embryo transfer to achieve equivalent pregnancy rates without the risks of multiple pregnancies.
133. The new approach was adopted despite a small anticipated reduction in success rates, as the change was felt to be a clinically appropriate given the high risks associated with multiple pregnancy.
134. However, 2 years on, this anticipated fall in success rates has not occurred. Indeed initial clinical data show the change in the pathway and the use of additional frozen embryos has led to a **higher** proportion of couples commencing a cycle successfully becoming pregnant in 2011 than had been the case prior to the change. The use of the subsequent frozen embryos appears to have more than compensated for the drop in pregnancy rate caused by moving significantly from the transfer of two embryos to one.
135. NHS Boards are advised to keep a careful eye on the increasing numbers of patients who have multiple frozen embryo transfers and the subsequent cost. This should be considered as part of the review in March 2015.
136. A recent report in the Lancet²⁹ (November 2012), recognised single embryo transfer in IVF as an important step in reducing early/ premature birth in developed countries.
137. Infertility Network Scotland¹⁴ developed a patient factsheet³⁰ on Single Embryo Transfer which is supplied to all four NHS IVF units in Scotland.
138. Further information on the benefits of elective single embryo transfer are set out on the HFEA website *One at a time*³¹.

7. Other areas on which we do not make recommendations

139. There were five areas which were discussed by the Group but where recommendations are not made because either they were considered to be outside the remit of the group or because there was insufficient evidence on which to make an authoritative recommendation.

7.1 Fertility preservation

- 140.** Patients who are to receive oncology treatments which are likely to compromise their fertility are clinically eligible for fertility preservation treatment. However, 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.
- 141.** SIGN Guideline 76: Long-term follow-up care of survivors of childhood cancer³² has made a big impact on numbers of patients seeking fertility preservation, and the Group foresees this trend increasing further over time. Additionally, there are treatments outwith oncology which impact on a patient's future fertility which will further increase the demand on this service.

7.2 Gamete donation

- 142.** Patients who require access to donated gametes (sperm or eggs) are currently not having their needs met. NHS Boards in Scotland are finding it increasingly difficult to manage recruitment of both egg and sperm donors.
- 143.** Initial discussions have taken place with the Scottish National Blood Transfusion Service regarding the possibility of providing gamete donation recruitment and storage nationally. This work will become stand alone once the National Infertility Group disbands at the end of January 2013, and further meetings will include representatives from each of the tertiary centres.
- 144.** Donor insemination and IVF with donor gametes is outwith the 12-month waiting time commitment.
- 145.** The Human Fertilisation and Embryology Authority (HFEA) conducted a consultation '*Donating sperm and eggs: have your say*', in early 2011³³, and in October 2011 set out new levels of compensation for sperm and egg donation services. 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. For egg donors this is triple the previous capped limit of £250, and this cost will need to be met by NHS providers. These are guidelines and whilst centres are allowed to pay these amounts, they are not obliged to do so.
- 146.** The HFEA also announced that, as a result of the consultation, it has agreed to take a proactive approach to donor recruitment, retention and care by working with the IVF sector, professional bodies and voluntary organisations to raise awareness, improve the care of donors and ensure that donation continues to take place within a safe and ethical environment.

7.3 Pre-implantation genetic diagnosis

147. The Scottish Pre-implantation Genetic Diagnosis (PGD) service³⁴ is centrally funded by National Services Division (NSD)¹ 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.

148. A short-life working group was convened in 2010 to define more clearly the access criteria for PGD, as it was not rigorously set out in the past. Members will ensure that NSD¹ is made aware of any decisions on access criteria made by the National Infertility Group.

7.4 Surrogacy IVF

149. IVF surrogacy is only provided where no other fertility treatment options are available to the couple, and the couple have been referred by a clinician as needing an IVF surrogacy cycle for medical reasons.

150. NHSScotland will not be involved in any of the process in identifying a surrogate or any financial or legal arrangements made between the surrogate and the genetic/commissioning couple. A patient can only be placed on the IVF waiting list once a surrogate has been identified.

- Surrogacy IVF should be provided to patients who meet the agreed access criteria.
- The age limit for couples needing surrogacy must be the same as that applied for IVF.
- Surrogates should meet all of the criteria applied to IVF, with one exception – they must have a child. The couple commissioning a surrogate must meet all of the access criteria without exception.

7.5 Intra-uterine insemination (IUI)

151. Over the course of the past 2¹/₂ years, the Group has discussed the provision and efficacy of intra-uterine insemination (IUI) many times, and has agreed the best way forward is to wait for publication of the NICE Fertility Guideline. Publication of the updated guideline is planned for 20 February 2013.

152. Previously, IUI was not covered by access criteria. However, as there is now a requirement for this procedure to be HFEA licensed, it could be argued that access criteria should now apply across Scotland, and NHS Greater Glasgow and Clyde currently do apply criteria. The Group considers that whilst NHS Boards across Scotland should apply consistent criteria for IUI, this should wait for the outcomes on IUI which are expected to be in the updated NICE Guideline on Fertility, when published.

8. What do we recommend?

8.1 Infertility in the context of the *Healthcare Quality Strategy for NHSScotland*

153. The 20:20 Vision provides the strategic narrative and context for taking forward the implementation of the *Healthcare Quality Strategy for NHSScotland*², and the required actions to improve efficiency and achieve financial sustainability. The National Infertility Group suggests the following Vision be considered for adoption by Ministers for all levels of infertility treatment: **“The NHS will provide equitable, timely investigation, intervention and/or support for couples with infertility needs.”**

154. The Group supports a further vision for IVF/ICSI treatment: **“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.”** The 20:20 Vision is what Scotland’s healthcare system will look like by the year 2020. In the context of infertility services, the National Infertility Group suggests the following as narrative for the approach we will take to achieve this:

- An integrated approach to infertility services, and more effective working with third sector organisations such as the Scottish Health Council³⁵ and Infertility Network Scotland¹⁴.
- A focus on prevention, and being aware of the risks of infertility and declines of fertility.
- When hospital treatment is required, and cannot be provided in a community setting, day case treatment should be the norm and it should be provided in the place which can guarantee highest quality, safety and a good experience.
- A focus on ensuring that people get back into their home or community environment as soon as appropriate, with minimal risk of re-admission.
- Care will be provided to the highest standards of quality and safety.

155. The Group’s Vision fits well with the manifesto commitment made by the Scottish Government 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.”**

8.2 Raising awareness of the risk of infertility in the general population

156. It is important that women are made aware of the age-related decline in their fertility and the increased risk of maternal and fetal complications associated with obesity and smoking.

157. 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.

158. 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 treatment in secondary care.

8.3 Improving the pathway of care

- 159.** This would, in turn, lead to an appropriate streamlined referral system beginning with Primary Care providers within Scotland, where lifestyle advice is given and basic investigations carried out prior to onward referral. In secondary care services more complex investigations may be undertaken, with appropriate treatment provided in a timely and cost-effective manner. Thereafter couples requiring tertiary care services, including IVF, are referred to specialist centres appropriately and timeously.
- 160.** An Infertility Referral Pathway and explanatory notes have been developed showing the expected pathway from primary to secondary care, with a further pathway outlining secondary to tertiary care. These have been updated to reflect access criteria as agreed by the Group, and have been amended to reflect comments from BMA Scotland, 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.
- 161.** 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. The Pathways should be refreshed as necessary, in line with the 2015 review.
- 162.** The Group recommends that a meeting is held with regional leads in secondary care in early 2013 to ensure that the Pathways are used in all Board areas.
- 163.** Further discussions should take place within NHS Boards to ensure that GPs are made aware of forthcoming changes to access criteria, in particular, support in weight loss and smoking cessation, and how they can support patients who need to make lifestyle changes to access treatment.
- 164.** The Pathways are set out in full at Appendix J.

8.4 Better patient support

- 165.** The Group recommends a more person centred approach with the patient's needs seen within the context of various other services including where necessary smoking cessation, weight management, and eventually maternity services for many couples. The Group's Pathways documents will help with some of this.
- 166.** NHS Boards and patient groups should develop a more joined up and collaborative approach with clearer roles and responsibilities, as improvement in this area is likely to improve public confidence overall as well as the patient experience.
- 167.** The illustration given earlier in the report at 6.4 of NHS Lothian and Infertility Network Scotland is a good example of collaborative working.

8.5 The same criteria for all Health Boards

168. It will no longer be acceptable for Boards to have different criteria in different areas. There will be no equity if Boards maintain separate access criteria and the Scottish Government should put in place robust plans so that a single agreed set of national access criteria for Scotland is in place and stays in place.

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

8.6.1 Definition of 'one cycle of IVF'

169. The report from EAGISS⁶ set out the number of NHS funded cycles of IVF for eligible patients as: Couples meeting the above eligibility criteria should be entitled to a maximum of three NHS funded cycles of assisted conception. Each couple should be entitled to a minimum of two transfers of fresh embryos obtained following a full cycle of down-regulation, ovarian stimulation and egg recovery. Where frozen embryos are available, the third NHS funded cycle should involve transfer of stored embryos.

170. The National Infertility Group has reached agreement 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."**

171. Whilst the Group understands that all NHS Boards across Scotland have voluntarily moved to this definition, we believe that it should remain a recommendation.

8.6.2 Definition of waiting time

172. We recommend the following definitions of the waiting time for IVF treatment after treatment:

- **Clock starts** when tertiary care agrees that treatment is required and all access criteria are fulfilled.
- **Clock stops** when the couple reaches the top of the waiting list and is seen for screening and consent.

173. Time between clock starting and stopping should be no more than 12 months and is the 'Waiting time'.

174. Data should measure the Waiting time, but also:

- time from referral from secondary care to the point of clock starting, and time from the clock stopping until first administration of the medical drug used to initiate the treatment cycle. If large variations exist in these additional measurements, then the pathways may need to be reviewed, and service development/re-design be considered. The short life Data Group should help to define these measurements.

175. Couples must fulfil all of the access criteria before being placed on the waiting list, including recommended BMI and non-smoking criteria. Smoking status should not rely on patient report but should be assessed using a cotinine test, which indicates nicotine use in the previous few days. It is important that couples do not reach IVF tertiary centres unless they meet all access criteria.

8.7 Recommended criteria for treatment and the date of introduction

176. The Group has considered criteria for tertiary level treatment only, examining current evidence of clinical effectiveness and best practice alongside the care dimensions of the *Quality Strategy*² and 20:20 Vision. The Group has also considered, where appropriate, obstetric, fetal and neonatal risks, along with the Scottish Government's National Outcome of giving every child the best possible start in life. The recommendations are based on the assumption that patients must be ready for treatment, and therefore must meet all criteria before they can be referred:

8.7.1 Definition of infertility for couples

- Infertility with an appropriate cause, of any duration
- or**
- Unexplained infertility of 2 years – heterosexual couples
 - Unexplained infertility following six to eight cycles of donor insemination – same sex couples

IVF treatment should be offered to couples who meet all of the following criteria:

8.7.2 Welfare of the child

- The HFE Act¹² 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.”

8.7.3 Sterilisation

- Neither partner to have undergone voluntary sterilisation.
- Couples who have undertaken a sterilisation reversal, even if paid for privately, will not be offered treatment.

8.7.4 Stable relationship

- Couples must have been co-habiting in a stable relationship for a minimum of 2 years.

8.7.5 Other medical conditions

- GPs and treating clinicians must take into account other medical conditions and offer pre-conception counselling with an appropriate specialist if required.

8.7.6 Previous or existing children

- **One partner has no genetic child** – this will eliminate cases where one partner is disadvantaged because their partner has a genetic child. A caveat should be added stating that if a woman has previously given up a child for voluntary adoption, then she would remain eligible for treatment.
- However, both partners must meet all other criteria without exception, including neither partner previously sterilised or received the maximum number of IVF treatment cycles in a previous relationship.

Members of the Group aspire to this as a criterion. However, until equity and reasonable waiting times are established along with further evidence on the effects this may have on the service, the Group's recommendation is to keep the current criterion.

- Currently the criterion that there should be no child in the home, as outlined in EAGISS⁶, stands.

8.7.7 Smoking, alcohol and drugs*

- Both partners must be non-smoking for at least 3 months before treatment and continue to be 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 treatment.
- Neither partner should drink alcohol prior to or during the period of treatment.

*There is a responsibility on patients to follow these access criteria which are in the interest of the welfare of the child and the effectiveness of treatment. Clinicians may conduct testing to ensure that patients adhere to the criteria, and in the event of a positive result, the patient will not be given treatment.

Where there is a known history of former drug addiction, alcohol abuse or domestic violence, patients must receive appropriate counselling prior to being referred as suitable for treatment, and will still be required to meet the welfare of the child criteria. NHS Boards should ensure engagement with the appropriate counselling services.

8.7.8 Body Mass Index (BMI)

- BMI of female partner must be above 18.5 and below 30. Couples should be advised that a normal BMI is best for both partners.

The International Classification of adult underweight, overweight and obesity according to BMI:

- BMI less than 18.5 – underweight
- BMI between 18.5 and 24.9 – normal weight
- BMI between 25.0 and 29.9 – overweight
- BMI 30.0 or above – obese
- Source: World Health Organization³ website.

8.7.9 Age – female

- 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.

8.7.10 Equalities Act

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. NHS Boards should be advised to reconsider their current policy in the light of the Equalities Act (2010)³⁶. The requirement of the Act has to be balanced against the duty of licensed provider units under the HFE Act¹². An extract from the welfare of the child provision is set out below.

- No treatment services regulated by the HFEA (including intra-uterine insemination – IUI) 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.

8.8 Number of cycles

- 177.** Eligible patients may be offered up to three cycles of IVF/ICSI where there is a reasonable expectation of a live birth. Clinical judgement should be used to determine this.

However, until equity and reasonable waiting times are established across Scotland, and the implications of new pathways and new definitions are understood, the Group's recommendation is to constrain this to up to 2 cycles of IVF/ICSI where there is a reasonable expectation of a live birth. Clinical judgement should be used to determine this.

- 178.** Response to treatment must be clinically assessed at the end of each cycle. Where indications are that treatment is unlikely to be clinically effective, no further treatment will be given.
- 179.** An assessment of ovarian reserve should be performed before the first cycle. If this is judged to be poor (e.g. low AMH, or low antral follicle count, or high FSH) eligible patients can be offered one cycle of treatment, if, in the treating clinician's view, it is in the patients' interest. This is on the understanding that, if there is no response to stimulation or a poor response (<3 eggs retrieved), no further IVF/ICSI treatment will be offered.

8.8.1 Previous cycles – NHS

- 180.** 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.
- 181.** 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.

8.8.2 Previous cycles – self-funded

182. 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.

8.8.3 Frozen embryos

183. 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.

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

8.9 Waiting list management

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

- Normally, there would be a gap of 6 to 11 months between cycles of IVF, for patients who remain eligible.

8.10 Increased activity within current capacity to reduce waiting times

186. The Scottish Government has established funding to support the 12-month waiting time for IVF and will include it as a HEAT target for the period 2013-15 to underpin the commitment.

187. Individual level data cannot be collected, therefore, anonymised aggregate data tables will be collected from each of the four units. The Scottish Government and Information Services Division¹ will continue to discuss the detail of this during 2013.

8.11 Communication

188. A short Communications plan has been produced, with key themes to be transmitted by the Government once the recommendations of the National Infertility Group have been considered by Ministers. These themes take into account the various stakeholders with an interest, namely, NHS Boards, fertility practitioners, general practitioners and the general public.

189. This plan provides a clear framework to help ensure that stakeholders have access to the right information about all aspects of the provision of infertility treatment in Scotland. An essential role will be around education and health promotion, including educating the public about the 'lifespan' of their fertility. Diet and lifestyle measures can improve the natural chance of conception as well as the chance of success of any treatment, and furthermore reduce risks to the pregnancy.

9. Summary of recommendations

Infertility Treatment Vision

- The National Infertility Group suggests that the following Vision be considered for adoption by Ministers for all levels of infertility treatment:
“The NHS will provide equitable, timely investigation, intervention and/or support for couples with infertility.”

Vision for IVF

- The National Infertility Group suggest that the following Vision be considered for adoption by Ministers for IVF/ICSI treatment:
“The NHS will meet the needs of all eligible infertile couples within 12 months of being diagnosed as requiring IVF or ICSI treatment.”

Increased investment announced by Scottish Government Ministers, has been made available to enable this to be achieved by March 2015.

Definition of a Cycle of IVF

- The Group recommends that NHS Boards should be advised that the definition of a cycle is considered to be one which includes the replacement/transfer of any viable embryos which have been frozen and stored after the fresh cycle, provided the couple still fulfil access criteria.

Single Embryo Transfer Core Principles

- The Group recommends that NHS Boards are advised that there is now a national set of core principles on single embryo transfer. These principles have been agreed by representatives of all four tertiary centres and should be used.

Equalities Act

- The Group recommends that NHS Boards 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. NHS Boards should be advised to reconsider their current policy in light of the Equalities Act (2010)⁴⁸, taking into account the ‘welfare of the child’ provision in the HFE Act 2008⁴⁹.

Preventative Work

- The Group further recommends that any central funding for infertility services includes a sum for preventative work, aimed at highlighting the risks to fertility of delayed conception and health related behaviours.

Gametes

- The National Infertility Group recommends a stand alone Group to look at the provision of Gametes in the NHS in Scotland. A representative from each of the four NHS centres should be involved in this work. The Group has suggested some further work around fertility preservation which could also be considered by a Gametes Group.

9.1 Information to NHS Boards

- The National Infertility Group recommends the Scottish Government drafts new guidance for NHS Boards to complement this work and the forthcoming waiting time, but separately and urgently gives new access criteria, in the form of a Chief Executive Letter to NHS Board Chief Executives, to be implemented by 1 April 2013, to NHS Boards.
- The Group recommends that a meeting is held with regional leads in secondary care during spring 2013 to ensure that the Pathways are used in all NHS Board areas.

9.2 Implementation of criteria

- 190.** All new patients from 1 April 2013 must meet all criteria. The Group recognises that criteria changes will have an impact on some existing patients, and this needs to be handled sensitively by NHS Boards, who are ultimately responsible for meeting the needs of their patients. NHS Boards should ensure consistency in their approach.
- 191.** Timing of the implementation of new criteria is key, and the Group recommends a phased approach to implementation. The Group accepts that patients in some areas may find some of the recommendations difficult, but the majority will benefit over the next few years.
- 192.** Scottish Government Ministers and NHSScotland will need to be satisfied that the four NHS Centres have the appropriate support, funding and capacity beyond the £12 million committed by the Scottish Government.
- 193.** The sustainability of NHS IVF provision is essential for the success of the phased approach set out below. Scottish Government funding should remove the current backlog to achieve a 12-month waiting time. But the long term sustainability of both the 12-month waiting time commitment, and changes to eligibility criteria, will need recurring funds from the Scottish Government along with further investment by Boards to ensure that no matter where couples live in Scotland, they will be able to access the same level of service.
- 194.** The National Infertility Group recognises that three full cycles of IVF gives patients the optimum chance of a live birth and the Group remains committed to the implementation of this criterion across Scotland. However, due to long waiting times, and uncertainty regarding the impact of new treatment pathways, it is recommended that up to two full cycles of treatment be the normal pathway for couples from 1 April 2013. This is already the case for 80% of couples across Scotland. Phasing in new access criteria recommendations over the coming years, including moving to three cycles of treatment, will give NHSScotland time and capacity to recover waiting times and establish equity.

9.3 Definition of infertility from 1 April 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

9.4 Access criteria recommendations for all couples from 1 April 2013

- 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 non-smoking for at least 3 months before treatment and continue to be 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 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.
- 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 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 6 to 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.

9.5 Phasing in of further criteria

- 195.** Group recommends a short focused review at end March 2015 to reflect on the implementation of the access criteria changes from 1 April 2013 and emerging clinical evidence in light of new treatment pathways, and also to consider the recurring service cost before any further criteria, including a third cycle of treatment are implemented.
- 196.** Consideration should be given to an earlier review if waiting times have reduced to 12 months across Scotland, and modelling proves quickly to be too conservative.
- 197.** The Group is keen to introduce the following criteria, when affordable and suggests the 2015 review proposes a timescale for further reassessment.

The recommended next step would be adoption by all NHS Boards of:

- 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 genetic child – as long as all further criteria are met by both partners

Currently the criterion that there should be no child in the home, as outlined in EAGISS, stands.

It is important that decisions on these criteria introductions should be taken at national level to ensure that equity is retained across Scotland as services are expanded.

Appendix A

Waiting times modelling scenarios

Discrete events simulation modelling led by Glasgow University

Key model assumptions

- The time between consecutive referrals follows an exponential distribution.
- Each unit operates for 46 weeks per year
- Pregnancy/treatment success is age-dependent, based on HFEA data.
- Treatment can only commence when there is sufficient capacity within the unit
- Patients are treated on a first-come, first served basis.
- Given sufficient funding, NHS-funded patients take precedence over self-funded patients.
- Reducing the NHS waiting time results in fewer people choosing to self fund.

Selection of scenarios considered by the Group

Scenario 1: 2013: Three cycles, re-enter at front, BMI / smoking, age < 40.

Scenario 2: 2013: Two cycles, re-enter at front, BMI / smoking, age < 40.

Scenario 3: 2013: Three cycles, re-enter at front, BMI / smoking, age < 38.

Scenario 4: 2013: Three cycles, re-enter at front, BMI / smoking, age < 40, 2015: One partner has no genetic child.

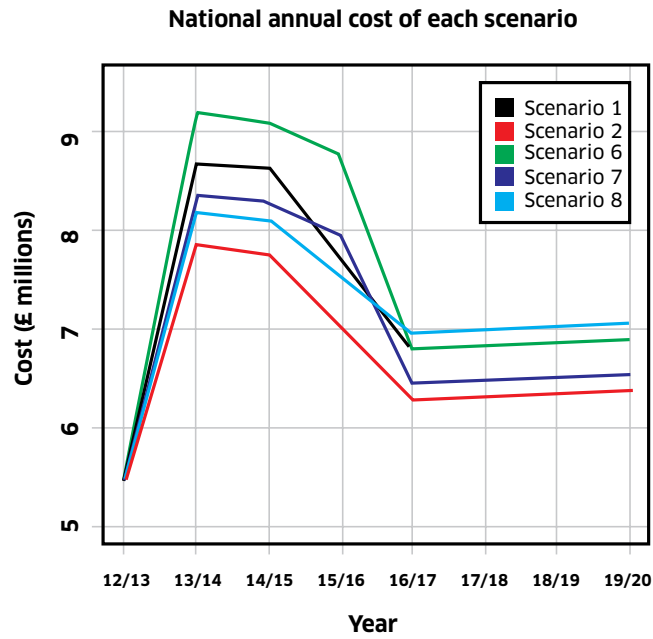
Scenario 5: 2013: Three cycles, re-enter at back, BMI / smoking, age < 40.

Scenario 6: 2013: Three cycles, re-enter at front, BMI / smoking (no purging), age < 40.

Scenario 7: 2013: Two cycles, re-enter at front, BMI / smoking (no purging), age < 40.

Scenario 8: 2013: Two cycles, re-enter at front, BMI / smoking, age < 40, 2015: Three cycles.

Scenarios considered in more detail by the Group

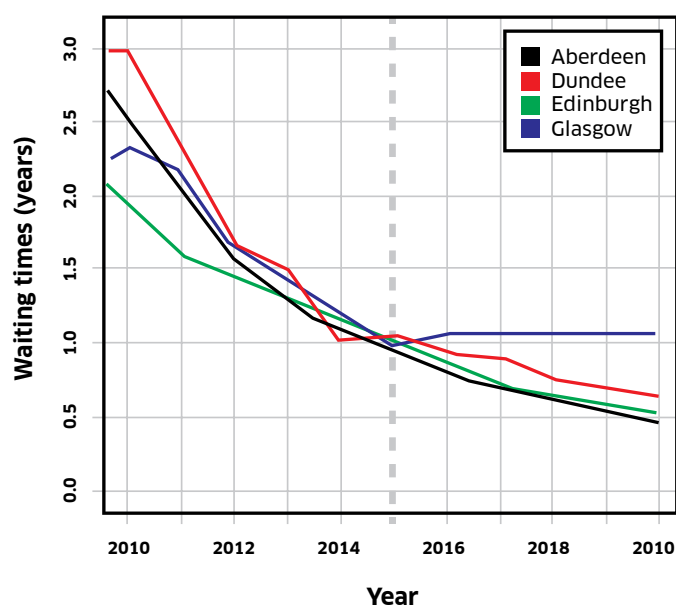


	Scenario 1	Scenario 2	Scenario 6	Scenario 7	Scenario 8
Total cost ((2013-2015)	17,310,496	15,647,868	18,306,125	16,645,561	16,388,007
Average annual cost (2015-2020)	6,963,338	6,854,988	7,215,007	6,782,807	7,084,477

Scenario recommended from 1 April 2013

Scenario 2 - waiting time upper limits

National annual cost of each scenario

**Scenario 2 - National**

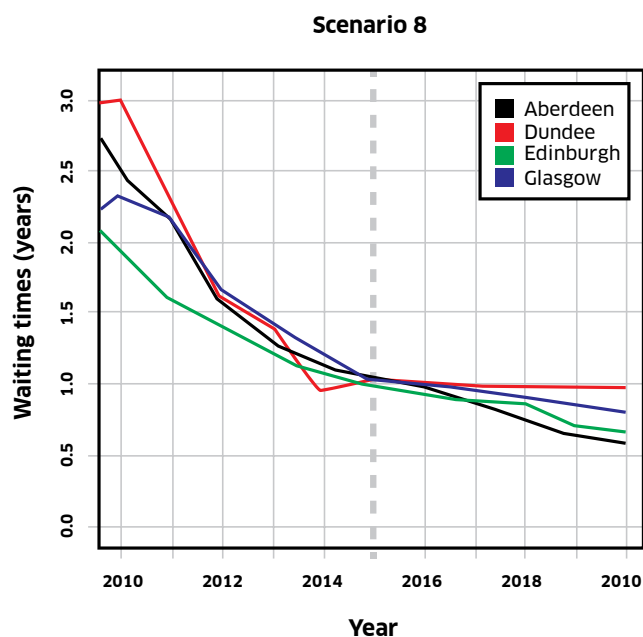
Board	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20
Aberdeen	300 (294,302)	322 (322,322)	322 (322,322)	276 (276,276)	276 (276,276)	276 (276,276)	282 (280,282)	275 (262,276)
Dundee	264 (255,278)	558 (522,564)	552 (552,552)	414 (414,414)	414 (414,414)	414 (414,414)	414 (414,414)	423 (423,423)
Edinburgh	224 (215,228)	322 (322,322)	322 (322,322)	322 (322,322)	322 (322,322)	322 (322,322)	329 (329,329)	322 (322,322)
Glasgow	724 (724,724)	982 (966,987)	966 (966,966)	966 (966,966)	736 (736,736)	736 (736,736)	736 (736,736)	752 (752,752)
National	1513 (1498,1529)	2185 (2162,2195)	2162 (2162,2162)	1978 (1978,1978)	1748 (1748,1748)	1748 (1748,1748)	1761 (1759,1761)	1772 (1759,1773)
Preg/cycle	0.26	0.27	0.27	0.28	0.27	0.26	0.26	0.26

Mean number of cycles performed (with 95% confidence interval) and success rate

Board	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20	Total
Aberdeen	1,078,668	1,159,200	1,159,200	993,600	993,589	993,496	1,014,440	990,644	
Dundee	952,139	2,009,189	1,987,200	1,490,400	1,490,400	1,490,400	1,490,400	1,522,800	
Edinburgh	808,052	1,159,200	1,159,200	1,159,200	1,159,200	1,159,200	1,184,400	1,159,171	
Glasgow	2,606,400	3,536,892	3,477,600	3,477,600	2,649,600	2,649,600	2,649,600	2,707,200	
National	5,445,259	7,864,481	7,783,200	7,120,800	6,292,789	6,292,696	6,338,840	6,379,816	53,517,881

Mean cost (£), assuming £3,600 per treatment cycle

Scenario 8 - waiting time upper limits



Scenario 8 - National

Board	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20
Aberdeen	300 (294,302)	368 (368,368)	368 (368,368)	322 (322,322)	322 (322,322)	322 (322,322)	329 (329,329)	322 (318,322)
Dundee	265 (255,279)	603 (598,611)	598 (598,598)	460 (460,460)	460 (460,460)	460 (460,460)	460 (460,460)	470 (470,470)
Edinburgh	224 (215,228)	322 (322,322)	322 (322,322)	322 (322,322)	322 (322,322)	322 (322,322)	329 (329,329)	322 (322,322)
Glasgow	724 (724,724)	982 (966,987)	966 (966,966)	966 (966,966)	828 (828,828)	828 (828,828)	828 (828,828)	846 (846,846)
National	1513 (1498,1530)	2275 (2254,2288)	2254 (2254,2254)	2070 (2070,2070)	1932 (1932,1932)	1932 (1932,1932)	1946 (1946,1946)	1960 (1956,1960)
Preg/cycle	0.26	0.27	0.27	0.27	0.27	0.27	0.27	0.27

Mean number of cycles performed (with 95% confidence interval) and success rate

Board	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20	Total
Aberdeen	1,078,668	1,324,800	1,324,800	1,159,200	1,159,200	1,159,142	1,184,288	1,157,753	
Dundee	954,738	2,170,937	2,152,800	1,656,000	1,656,000	1,656,000	1,656,000	1,692,000	
Edinburgh	808,052	1,159,200	1,159,200	1,159,200	1,159,200	1,159,200	1,184,400	1,159,200	
Glasgow	2,606,400	3,533,670	3,477,600	3,477,600	2,980,800	2,980,800	2,980,800	3,045,600	
National	5,447,858	8,188,607	8,114,400	7,452,000	6,955,200	6,955,142	7,005,488	7,054,553	57,173,248

Mean cost (£), assuming £3,600 per treatment cycle

All modelling will be available to view, from 10 May 2013, at:

<http://www.scotland.gov.uk/infertility>

Appendix B

Economic modelling

All modelling will be available to view, from 10 May 2013, at:
<http://www.scotland.gov.uk/infertility>

Summary costs for all Scotland	Column reference	Cost	Increase/Decrease from A. current cost	%	Increase/Decrease from B. expected cost	%
A. Current cost per annum of NHS IVF based on the number of cycles of NHS funded IVF performed during 2011/12	12	£4.92				
B. Expected cost if all eligible patients referred per annum were able to have NHS funded IVF (i.e. no waiting list)	13	£10.07				
Single scenarios						
Cost of NHS IVF if age criteria extended to <40	15	£10.16	£5.23	106%	£0.09	1%
Costs if criteria restricted for BMI and Smoking (adjusted)	16	£7.27	£2.35	48%	-£2.79	-28%
Costs if criteria restricted for BMI and Smoking (alternative adjustment for stopping smoking/losing weight)	17	£7.78	£2.85	58%	-£2.29	-23%
Costs if criteria allowed for 2 cycles	18	£10.11	£5.19	105%	£0.05	0%
Costs if criteria allowed for 3 cycles	19	£13.08	£8.15	166%	£3.01	30%
Costs if waiting list reduced to 12 months	20	£11.07	£6.15	125%	£1.01	10%
Costs if criteria adjusted for no genetic child	21	£11.78	£6.85	139%	£1.71	17%
Costs if consistent parameters across centres	22	£10.44	£5.52	112%	£0.38	4%
Combination scenarios						
Base ('B.' plus increase of 10% for reduced wait)		£11.07				
Scenario 1 (BMI/Smoking*, 2 cycles, reduced wait)	23	£8.58	£3.65	74%	-£1.49	-15%
Age, BMI/Smoking, 2 cycles	24	£7.87	£2.94	60%	-£2.20	-22%
Age, BMI/Smoking, 3 cycles	25	£10.17	£5.25	107%	£0.10	1%
Age, BMI/Smoking, 2 cycles, reduced wait	26	£8.65	£3.73	76%	-£1.41	-14%
Age, BMI/Smoking, 3 cycles, reduced wait	27	£11.19	£6.26	127%	£1.12	11%
Age, BMI/Smoking, No genetic child, 2 cycles	28	£9.20	£4.28	87%	-£0.86	-9%
Age, BMI/Smoking, No genetic child, 3 cycles	29	£11.90	£6.97	142%	£1.83	18%
Age, BMI/Smoking, No genetic child, reduced wait, 2 cycles	30	£10.13	£5.20	106%	£0.06	1%
Age, BMI/Smoking, No genetic child, reduced wait, 3 cycles	31	£13.09	£8.16	166%	£3.02	30%
Scenario 2 (BMI/Smoking*, age, no genetic child, reduced wait, 3 cycles)	32	£12.92	£7.99	162%	£2.85	28%

	1	2	3	4	5	6	7	8	9	10
Baseline inputs	Population (mid year est 2011)	Rate of couples presenting at GP surgery per 1,000	Number of couples expected to present at GP surgery	Number expected to be referred on for 2ary or 3ary treatment (71%)	Number expected to have IVF (patients) (53%)	% NHS	Number expected to have NHS IVF treatment (patients)	Average number of cycles per patient	Number expected to have NHS IVF treatment (cycles)	Actual number (2011/2012) having NHS IVF (cycles)
Glasgow										
Glasgow	1,210,254	1.51	1823	1294	687	64%	440	1.70	749	388
Lanarkshire	563,185	1.47	829	588	312	64%	200	1.70	341	185
Ayrshire & Arran	366,890	1.58	580	412	219	64%	140	1.70	238	118
Dumfries & Galloway	148,060	0.84	124	88	47	64%	30	1.70	51	33
Edinburgh										
Lothian	848,727	1.60	1358	964	512	43%	220	1.60	352	195
Borders	113,150	1.65	187	133	70	43%	30	1.60	48	33
Aberdeen										
Grampian	555,280	1.13	625	444	236	51%	120	2.20	265	120
Highland	311,960	1.00	312	221	118	51%	60	2.20	132	70
Orkney	20,160	2.32	47	33	18	51%	9	2.20	20	12
Shetland	22,500	1.85	42	30	16	51%	8	2.20	18	10
Dundee										
Fife	367,292	2.20	808	574	305	46%	140	1.50	211	55
Forth Valley	295,541	2.53	748	531	282	46%	130	1.50	195	54
Tayside	405,721	1.56	633	449	239	46%	110	1.50	165	85
Western Isles	26,080	1.67	44	31	16	46%	8	1.50	11	10
Scotland	5,254,800		8,158	5,792	3,077		1,645		2,796	1,368
Centre totals										
Glasgow	2,288,389		3,356	2,383	1,266		810		1,379	724
Edinburgh	961,877		1,545	1,097	583		250		401	228
Aberdeen	909,900		1,025	728	387		197		434	212
Dundee	1,094,634		2,232	1,585	842		387		582	204
Scotland	5,254,800		8,158	5,792	3,077		1,645		2,796	1,368

	11	12	13	14	15	16	16*	17	18	19	20	21
Costs	Average cost of IVF cycle (£)	Baseline cost of NHS IVF (£M)	Costs of NHS IVF if all eligible couples treated (baseline criteria) (£M)	Increase in demand for NHS IVF if age criteria extended to <40 years	Cost of NHS IVF if age criteria extended to <40	Costs if criteria restricted for BMI and smoking (allowing for stopping/losing weight)	Costs if criteria restricted for BMI and smoking (no allowance for stopping/losing)	Costs if cycles set to max. of 2 (Actual ave 1.69-1.72))	Costs if cycles set to max. of 3 (Actual ave 2.17-2.24)	Cost if NHS demand increases by 10% due to reduced waiting list	Cost if NHS demand increases by 17% due to one partner has no genetic child	Cost if parameters across centres were consistent
		(Costs of actual cycles of NHS IVF, as at end 2011)	(Costs of expected cycles of NHS IVF)									
Glasgow												
Glasgow	3,600	£1.40	£2.70	0%	£2.70	£1.81	£2.00	£2.71	£3.50	£2.97	£3.16	£2.41
Lanarkshire	3,600	£0.67	£1.23	0%	£1.23	£0.82	£0.91	£1.23	£1.59	£1.35	£1.43	£1.12
Ayrshire & Arran	3,600	£0.42	£0.86	0%	£0.86	£0.58	£0.64	£0.86	£1.11	£0.94	£1.00	£0.73
Dumfries & Galloway	3,600	£0.12	£0.18	0%	£0.18	£0.12	£0.14	£0.18	£0.24	£0.20	£0.22	£0.29
Edinburgh												
Lothian	3,600	£0.70	£1.27	0%	£1.27	£1.27	£1.27	£1.34	£1.72	£1.40	£1.48	£1.69
Borders	3,600	£0.12	£0.17	0%	£0.17	£0.17	£0.17	£0.18	£0.24	£0.19	£0.20	£0.22
Aberdeen												
Grampian	3,600	£0.43	£0.95	0%	£0.95	£0.58	£0.75	£0.73	£0.94	£1.05	£1.11	£1.10
Highland	3,600	£0.25	£0.48	0%	£0.48	£0.29	£0.38	£0.37	£0.47	£0.52	£0.56	£0.62
Orkney	3,600	£0.04	£0.07	0%	£0.07	£0.04	£0.06	£0.05	£0.07	£0.08	£0.08	£0.04
Shetland	3,600	£0.04	£0.06	0%	£0.06	£0.04	£0.05	£0.05	£0.06	£0.07	£0.07	£0.04
Dundee												
Fife	3,600	£0.20	£0.76	12%	£0.85	£0.56	£0.52	£0.87	£1.13	£0.83	£0.89	£0.73
Forth Valley	3,600	£0.19	£0.70	0%	£0.70	£0.52	£0.48	£0.80	£1.05	£0.77	£0.82	£0.59
Tayside	3,600	£0.31	£0.59	0%	£0.59	£0.44	£0.40	£0.68	£0.89	£0.65	£0.69	£0.81
Western Isles	3,600	£0.04	£0.04	0%	£0.04	£0.03	£0.03	£0.05	£0.06	£0.04	£0.05	£0.05
Scotland		£4.92	£10.07		£10.16	£7.27	£7.78	£10.11	£13.08	£11.07	£11.78	£10.44

	23 Scenario 1 BMI/ smoking (non- adjusted), 2 cycles	24 Combination of age, BMI/ smoking, 2 cycles	25 Combination of age, BMI/ smoking, 3 cycles	26 Combination of age, BMI/ smoking, 2 cycles, reduced wait	27 Combination of age, BMI/ smoking, 3 cycles, reduced wait	28 Combination of age, BMI/ smoking, genetic child, 2 cycles	29 Combination of age, BMI/ smoking, genetic child, 3 cycles	30 Combination of age, BMI/ smoking, genetic child, reduced wait, 2 cycles	31 Combination of age, BMI/ smoking, genetic child, reduced wait, 3 cycles	32 Combination of age, BMI/ smoking*, genetic child, reduced wait, 3 cycles
Glasgow										
Glasgow	£2.20	£2.00	£2.59	£2.20	£2.85	£2.34	£3.03	£2.58	£3.34	£3.29
Lanarkshire	£1.00	£0.91	£1.18	£1.00	£1.30	£1.07	£1.38	£1.17	£1.52	£1.50
Ayrshire & Arran	£0.70	£0.64	£0.82	£0.70	£0.91	£0.75	£0.96	£0.82	£1.06	£1.05
Dumfries & Galloway	£0.15	£0.14	£0.18	£0.15	£0.19	£0.16	£0.21	£0.18	£0.23	£0.22
Edinburgh										
Lothian	£1.48	£1.34	£1.72	£1.48	£1.89	£1.57	£2.01	£1.73	£2.22	£2.19
Borders	£0.20	£0.18	£0.24	£0.20	£0.26	£0.22	£0.28	£0.24	£0.30	£0.30
Aberdeen										
Grampian	£0.64	£0.58	£0.75	£0.64	£0.82	£0.68	£0.87	£0.75	£0.96	£0.95
Highland	£0.32	£0.29	£0.37	£0.32	£0.41	£0.34	£0.44	£0.37	£0.48	£0.47
Orkney	£0.05	£0.04	£0.06	£0.05	£0.06	£0.05	£0.07	£0.06	£0.07	£0.07
Shetland	£0.04	£0.04	£0.05	£0.04	£0.05	£0.05	£0.06	£0.05	£0.06	£0.06
Dundee										
Fife	£0.65	£0.66	£0.86	£0.73	£0.95	£0.77	£1.01	£0.85	£1.11	£1.09
Forth Valley	£0.60	£0.55	£0.71	£0.60	£0.78	£0.64	£0.83	£0.70	£0.92	£0.90
Tayside	£0.51	£0.46	£0.60	£0.51	£0.66	£0.54	£0.70	£0.60	£0.78	£0.77
Western Isles	£0.04	£0.03	£0.04	£0.04	£0.05	£0.04	£0.05	£0.04	£0.05	£0.05
Scotland	£8.58	£7.87	£10.17	£8.65	£11.19	£9.20	£11.90	£10.13	£13.09	£12.92
Centre totals										
Glasgow	£4.06	£3.69	£4.77	£4.06	£5.25	£4.31	£5.58	£4.75	£6.14	£6.06
Edinburgh	£1.68	£1.53	£1.96	£1.68	£2.15	£1.79	£2.29	£1.96	£2.52	£2.49
Aberdeen	£1.05	£0.95	£1.22	£1.05	£1.34	£1.11	£1.43	£1.22	£1.57	£1.55
Dundee	£1.80	£1.70	£2.22	£1.87	£2.44	£1.99	£2.59	£2.19	£2.85	£2.82
Scotland	£8.58	£7.87	£10.17	£8.65	£11.19	£9.20	£11.90	£10.13	£13.09	£12.92

Notes

Figures are subject to change as centres are still verifying parameters.

Column ref

1	Population of NHS Board, Mid-year estimate 2011 from NRS http://www.gro-scotland.gov.uk/statistics/theme/population/estimates/mid-year/index.html
2	Rate of couples presenting at GP surgery per 1,000 population Rates are based on centres knowledge of the numbers of patients being referred for IVF
3	Number of couples expected to present at GP surgery Calculated from columns 1 and 2.
4	Number expected to be referred on for 2ary or 3ary treatment (71%) Figure of 71% taken from the Merck Serono model.
5	Number expected to have IVF (patients) (53%) Figures are based on a decision tree process used in the Merck Serono model which calculates the numbers expected to be referred through 2ary to 3ary and then onto IVF and also those expected to be referred straight to 3ary and then on for IVF.
6	% NHS This is the percentage of the population of the NHS Board that have NHS funded IVF. The denominator is all women in the NHS Board that have IVF (including those going to private clinics and those that self fund).
7	Number expected to have NHS IVF treatment (patients) Calculated from columns 5 and 6.
8	Average number of cycles per patient This is calculated from data collected from the boards at the end of 2011 on the numbers of patients having treatment and the numbers of cycles they received.
9	Number expected to have NHS IVF treatment (cycles) This represents all women who would be expected to be referred for NHS IVF annually if there were no restriction on waiting time. Calculated from columns 7 and 8.
10	Actual number (2011/2012) having NHS IVF (cycles) This is the actual number of cycles performed during the 2011/12 period, and has been provided by the centres.
11	Average Cost of IVF cycle (£) The average cost of a cycle of IVF has been calculated using recent data from NHS Boards for total costs for NHS IVF and the number of NHS cycles performed. The figure has been compared to costs used in the NICE consultation and is comparable to the cost stated for one fresh cycle plus a proportion of patients (25%) also receiving a frozen embryo transfer. http://www.nice.org.uk/nicemedia/live/12157/59278/59278.pdf As this figure is based on an average cost it may be that it is not reflective of the costs of incremental cycles.

12	<p>Baseline Cost of NHS IVF (£M)</p> <p>This represents the current cost of NHS IVF and is calculated from the number of NHS cycles performed in 2011/12 and the average cost of a cycle (columns 10 and 11).</p>
13	<p>Costs of NHS IVF if all eligible couples treated (baseline criteria) (£M)</p> <p>This represents the cost if all eligible couples who are referred for NHS funded IVF (under current access criteria) were to be treated, assuming no waiting list. Calculated from columns 9 and 11.</p>
14	<p>Increase in demand for NHS IVF if age criteria extended to <40 years</p> <p>Many centres are already treating women up to the age of 40 years, however, due to the length of the waiting list, some women do not get treatment as they reach the age cut off whilst on the waiting list.</p> <p>It is difficult to measure precisely the impact on numbers for each centre and therefore approximate increases have been estimated based on the current length of the waiting list.</p> <p>Boards whose age cut off is currently <38 years (NHS Fife) are assumed to experience a 12% increase in NHS demand once the age range is extended to <40years.</p>
15	<p>Cost of NHS IVF if age criteria extended to <40</p> <p>Calculated based on columns 9, 11 and 14.</p>
16	<p>Costs if criteria restricted for BMI and smoking (allowing for stopping/losing weight)</p> <p>Data on numbers of women having IVF who smoke or are outwith the BMI range 18-29.9 have been obtained from Aberdeen and Dundee centres. Edinburgh no longer treat smokers or those outwith the BMI range. Data for Glasgow have been estimated using the Aberdeen and Dundee data.</p> <p>Assumptions have been made regarding the numbers of patients that would give up smoking or lose/gain weight in order to meet the eligibility criteria based on current experience in Edinburgh.</p> <p>The resulting decrease in NHS demand has therefore been estimated to be -26% (Dundee), -39% (Aberdeen) and -33% (Glasgow).</p>
16*	<p>Costs if criteria restricted for BMI and smoking (adjusted allowance for stopping/losing)</p> <p>Adjusted according to revised information from centres resulting in decreases in NHS demand of -32% (Dundee), -21% (Aberdeen), -26% (Glasgow).</p>
17	<p>Costs if cycles set to max. of 2 (Actual ave 1.69-1.72)</p> <p>Current data from the centres shows that the average number of cycles a patient receives varies from 1.5 to 2.2. This scenario looks at the expected costs if all centres offered 2 cycles.</p> <p>A number of women, dependent on the success rates of treatment, will only require 1 cycle and therefore the actual average number of cycles will be less than 2.</p> <p>Information from the Merck Serono model and verified, where possible, by centres shows that the actual average number of cycles received if patients were eligible for a maximum of 2 would be:</p> <p>1.71 (Glasgow), 1.69 (Edinburgh), 1.70 (Aberdeen), 1.72 (Dundee).</p> <p>The analysis is based on a simplified version of the types of embryo transfers that take place and the success rates for live births according to the data that were available at the time.</p> <p>The reality is more complex involving different combinations of embryo transfers and frozen embryo transfers.</p>

18	<p>Costs if cycles set to max. of 3 (Actual ave 2.17-2.24)</p> <p>Similar to the situation described above, this scenario looks at the expected costs if all centres offered a maximum of 3 cycles.</p> <p>The actual average number of cycles received if patients were eligible for 3 would be: 2.21 (Glasgow), 2.17 (Edinburgh), 2.18 (Aberdeen), 2.24 (Dundee).</p>
19	<p>Cost if NHS demand increases by 10% due to reduced waiting list</p> <p>It is assumed that if the waiting list were to be reduced to 12 months there would be greater demand for NHS funded IVF. This increase in demand is assumed to be 10%.</p>
20	<p>Cost if NHS demand increases by 17% due to one partner has no genetic child</p> <p>It is assumed that if the eligibility criteria were extended to allow for one partner having no genetic child the demand for NHS funded IVF would increase. This increase in demand is assumed to be 17%.</p>
21	<p>Cost if parameters across centres were consistent</p> <p>Where possible the model parameters (such as referral rates, the proportion of NHS/Self-Funded/Private cycles and the average number of cycles per patient) have been amended to reflect different practice across centres. This column, however, assumes that these rates are the same across boards/centres so that the impact of the differences can be gauged.</p> <p>Referral rates are assumed to be 1.55 per 1,000. The proportion of NHS funded cycles is assumed to be 56%. The average number of cycles is 1.69.</p>
22	<p>Base Scenario</p> <p>This assumes that all women who are referred for IVF (under current eligibility criteria) are treated (ie same as 'B. Expected cost' but allowing for the fact that there will be a 10% increase in demand due to the reduced wait).</p>
23	<p>Scenario 1</p> <p>Restrictive criteria ie. only BMI/smoking (no adjustment) criteria is assumed with 2 cycles.</p>
24	<p>Combination of age, BMI/smoking, 2 cycles</p> <p>This column provides the expected cost if a combination of eligibility criteria were adopted.</p> <p>Age (column 15), BMI/smoking (column 16) and max. of 2 cycles (column 17) are combined.</p>
25	<p>Combination of age, BMI/smoking, 3 cycles</p> <p>Age (column 15), BMI/smoking (column 16) and max. of 3 cycles (column 18) are combined.</p>
26	<p>Combination of age, BMI/smoking, 2 cycles, reduced wait</p> <p>Age (column 15), BMI/smoking (column 16) and max. of 2 cycles (column 17) and increase in demand (10%) if wait reduced to 12 months are combined.</p>
27	<p>Combination of age, BMI/smoking, 3 cycles, reduced wait</p> <p>Age (column 15), BMI/smoking (column 16) and max. of 3 cycles (column 17) and increase in demand (10%) if wait reduced to 12 months are combined.</p>
28	<p>Combination of age, BMI/smoking, Genetic Child, 2 cycles</p> <p>Age (column 15), BMI/smoking (column 16), increase in demand (17%) if one partner has no genetic child, and max. of 2 cycles (column 17) are combined.</p> <p>Combination of age, BMI/smoking, genetic child, 3 cycles</p>
29	<p>Age (column 15), BMI/smoking (column 16), increase in demand (17%) if one partner has no genetic child, and max. of 3 cycles (column 18) are combined.</p> <p>Combination of age, BMI/smoking, genetic child, reduced wait, 2 cycles</p>

30	Age (column 15), BMI/smoking (column 16), increase in demand (17%) if one partner has no genetic child, increase in demand (10%) if wait reduced to 12 months, and maximum of 2 cycles (column 17) are combined.
31	Combination of age, BMI/smoking, genetic child, reduced wait, 3 cycles Age (column 15), BMI/smoking (column 16), increase in demand (17%) if one partner has no genetic child, increase in demand (10%) if wait reduced to 12 months, and maximum of 3 cycles (column 18) are combined.
32	Scenario 2 Combination of age, BMI/smoking* (non-adjusted), genetic child, reduced wait, 3 cycles

Appendix C

Membership and original remit

Membership of the National Infertility Group during 2012

Name	Role	Organisation
Ian Crichton (Chair)	Chief Executive	NHS National Services Scotland
Gwenda Burns	Scottish Branch Co-ordinator	Infertility Network Scotland
Dr Catherine Calderwood	Senior Medical Officer (Women and Children's Health)	Scottish Government
Dr Charles Clark	Public Health Consultant and Child Health Commissioner	NHS Lanarkshire
Dr James Chalmers	Consultant in Public Health Medicine	NHS Information Services Division
Sarah Corcoran	Policy Manager, Maternal and Infant Health Branch	Scottish Government
Dr Heather Currie	Department of Obstetrics and Gynaecology, Dumfries and Galloway Royal Infirmary	NHS Dumfries and Galloway
Celina Davis	Principal Information Analyst	NHS Information Services Division
Ellen Drew	Clinical Embryologist, Ninewells Hospital Dundee	NHS Tayside
John Froggatt	Deputy Director, Child and Maternal Health	Scottish Government
Janette Hannah	Policy Officer, Maternal and Infant Health	Scottish Government
Dr Mark Hamilton	Consultant Gynaecologist, Assisted Reproduction Unit, Department of Obstetrics and Gynaecology, 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

Name	Role	Organisation
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
Dr David McQueen	Consultant Gynaecologist & Director of Medical Education, Forth Valley Royal Hospital	NHS Forth Valley
Alison McTavish	Nurse Manager, Assisted Reproduction Unit, Department of Obstetrics and Gynaecology, Aberdeen Maternity Hospital	NHS Grampian
Lynne Nicol	Head of Maternal and Infant Health Branch	Scottish Government
Susan Seenan	Deputy Chief Executive	Infertility Network
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
Sheena Young	Head of Business Development	Infertility Network

Role and Remit of National Infertility Group - April 2010

The Group, Chaired by Ian Crichton, Chief Executive of NHS National Services Scotland, 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 Infertility Group.

Ministerial advice and support

The Group will provide Ministers with an interim report by end 2011, and a final report by end December 2012.

The Group will provide proactive and reactive advice and further guidance to Ministers as appropriate.

Workplan

The Group's workplan will be driven initially by the role and remit. Issues for the Group to consider and make recommendations to Scottish Government Ministers include:

- Waiting times and Implementation of current EAGISS guidelines and updated 2007 criteria
- Patient access to IUI
- Definition of a cycle
- Effective, person-centred, pathways of care
- Standardising of access criteria to ensure high quality and equitable care across Scotland. This includes social criteria such as children living in the home, patients who smoke and BMI limit
- Review of EAGISS guidelines and updated 2007 criteria
- Same sex couples – access to services – all NHS Boards must be compatible with the Equality Act
- Data collection – to be led by colleagues in Information Services Division in collaboration with the HFEA

It is anticipated that some of the work will be developed in small sub-groups.

Appendix D

Number of cycles and births in Scotland

Year ending fourth Quarter 2010

A. Own eggs, fresh embryos

IVF activity and success rates of Scottish units

Births

										ALL SCOTTISH UNITS
	NHS Hospitals only					Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total	
<35	66	67	112	70	315	86	15		101	416
35-37	47	54	48	34	183	57	6		63	246
38-39	11	20	23	18	72	33	6		39	111
40-42	5	3	7	3	18	23	2		25	43
43-44	0	0	0	0	0	2	2		4	4
>44	0	0	0	0	0	0	0		0	0
All ages	129	144	190	125	588	201	31	0	232	820

Cycles

										ALL SCOTTISH UNITS
	NHS Hospitals only					Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total	
<35	188	222	409	206	1025	250	69		319	1344
35-37	138	142	207	114	601	176	44		220	821
38-39	81	65	158	55	359	144	35		179	538
40-42	62	65	117	48	292	151	49		200	492
43-44	18	19	7	0	44	42	5		47	91
>44	1	3	3	0	7	25	0		25	32
All ages	488	516	901	423	2328	788	202	0	990	3318

Number of cycles and births in Scotland

Year ending fourth Quarter 2010

B. Own eggs, frozen embryos

Births

										ALL SCOTTISH UNITS	
	NHS Hospitals only						Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total		
<35	6	10	31	18	65	21	9		30	95	
35-37	9	3	10	11	33	14	3		17	50	
38-39	3	4	4	7	18	4	4		8	26	
40-42	2	2	4	0	8	3	1		4	12	
43-44	0	2	0	0	2	0	2		2	4	
>44	1	0	0	0	1	0	0		0	1	
All ages	21	21	49	36	127	42	19	0	61	188	

Cycles

										ALL SCOTTISH UNITS	
	NHS Hospitals only						Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total		
<35	44	46	127	59	276	73	5		78	354	
35-37	36	28	59	27	150	29	27		56	206	
38-39	26	29	40	30	125	30	17		47	172	
40-42	20	18	21	4	63	26	32		58	121	
43-44	6	6	4	2	18	2	11		13	31	
>44	1	3	0	1	5	1	0		1	6	
All ages	133	130	251	123	637	161	92	0	253	890	

Number of cycles and births in Scotland

Year ending fourth Quarter 2010

C. Donor eggs, fresh embryos

										ALL SCOTTISH UNITS	
	NHS Hospitals only						Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total		
Births	4	2	2	11	19	10	1		11	30	
Cycles	10	6	13	20	49	37	5		42	91	

D. Donor eggs, frozen embryos

										ALL SCOTTISH UNITS	
	NHS Hospitals only						Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total		
Births	1	0	0	0	1	4	0		4	5	
Cycles	7	3	3	4	17	15	1		16	33	

Overall total

										ALL SCOTTISH UNITS	
	NHS Hospitals only						Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total		
Births	155	167	241	172	735	257	51	0	308	1043	
Cycles	638	655	1168	570	3031	1001	300	0	1301	4332	

Number of cycles and births in Scotland

Year ending fourth Quarter 2010

Total births by age (own eggs, fresh and frozen cycles)

										ALL SCOTTISH UNITS
	NHS Hospitals only					Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total	
<35	72	77	143	88	380	107	24	0	131	511
35-37	56	57	58	45	216	71	9	0	80	296
38-39	14	24	27	25	90	37	10	0	47	137
40-42	7	5	11	3	26	26	3	0	29	55
43-44	0	2	0	0	2	2	4	0	6	8
>44	1	0	0	0	1	0	0	0	0	1
All ages	150	165	239	161	715	243	50	0	293	1008

Total cycles by age (own eggs, fresh and frozen cycles)

										ALL SCOTTISH UNITS
	NHS Hospitals only					Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total	
<35	232	268	536	265	1301	323	74	0	397	1698
35-37	174	170	266	141	751	205	71	0	276	1027
38-39	107	94	198	85	484	174	52	0	226	710
40-42	82	83	138	52	355	177	81	0	258	613
43-44	24	25	11	2	62	44	16	0	60	122
>44	2	6	3	1	12	26	0	0	26	38
All ages	621	646	1152	546	2965	949	294	0	1243	4208

Number of cycles and births in Scotland

Year ending fourth Quarter 2010

Success rate

										ALL SCOTTISH UNITS
	NHS Hospitals only					Private Hospitals				
Age	Aberdeen	Edinburgh	Glasgow	Dundee	Total	GCRM	GNH	IVF Scotland	Total	
<35	31%	29%	27%	33%	29%	33%	32%		33%	30%
35-37	32%	34%	22%	32%	29%	35%	13%		29%	29%
38-39	13%	26%	14%	29%	19%	21%	19%		21%	19%
40-42	9%	6%	8%	6%	7%	15%	4%		11%	9%
43-44	0%	8%	0%	0%	3%	5%	25%		10%	7%
>44	50%	0%	0%	0%	8%	0%	0%		0%	3%
All ages	24%	26%	21%	29%	24%	26%	17%		24%	24%

Success rates in all units are consistent with the national average live birth rate

GCRM Glasgow Centre for Reproductive Medicine

GNH Glasgow Nuffield Hospital

IVF Scotland is a new private unit in Edinburgh. There are no results published yet.

[Source www.hfea.org](http://www.hfea.org)

Accessed 7 December 2012

In 2010, there were 4332 cycles of IVF delivered in Scotland, resulting in the birth of 1043 live babies. This is an increase of 25% on 2 years previously. 3031 of these cycles are delivered in the four NHS units, although only 1374 cycles (45%) are commissioned by NHS Boards. The remainder are provided to fee paying patients.

Appendix E

Comparison of IVF data delivered regionally across the UK

Number of clinics performing IVF and DI, by region, and number of women receiving fertility treatment, 2010

All licensed generic IVF treatments in 2010

Region	Cycles	Centres	Patients	Live births	Cycles per 1000 live births	Patients treated per 1000 live births	Cycles per patient	Average number of cycles per centre
East Midlands	3,748	4	3,019	55,232	67.9	54.7	1.24	937
East of England	3,877	4	2,938	73,001	53.1	40.2	1.32	969
London	16,949	15	13,182	133,111	127.3	99.0	1.29	1130
North East	2,376	5	1,761	30,826	77.1	57.1	1.35	475
North West	5,866	4	4,623	89,199	65.8	51.8	1.27	1467
South East	6,559	10	5,054	106,434	61.6	47.5	1.30	656
South West	3,280	6	2,498	60,144	54.5	41.5	1.31	547
West Midlands	4,033	7	3,176	72,090	55.9	44.1	1.27	576
Yorkshire and the Humber	3,689	4	2,879	66,970	55.1	43.0	1.28	922
England	50,377	59	39,130	687,007	73.3	57.0	1.29	854
England (excluding London)	33,428	44	25,948	553,896	60.4	46.8	1.29	760
Scotland	4,475	7	3,277	5,8791	76.1	55.7	1.37	639
Wales	1,326	3	1,052	35,952	36.9	29.3	1.26	442
Northern Ireland	1,478	2	1,238	25,300	58.4	48.9	1.19	739
UK	57,656	71	44,697	807,050	71.4	55.4	1.29	812
UK (Excluding London)	40,707	56	31,515	673,939	60.4	46.8	1.29	727

Source: a) HFEA http://www.hfea.gov.uk/docs/2011-11-16_-_Register_Publication_Results.xlt

b) ONS Reported Registered live births in the UK, using individual registrars online annual reports

- To compare the amount of IVF being delivered in different regions of the UK, data on the number of cycles and patients has been abstracted from the most recent HFEA report. To provide a denominator, information on the number of registered births has been derived from the Registrar Generals annual report. Using a denominator in this way allows the calculation of rates which can be used for comparison of different areas.
- There are significant limitations to this analysis. It includes all the clinics in the area, whether they are predominantly NHS or private. Thus, London, which has a large concentration of private clinics (as well as NHS clinics serving a wider area of the South East), provides a disproportionately large number of IVF cycles. Patients treated in London will probably include a significant number of patients who are not UK residents.
- Nevertheless, some broad conclusions can be reached. Compared with the rest of the UK, and excepting London, Scotland provides more cycles of treatment, treats more patients and delivers more cycles of treatment for patients than any other region of the UK apart from the North East of England.

Appendix F

Commissioning rate by NHS Board

NHS Board	Waiting time (December 2012)	Eligible population (women aged 30-39)	Cycles per 1,000 eligible women
Greater Glasgow & Clyde	1 year, 11 months	80,161	4.22
Ayrshire & Arran	1 year, 10 months	20,171	5.85
Dumfries & Galloway	1 year	7,206	4.58
Lanarkshire	1 year	35,044	5.28
Grampian	3 years, 8 months	33,300	3.60
Highland	1 year, 10 months	16,598	4.22
Orkney	3-6 months	1,109	10.82
Shetland	3-6 months	1,403	7.13
Lothian	1 year	61,617	3.16
Borders	No wait	5,769	5.20
Tayside	1 year, 6 months	22,100	3.89
Fife	1 year, 6 months	21,420	2.57
Forth Valley	1 year, 6 months	18,093	4.59
Western Isles	3 months	1,456	

Appendix G

Cost effectiveness of IVF

Age	Scottish NHS Unit success rate	Total cost per live birth
<35	29.2%	£ 12,325.26
35-37	28.8%	£ 12,516.67
38-39	18.6%	£ 19,360.00
40-42	7.3%	£ 49,153.85
43-44	3.2%	£ 111,600.00
>44	8.3%	£ 43,200.00
All ages	24%	£ 14,928.67
Cost per cycle of treatment		£ 3,600.00

At the current average NHS cost of £3,600, the average cost per live birth is £12,325 for women below the age of 35, rising to £19,360 for women aged 38 to 39. In the few women treated over the age of 40 the cost per live birth is considerably more.

Appendix H

Proportion of births due to IVF/ICSI

Proportion of total births due to IVF/ICSI in Scotland (2010)

Maternal age	IVF/ICSI live births	Total Scottish live births (GROS)	% of total births due to IVF/ICSI	Previous figures 2008
<35	511	46,993	1.09%	0.80%
35-37	296	6,709	4.41%	3.29%
38-39	137	2,890	4.74%	3.46%
40-42	55	1,792	3.07%	2.30%
43-44	8	288	2.78%	0.33%
>44	1	98	1.02%	2.02%
All ages	1008	59,030	1.71%	1.26%

Sources <http://www.hfea.gov.uk/7303.html>

<http://www.isdscotland.org/Health-Topics/Maternity-and-Births/Births>
(accessed 7/12/2012)

Proportion of first births due to IVF in Scotland (2010)

Maternal age	IVF/ICSI live births	Total Scottish live births (GROS)	% of total births due to IVF/ICSI	Previous figures
<35	511	24,586	2.08%	1.60%
35-39	433	3,181	13.61%	10.60%
40+	64	632	10.13%	8.50%
All ages	1008	28,399	3.55%	2.80%

Sources <http://www.hfea.gov.uk/7303.html>

<http://www.isdscotland.org/Health-Topics/Maternity-and-Births/Births>
(accessed 7/12/2012)

One in seven of first births in women aged 35-39 are aided by assisted conception techniques.

Appendix I

Single embryo transfer principles

The following principles underpin the advice which patients should receive about the appropriate number of embryos to transfer in a treatment cycle.

Embryo transfer principles in Scotland

Provider units are supportive of the need to address public health concerns of multiple pregnancies after IVF. A national strategy to reduce this figure in Scotland is required while at the same time maintaining overall live birth rates.

Several core principles should underpin the advice which patients receive from health care professionals about the appropriate number of embryos to transfer in a treatment cycle. These include:

1. Female age

- Embryo implantation rates fall with increasing female age. Units should therefore take account of female age in recommending the number of embryos to be transferred.

2. Previous pregnancies

- Women who have had a child in the past will have a higher chance of conception than those who are childless. This may influence the recommended number of embryos to transfer.

3. The number of good quality embryos available

- High numbers of good quality embryos are associated with higher implantation rates. In cycles where a sufficient number of good quality embryos are available for transfer Units should be mindful of the risk of multiple pregnancies after double embryo transfer.

4. The effectiveness of cryopreservation in the Unit

- A successful eSET policy is dependent on good survival and implantation rates after freeze/thaw of stored embryos. Decisions on ET numbers should take account of Unit specific data on embryo quality after cryopreservation.

5. The number and outcome of previous treatment cycles

- Women who have had successful treatment in the past will have higher success rates than those with previously unsuccessful treatment. This may influence the number of embryos to transfer.

6. Medical factors associated with obstetric risk

- Some patients have medical conditions which pose major risks to mother and baby if a multiple pregnancy occurs. Units must take account of obstetric factors in determining the number of embryos to transfer.

7. The source of the embryos to be transferred

- Patients in egg donation programmes may have higher implantation rates even at higher female age ranges. Single embryo transfer should be considered in these cases.

Monitoring progress of multiple births minimisation

Units are bound by national regulatory requirements in limiting the number of multiple births after assisted reproduction treatment. All Units have a **multiple births minimisation** strategy which outlines individual approaches to the issue. This encompasses elements of clinical and laboratory practice and communication with patients.

The outcome of licensed centres' individualised approaches to multiple births minimisation and Units' progress towards national regulatory targets are provided to the HFEA as a matter of course. Licensed centres should be accountable to those who fund NHS treatment and the Scottish Government should thus have access to similar data.

Appendix J

Pathway infertility referral

Information for you:	<p>PRIMARY CARE</p> <p>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</p>
Information to give to patient(s):	<p>COUPLE PRESENT WITH INFERTILITY – UNLESS INDICATED AS IN EARLY REFERRAL, DO NOT REFER, BUT DO:</p> <p>Reassure—84% of couples will conceive in 1st year of having unprotected sexual intercourse and 92% will conceive by first the 2nd year (NICE)</p> <p>Advise sexual intercourse every 2-3 days rather than timing intercourse with the menstrual cycle</p> <p>Consider underlying psychosexual problems</p> <p>Consider need for preconception counselling if pre-existing medical condition</p> <p>Offer lifestyle advice and support to couples to meet lifestyle changes</p> <p>Smoking cessation – both partners must be non-smoking</p> <p>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.</p> <p>BMI for female partner must 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</p> <p>Recreational drug cessation for both partners – both partners must abstain from illegal and abusive substances</p> <p>Methadone – both partners must be methadone free</p> <p>Stable relationship – couples must have been co-habiting in a stable relationship for a minimum of 2 years</p> <p>Caffeine only to be taken in moderation by both partners</p> <p>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</p> <p>Arrange routine investigations:</p>

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

Referral Form

MALE PARTNER

Mr Other

First name Middle name Surname

Date of birth CHI

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)

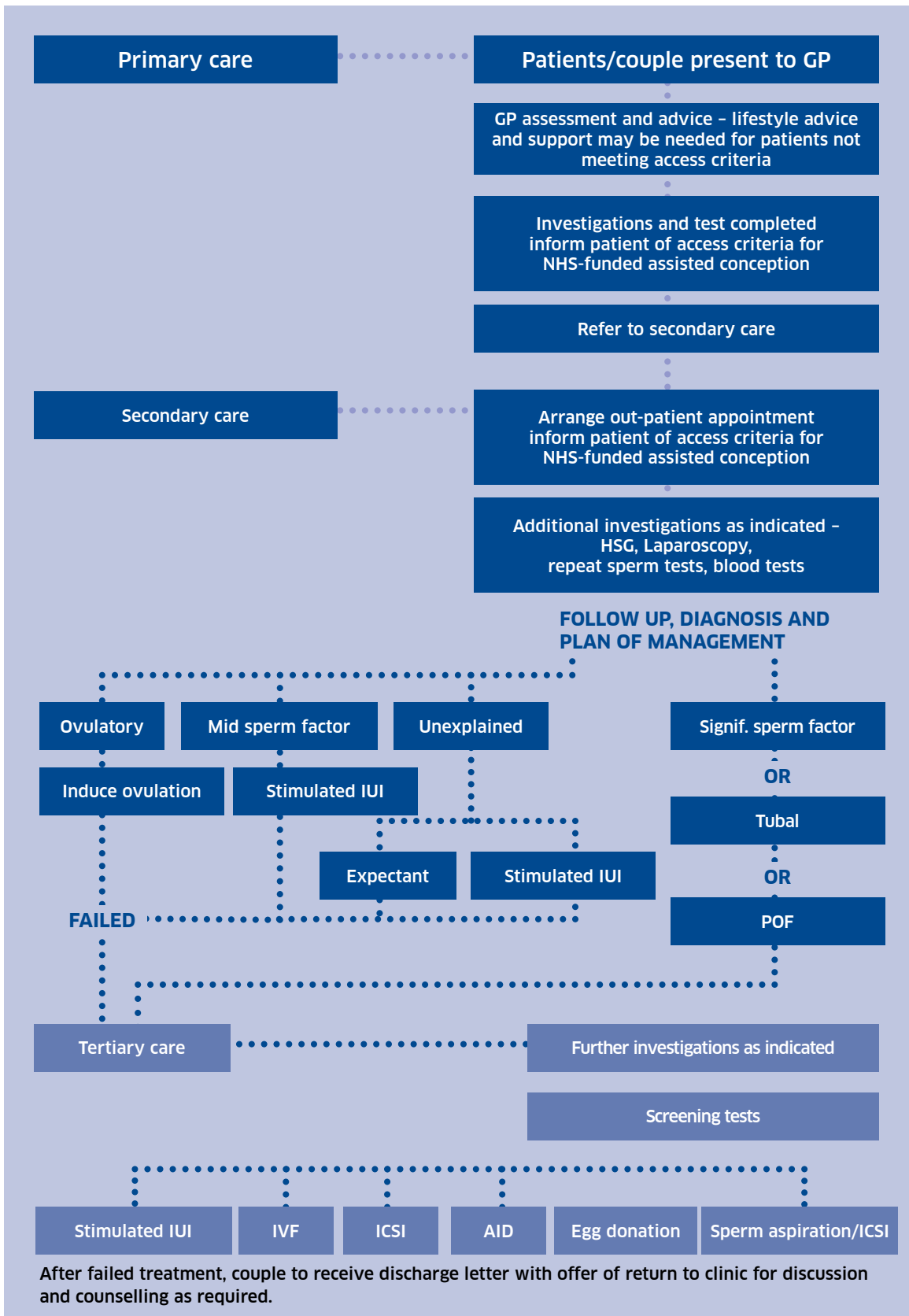
Allergies Relevant family history

BMI Relevant findings on examination

Previous fertility treatment

Semen analysis	Sample 1	Sample 2	Lower reference limits
Date	<input type="text"/>	<input type="text"/>	
Semen volume (ml)	<input type="text"/>	<input type="text"/>	1.5 (1.4-1.7)
Total sperm number (10 ⁶ per ejaculate)	<input type="text"/>	<input type="text"/>	39 (33-46)
Sperm concentration (10 ⁶ per ml)	<input type="text"/>	<input type="text"/>	15 (12-16)
Total motility (PR+NP, %)	<input type="text"/>	<input type="text"/>	40 (38-42)
Progressive motility (PR %)	<input type="text"/>	<input type="text"/>	32 (31-34)
Vitality (live spermatozoa, %)	<input type="text"/>	<input type="text"/>	58 (55-63)
Sperm morphology (normal forms, %)	<input type="text"/>	<input type="text"/>	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 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 must be above 18.5 and below 30 before treatment
- Smoking – Both partners must be non-smoking for at least 3 months prior to treatment and continue to be non-smoking during treatment
- 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 treatment
- Alcohol – Neither partner should drink alcohol prior to or during the period of treatment
- Both partners must abstain from illegal and abusive substances
- 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, or stimulated IUI for mild male factor), 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	<input type="checkbox"/> Date <input type="text"/> Result <input type="text"/>
Laparoscopy and dye test	<input type="checkbox"/> Date <input type="text"/> Result <input type="text"/>
Scan	<input type="checkbox"/> Date <input type="text"/> Result <input type="text"/>
Infection screen	<input type="checkbox"/>
AMH	<input type="checkbox"/>
Further blood results as indicated	

SECONDARY TO TERTIARY CARE REFERRAL - continued

MALESA and concentration FSH, LH Testosterone Cystic Fibrosis screen Karyotype Infection screen Further blood results as indicated **DIAGNOSIS**Unexplained Tubal Male factor Ovulatory Other **SUMMARY OF PREVIOUS TREATMENTS****CONFIRMATION OF ELIGIBILITY FOR NHS TREATMENT**Female Age Female BMI Neither partner smoking Previous children Ovulatory Previous NHS cycles Sterilisation

Appendix K

Glossary

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), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), donor insemination and egg donation.
Body mass index (BMI)	The measurement used to define the range of healthy weight. Your BMI is calculated by dividing your weight in kilograms by your height in metres squared (that is, your height in metres multiplied by itself).
Cryopreservation	The freezing of eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.
Cryostorage	The storage of frozen eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.
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 by the Clinical Resource and Audit Group (CRAG) under the auspices of the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH). EAGISS developed a National Service Framework which aimed to provide equity of access and improve the overall quality and effectiveness of service.
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.
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.
Embryo	A fertilised egg.
Embryo transfer	Transfer of one or two embryos into the womb as part of IVF.
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.

In vitro 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.
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 on promoting good health and preventing and treating ill health.
Primary Care Trusts (PCT)	An NHS primary care trust (PCT) is a type of NHS trust, part of the National Health Service in England.
Sperm	The male reproductive cell produced by men, which fertilises a woman's eggs.

Appendix L

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