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A REVIEW OF PUBLICLY FUNDED FERTILITY SERVICES IN NORTHERN IRELAND

Consultation Document

October 2008

FOREWORD

In October 2006 a new set of criteria for publicly funded fertility services were introduced. These replaced interim criteria which had operated from the introduction of a publicly funded specialist fertility service in December 2001.

Since publicly funded fertility services were first introduced in Northern Ireland approximately 3000 cycles of IVF treatment have been provided. In the first year following the introduction of the new 2006 criteria, which increased the age limit for access to treatment, and removed restrictive criteria in other areas, an additional 233 patients accessed publicly funded fertility services who would previously have been ineligible.

Some time having now passed following the introduction of revised access criteria it is appropriate to once again review how the service is performing in meeting the needs of patients, and look at whether there are areas in which we can improve. This is not an area of treatment where things stand still; technological advances are steadily improving along with success rates; new types of treatment and variations on existing treatments are constantly being developed. Legislation in the area is also under review. As I launch this consultation the Human Fertilisation and Embryology Bill is currently being debated in Westminster.

This consultation is your opportunity to tell us what you think about publicly funded fertility treatment in Northern Ireland – what we are doing right and where we can improve. I hope you will take this opportunity to put forward your views.

MICHAEL MCGIMPSEY MLA

Minister for Health, Social Services and Public Safety

LIST OF ABBREVIATIONS USED IN THIS PAPER

AI	Artificial insemination
ART	Assisted reproductive techniques
DI	Donor Insemination
FET	Frozen Embryo Transfer
GIFT	Gamete intrafallopian tube transfer
GP	General (Medical) Practitioner
HFEA	Human Fertilisation and Embryology Authority
HSC	Health and Social Care
ICSI	Intra-cytoplasmic Sperm Injection
IVF	In-vitro fertilisation
LBR	Live Birth Rate
NICE	National Institute for Clinical Excellence
OHSS	Ovarian Hyperstimulation Syndrome
RCOG	Royal College of Obstetricians and Gynaecologists
SIUI	Stimulated Intrauterine insemination
STI	Sexually Transmitted Infection
WHO	World Health Organisation
ZIFT	Zygote intra-fallopian tube transfer

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Section 1: Introduction

Public Debate & Review of current criteria

1.1 In October 2007 the Northern Ireland Assembly debated the issue of publicly funded fertility treatment and approved a Motion calling for the Minister "to commence a comprehensive review into the current criteria used to assess eligibility, including the age weighting criteria, the ongoing problem with waiting lists, and the number of IVF treatments available on the NHS, with a view to establishing a more equitable and accessible policy".

1.2 In order to take the review forward a stakeholder group (See Annex D) was established and their input, along with the review carried out by the service in 2007, has formed the basis for the proposals contained in this paper. The Department is grateful to those on the stakeholder group for their input.

1.3 This paper builds upon the previous consultation document issued in October 2003 "From People to Parents" and, for ease of reference, information contained in that document relating to the causes of infertility and the services available is provided again in Annex A. For more background information, the full text of "From People to Parents" can be assessed at http://www.dhsspsni.gov.uk/fertility-consultation-finalv-pge1-34.pdf.

1.4 This paper focuses on services that can be provided to assist reproduction in those people who have a fertility problem. It does not cover the many – and varied – related issues, such as adoption, surrogacy, or the role of clinical genetics in reproduction. Nor does it provide a detailed explanation of infertility, its diagnosis and possible treatment.

1.5 The purpose of this paper is to provide an evaluation of the current criteria and seek views on what amendments should be made to those criteria to ensure a safe, fair and accessible service is provided.

1.6 This paper is being sent out to a range of organisations and individuals. It is also available direct to the public on request and through the Internet. The document can be made available in large type, braille, audio-cassette, Irish and Cantonese. Requests will be considered for translations into other minority languages. The consultation process will give the public an opportunity to make known its views on current fertility services and to influence decisions about the future development of those services.

Comments

1.7 Comments on any of these questions, or on any of the issues raised in this paper will be very welcome. If you want to express a view, you should write to, fax or e-mail the contact point below before 13 January 2009. Please note that, in keeping with the Department's policy on openness, responses may be made available to the public. If you do not wish your response to be used in this way, or if you would prefer it to be used anonymously, please indicate this when responding.

1.8 Your views will help the Minister to decide the future access to fertility services. All responses to the consultation will be taken into consideration before final decisions are made.

1.9 The central point of contact for all responses and copies of the paper is:

- The Department of Health, Social Services and Public Safety,
  Secondary Care Directorate, Room 1, Annexe 1, Castle Buildings,
  Stormont, Belfast, BT4 3SQ
  Phone: (028) 9052 8152
  Fax: (028) 9052 3302
  E-mail: secondary.care@dhsspsni.gov.uk

1.10 All comments should be submitted no later than **13 January 2009**.

Section 2: Background and proposals for change

2.1 Fertility services can be categorised into 3 separate levels of service. Level 1 is where infertility investigation and management is provided by a GP and his/her team. Level 2 services provide for the investigation and management by a gynaecologist (with a special interest in infertility) and his/her team in a designated hospital and level 3 services are provided by a specialist gynaecologist or other specialist in a dedicated fertility treatment centre. This consultation paper concentrates on access to specialist or level 3 services only.

Specialist Fertility Service Access Criteria

2.2 Publicly funded fertility treatment has been available in Northern Ireland since 2001, initially on an interim basis pending formal consultation on the provision of publicly funded fertility treatment. The interim criteria specified that, to avail of the interim service, couples should have no children living with them; they should have had three or fewer previous unsuccessful treatment cycles (whether publicly or privately funded); that the woman should be under 38 at the time of treatment; and that there is a diagnosed medical reason for the infertility, lasting for over three years. This interim service offered eligible couples up to a maximum of two publicly funded treatment cycles

2.3 In 2003, with the publication for consultation of "*From People to Parents*" a full public debate on the future of publicly funded fertility services took place covering each of the following areas:

- Information
- Counselling
- Duration of infertility
- Age of female partner when using own eggs
- Age of women when using donated eggs; age of men
- Number of previous unsuccessful treatment cycles

- Number of publicly funded treatment cycles
- Existence of Dependent Children
- Sterilisation
- Status of couples
- Status of the child.

2.4 Following this consultation, in September 2006 Paul Goggins, the then Minister for Health, confirmed arrangements for a publicly funded specialist fertility service and issued a set of criteria which widened access to these services in a number of areas. The upper age limit for women to receive treatment using their own eggs was raised from 37 to 39 and those with dependent children were allowed to start accessing the service. Those who had previously been sterilised could also begin to access the service at the discretion of the clinician involved.

2.5 The interim fertility service offered eligible patients up to a maximum of 2 publicly funded treatment cycles. However, the restrictive eligibility criteria at that time meant many couples were unable to access the service at all. Recognising that the relaxation of eligibility criteria in 2006 would increase demand for the publicly funded service, while no extra funding was available for that service, it was considered necessary to limit patients to one treatment cycle. This was in line with much of England and Wales at that time. Further discussion on the number of cycles offered to patients here is contained in Section 4 of this document.

Service review of existing criteria

2.6 Following a year of operation under the 2006 criteria the four Health and Social Services Boards and Belfast Health and Social Care Trust carried out a review to consider the impact of the revised criteria on referrals; the ability of the Regional Fertility Centre to respond in a timely manner to the level of referrals; a breakdown of activity and waiting times and an assessment of the effectiveness of the new waiting list management system.

Evaluation of existing criterion

2.7 The EHSSB review showed that between September 2006 and September 2007 the relaxation of the age and the dependent children criteria in particular led to an additional 233 couples accessing fertility treatment who would previously have been ineligible (a 55% increase in eligible patients). The evaluation highlighted that, even with the reduction to one cycle, the increasing demand for treatment exceeded the available resource with the result that waiting times increased. The need to address this situation, and the need to consider the relative importance which service users place on a reduction in waiting times against an increase in funded treatment cycles, is addressed in Section 4.

2.8 This Departmental review considered the existing criteria and whether any further changes were needed to reflect changes to the evidence base or equality issues. The rationale for change or otherwise is set out below. Access to treatment will inevitably be determined by eligibility to health service treatment in Northern Ireland along with current legal requirements in relation to consideration of the needs and rights of any future children.

Existing Criteria and proposals for change

Duration of Infertility

Women with an appropriately diagnosed cause of infertility can be placed directly on the waiting list for IVF treatment. Those couples with unexplained infertility have a 3 year qualifying period. NICE guidelines recommend that where a couple has been trying to conceive for more than one year, tests should be offered to evaluate their fertility. However NICE also recommends that IVF treatment should only be offered where there is an appropriately diagnosed cause of infertility of any duration, or unexplained infertility of at least 3 years duration.

The stakeholder group considered that this criterion remained fair and in line with medical evidence and therefore it is not proposed to make any change.

- ***Are you content that these qualifying periods remain unchanged?***
- ***If not what changes should be made to the criterion and why?***

<u>Age of female partner when using own eggs</u>

The upper limit at which female partners using their own eggs may access publicly funded IVF treatment is 39. NICE guidance recommends that fertility treatment is made available to women in the age range 23-39 years. Evidence shows that the success rates for woman over 40 decrease significantly.

The Stakeholder group supported this criterion and it is not therefore proposed to introduce changes.

- ***Are you content that this age limit remains unchanged?***
- ***If not what changes should be made to the criterion and why?***

<u>Age of female partner when using donated eggs</u>

Currently women using donated eggs can access publicly funded fertility treatments if they are 49 years or younger, with due consideration given to the impact on any child born to older parents. Currently there is no NICE guidance on the age criterion for women using donated eggs.

The stakeholder group concluded that this policy raised issues of equitable access to the service though the numbers affected are small due to the difficulty in sourcing egg donors. It is proposed that this age limit should be reduced to 39 in line with that for women using their own eggs.

- ***Are you content that the upper age limit for treatment for women using donated eggs should be reduced to 39?***
- ***If not, please give your reasons.***

Age of men

There is no age criterion for men accessing the service and there is no NICE guidance on the age of the male partner within a couple.

There is no medical reason for limiting treatment to men though due consideration is always given to the impact on any child born to older parents. It is not therefore proposed to change this criterion.

- ***Are you content that this criterion remains unchanged?***
- ***If not what changes should be made to the criterion and why?***

Number of previous unsuccessful treatment cycles

Access to publicly funded fertility services is restricted to those couples who have had three or fewer previously unsuccessful treatment cycles, whether publicly or privately funded. Current HFEA data show that IVF success rates fall significantly with increasing number of previous unsuccessful treatment cycles. There is, however, no NICE guidance on access to the service on the basis of the number of previously unsuccessful treatment cycles.

It is proposed that this criterion should remain unchanged.

- ***Are you content that this criterion remains unchanged?***
- ***If not what changes should be made to the criterion and why?***

Dependent Children

A previous restriction in the interim criterion was removed and couples who have children living with them (in any capacity) now have the same access to services as those without children. This change had a significant impact in permitting many

couples, previously ineligible for treatment, the opportunity to avail of fertility treatment. There is no NICE guidance on this issue.

It is proposed that, on the basis of equality, this criterion should remain as it is.

- ***Are you content that this criterion remains unchanged?***
- ***If not what changes should be made to the criterion and why?***

Voluntary Sterilisation

It is acknowledged that in particular circumstances, for example, following the death of a child/partner, it may be appropriate to grant access to publicly funded treatment where either partner was voluntarily sterilised. Clinicians are therefore permitted to exercise their discretion to provide access to services in a limited, pre-agreed range of circumstances for couples where either partner has been voluntarily sterilised. NICE guidance does not address this issue.

It is proposed that this criterion should remain unchanged.

- ***Are you content that this criterion remains unchanged?***
- ***If not what changes should be made to the criterion and why?***

Status of the couple

Access to publicly funded fertility services is currently restricted to couples, including same sex couples, in a "stable relationship".

Section 75 of the Northern Ireland Act 1998 states that a public authority shall in carrying out its functions relating to Northern Ireland have due regard to the need to promote equality of opportunity. This includes areas such as people of different marital status, sexual orientation and men and women generally. Legislation in the area is also shifting. The Human Fertilisation and Embryology Bill, which is currently

being debated at Westminster, proposes the removal of the requirement for those providing fertility treatment to consider the need of the child for a father and to replace that requirement with an obligation to consider the child's need for supportive parenting. Any amendments to the legislation as a consequence of the Human Fertilisation and Embryology Bill will be applicable in Northern Ireland.

It is suggested that the criterion, which specifies that only persons in a "stable relationship" may access the service, should be removed with the proviso that publicly funded fertility treatment will only be provided to those with an appropriately diagnosed medical fertility problem.

- ***Are you content that this criterion should be removed, opening access to treatment to all those with a medical fertility problem regardless of their relationship status?***

Status of the child

Couples applying for publicly funded fertility services are currently subject to vetting in line with the HFEA Code of Practice for Level 3 Centres.[1] This guidance relates to all aspects of the welfare of the child born as a result of fertility treatment or other children affected by the birth. This vetting is **mandatory** for all clinics licensed to provide fertility treatment and therefore no changes will be made to this criterion.

Information & Counselling

2.9 There continues to be value in ensuring that both the public and professionals have access to good quality information on the services available. NICE guidance states that patients have the right to be involved in and make decisions on their care and treatment. To facilitate this, patients should be provided with information in writing or in some other form, which they can

[11] **Level 3** - infertility investigation and management provided by a specialist gynaecologist or other specialist in a dedicated fertility treatment centre.

easily access and understand. In addition, The Human Fertilisation and Embryology Authority (HFEA) requires all Licensed Centres to make counselling services available to patients; patient uptake of counselling is not however mandatory. NICE guidance recommends that patients should have the opportunity to see a qualified counsellor before, during and after treatment. The counsellor should be someone who is not directly involved in managing the patient's treatment. This service will therefore continue to be provided.

Summary

2.10 To summarise therefore it is proposed that changes will be made to the criteria relating to:

- *Age of the female partner when using donated eggs* – this will be brought into line with the age criterion for women using their own eggs;
- *Status of the Couple* – this change will allow access to the service by people with a medically diagnosed fertility problem regardless of their relationship status.

2.11 The next section sets out our proposals to improve the waiting list management for access to the service.

Section 3 Waiting lists

Waiting list management

3.1 With the increasing demand for fertility services, clear protocols need to be in place for waiting list management. Good waiting list management practice will give clarity about the length of time patients can expect to wait for treatment.

3.2 At present waiting lists for fertility treatments are managed by the Regional Fertility Centre but are by Health and Social Services Board area and separate lists are maintained for each of the available treatments. Moving forward it is considered that it would provide both greater equity of access and greater transparency on waiting times if the lists for treatment were to be managed at a regional level with consolidation to a single list. Also, it would be helpful to provide guidance to GPs and gynaecologists on our referral criteria and advice on diagnostic investigations appropriate before a couple are referred to regional fertility services.

Waiting times

3.3 The current number on the waiting list for treatment is approximately 613 – the numbers being added every month exceed the numbers being treated. At present waiting times for treatment can be as long as 24 months. It is proposed that, as resources permit, maximum waiting times will be reduced.

3.4 The current public spend on IVF and related fertility treatment is £1.5 million per annum. This provides approximately 241 cycles of IVF and 179 cycles of ICSI treatments annually.

3.5 There have been proposals that patients approaching the upper age limit for treatment should be prioritised on the waiting list. Key stakeholders have made it clear that they do not think that this should occur due to concerns in

relation to inequity and the difficulty of managing the waiting list. The provision of guidance and the management of waiting lists on a regional basis are matters which will be taken forward by HSS Boards in tandem with this consultation on access criteria.

3.6 Women approaching the upper age limit could only be moved up the waiting list by increasing the waiting time for other, younger, women. This not only goes against the principle of equal access to treatment for all those of equal clinical priority but, given that the chances of success decrease with age, could affect treatment outcomes for women whose treatment is delayed as a result.

3.7 At present the issue of women breaching the upper age limit is exacerbated by the length of waiting times for treatment. It is proposed that reducing waiting times should be the priority for any extra funding that becomes available for the service thereby reducing this problem.

- ***It is recommended that all those on the waiting list should be treated in the order in which they were placed on the list without prioritisation of any one group except for reasons of clinical urgency. Do you agree?***

Section 4 Prioritisation of funding

Number of publicly funded treatment cycles

4.1 NICE guidelines recommend that eligible couples should be offered up to three stimulated cycles of in vitro fertilisation treatment. If two or more unused embryos are frozen following a stimulated cycle then they should be transferred before the next stimulated treatment cycle. This minimises ovulation induction and egg collection, both of which carry risks for the woman. Therefore, the utilisation of previously frozen embryo transfer (FET) provides patients the opportunity to have further fertility treatment that is less invasive and carries less of a clinical risk. It is also less resource intensive for the local health service, both in Human Resources and financial terms.

4.2 It is the HFEA's intention, working with the fertility sector, to reduce the multiple birth rate resulting from fertility treatment from an average of 25% across the UK in 2005 to about 10% over a three year period starting in 2009. It is recognised that the use of multiple embryos during a cycle of fertility treatment increases the chances of multiple births. Multiple births can however lead to low birth weight and premature babies, which can affect the short and long term health of the child. A reduction in multiple births could be achieved through a shift towards single embryo transfer as part of fertility treatment.

4.3 We recognise that the promotion of single embryo transfer will raise concern among patients that their chances of a successful pregnancy will be reduced. While they are limited to one treatment cycle, patients may have a preference for multiple embryo transfer.

4.4 At present the availability of resources for publicly funded fertility services mean that we can only offer patients one cycle of publicly funded fertility treatment, either a stimulated cycle or a frozen embryo transfer. In the longer term we would aspire to have provision in line with that recommended by NICE however achieving this standard would have significant resource implications.

4.5 Without extra funding, increasing the number of cycles provided to each patient would mean a significant increase in already lengthy waiting times. Ultimately many prospective patients would be unable to access the service at all.

4.6 Our aspiration would be to improve access to fertility services by providing more than one cycle of treatment, particularly in the context of NICE guidance and the trend towards single embryo transfer. We, therefore, propose that, as resources become available, the first step towards increasing the number of publicly funded cycles would be to provide patients with one stimulated cycle followed, where clinically appropriate, by one cycle of frozen embryo transfer (FET).

Prioritisation

4.7 We consider that the first priority should be to reduce waiting times for all patients to a maximum of 52 weeks, and maintain them at this level.

4.8 Once that objective has been achieved, any further funding could be directed either towards a further reduction in waiting times or towards an increase in the level of provision to each patient. In such circumstances we would propose increasing the level of provision to each patient to provide a stimulated treatment and a frozen embryo transfer (FET) where clinically appropriate.

4.9 Our view, which takes account of input from stakeholders, is that a second treatment (ie one stimulated cycle and one FET) offers couples a better service and improves the opportunity for them to have a child or children. Therefore, we propose:

Once a waiting time of 52 weeks is achieved the next priority should be an increase in the number of cycles provided to each patient – this would start with the provision of a cycle of FET following a stimulated cycle where clinically appropriate.

- ***Do you agree with this proposal or would you prefer to see a further reduction in waiting times?***

Section 5 – Summary

5.1 Our proposals can be summarised as follows;

- to reduce the age limit for women using donated eggs to 39 and therefore be in keeping with the age limit for women using their own eggs;
- to remove the need for an individual to be in a stable relationship in order to access fertility treatment;
- better management of the waiting list by moving to one regional waiting list per treatment;
- the first priority for additional funding should be to reduce waiting times for all patients to a maximum of 52 weeks, and maintain them at this level; and
- once the waiting time is reduced to 52 weeks the next priority would be to increase the level of provision to each patient to provide a stimulated treatment and a frozen embryo transfer.

Your views on these proposals will be very valuable in assisting the Minister in deciding the further provision of fertility services.

Section 6 Equality Obligations

6.1 The Northern Ireland Act 1998 placed new statutory equality obligations on all public bodies, including health and social services organisations. From 1 January 2000, the Department and all of its associated bodies must, in carrying out their functions, have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between persons with a disability and persons without; and
- between persons with dependants and persons without.

6.2 Public bodies are also required, in carrying out their functions, to have regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group.

6.3 In line with its duties under the equality legislation, the Department carried out a full Equality Impact Assessment during the last review of the criteria. The changes proposed under this review have been screened for equality implications and it has been concluded that they do not have a significant impact on equality of opportunity and therefore do not require a full Equality Impact Assessment.

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Section 7 Next Steps

7.1 This paper has been developed to facilitate the debate on the long-term provision of fertility services. All responses will be taken into consideration before final decisions are made.

7.2 Once decisions have been taken about the future development of fertility services, the Department will be publicising the new arrangements and giving information about when they will come into effect.

ANNEX A

Extract from Future of Fertility Services in Northern Ireland (From People to Parents) - Public Consultation Document - October 2003

1. Infertility: diagnosis and treatment

What is infertility?

1.1 The World Health Organisation (WHO) defines infertility as "*the failure to conceive following one year of unprotected sexual intercourse*". To allow ample opportunity for conception to take place spontaneously, health professionals do not normally begin assistive action until a period of at least a year has elapsed.

1.2 Primary infertility is a term used to describe a couple who are not able to achieve a pregnancy after a minimum of 1 year of attempting to do so through unprotected intercourse.

1.3 Secondary infertility is defined as an inability to conceive following a previous pregnancy.

Demand for Fertility Services

1.4 A recent local survey of General Practitioners (GPs) indicates that about 5,500 couples in Northern Ireland attend GPs annually with a fertility problem. A recent local survey of gynaecologists indicates that there are over 2,500 new referrals for infertility made annually in Northern Ireland.

1.5 Fertility treatments have developed rapidly in recent years and this has led to greater demand for services to treat fertility problems. This trend is likely to continue as a result of current trends toward later first pregnancies, an

increasing number of remarriages and growing public awareness of treatment possibilities.

What causes infertility?

1.6 There are many factors which may cause or contribute to infertility. About one-third of infertility can be attributed to male factors and about one-third to factors which affect the female partner. For the remaining one-third of infertile couples, infertility is caused by a combination of problems in both partners, or is unexplained.

1.7 In men, the main causes of infertility relate to the quality or quantity of sperm produced. Some men are unable to produce enough sperm to achieve fertilisation by natural means. Mumps in adult life, or injury to the testes, may result in the production of poor quality sperm. Inflammation of the prostate gland or excessive use of tobacco or alcohol may reduce the effectiveness of sperm.

1.8 The most common cause of female fertility problems is ovulatory failure – when the ovaries don't release an egg into the fallopian tubes. Blockage or damage to the tubes themselves also reduces the possibility of an egg being in the best position to be fertilised. Damaged fallopian tubes may be the result of a range of pelvic inflammatory diseases. Endometriosis, a condition where tissue that normally lines the inside of the uterus is found outside the uterus, may cause infertility in severe cases.

1.9 Some couples, because of physical or psychological problems, are unable to have sexual intercourse. While they do not meet the WHO definition of infertility they may present at fertility clinics where they can benefit from the treatments available to assist conception.

1.10 There are other causes of infertility. The trend toward later childbearing is likely to highlight fertility problems. Lifestyle factors, such as smoking, drug misuse or excessive alcohol consumption may also affect fertility in either men or women. Sexually transmitted infections (STIs) in females may result in pelvic inflammatory disease that can damage the fallopian tubes and affect fertility. Given the recent rise in STIs, particularly among young adults, we may expect to see an increase in fertility problems in the future.

Treatment

1.11 There are three main approaches to treating fertility problems:

Medical – largely through the administration of specialist drugs, this is designed to address the condition causing the couple to be infertile e.g. ovulation problems, thus enabling conception to take place in the normal way;

Surgical – designed to address, through surgical techniques, the condition causing the couple to be infertile e.g. treating endometriosis in mild cases;

Assisted reproduction – for example IVF, ICSI and related treatments - the fertilisation of an egg in the laboratory followed by transfer of embryos to the womb.

1.12 These various approaches are explained in more detail below. In general, the latter two procedures were initially intended for use with couples whose infertility was due to unknown or untreatable causes. However, there has been a growing tendency in recent years for IVF to replace medication or surgery as the first treatment option.

Benefits and Risks of Assisted Conception

1.13 The primary benefit of assisted reproduction is that couples with infertility problems are able to have a family.

1.14 However, assisted conception is not without its risks and several short and long-term problems have been identified. The most publicised risk is Ovarian Hyperstimulation Syndrome (OHSS), which can sometimes occur as a result of the drug treatment given in the stages before egg collection. This usually occurs when the patient over-responds to the fertility drugs. While OHSS is rare, it may require hospital admission and can, on occasion, be very serious.

1.15 There has also been some discussion of a long-term risk of cancer as a result of ovarian stimulation with fertility drugs. A number of large, long-term studies which aim to answer this question are currently underway. Some studies have found a slightly higher rate of ovarian cancer among IVF patients than among similar women in the general population. However, other studies have failed to confirm these results.

1.16 There is evidence that males born following ICSI, a technique employed when the male partner has inadequate sperm for IVF, are more likely to be sub-fertile in adult life. For this reason, many fertility centres insist on thorough counselling and some genetic screening before treatment and follow-up during and after pregnancy.

1.17 Infertility treatments, particularly IVF, are associated with an increased incidence of multiple pregnancies. Statistics also indicate a five- to six-fold increase in neonatal problems for children born through IVF. However, many of these problems are due to prematurity associated with multiple pregnancies.

1.18 The higher incidence of multiple births is assumed to be associated with the practice of replacing more than one embryo in the womb. Professionals caring for people with reproductive disorders are obliged to provide counselling on the medical, social and economic consequences of multiple births and prematurity associated with fertility treatments.

2. The Patient's Journey

Levels of Care

2.1 Ideally, the provision of fertility services involves a network of three levels of care:

Level 1 - infertility investigation and management provided by a GP and his or her team;

Level 2 - infertility investigation and management provided by a gynaecologist with a special interest and his or her team in a designated hospital; and

Level 3 - infertility investigation and management provided by a specialist gynaecologist or other specialist in a dedicated fertility treatment centre.

2.2 Each of these levels is explained in greater detail below.

Level 1

2.3 Couples will usually seek initial advice from their GP, who should initiate the procedure of history-taking and examination. These are important to confirm the couple's general health status and their likely ability to conceive. Investigations are usually aimed at confirming that the woman is ovulating and that the man is producing semen of adequate quality and quantity. Blood sampling for hormonal levels and semen analysis may be part of any initial investigation.

2.4 Other aspects that the GP may focus on include:

- A detailed drug history from both partners – this will include their use of any recreational drugs;
- An occupational history: environmental factors can affect fertility;
- Advice on smoking and alcohol consumption - for both partners;
- Other issues – for example, men with poor results on semen analysis may be advised to wear loose fitting underwear and to avoid exposure to high temperature environments.

2.5 Once this initial investigation has been completed, the couple may be referred to their local fertility clinic, where further investigation may include tests of the female reproductive system and, if indicated, further examination of semen.

2.6 In practice, it is recognised that pressures on primary care services and a lack of available information at this level may hamper the extent to which the primary care team can manage a couple's infertility problem.

Level 2

2.7 Medical treatments such as ovarian stimulation or surgical treatments such as tubal surgery may be undertaken at this level. Treatment at a level 2 facility may include ovulation induction if adequate monitoring facilities are available to assess the correct dose of drugs to produce ovulation. Ovarian stimulation with intrauterine insemination (SIUI) may also be conducted at a level 2 facility. This can be a very successful procedure for many couples and is often conducted before referral to IVF and related treatments.

2.8 Other treatments appropriate at level 2 include the treatment of polycystic ovarian disease, treatment of endometriosis and the treatment of male factor infertility.

Level 3

2.9 If treatment has not been successful at a level 2 centre, couples may be referred to level 3 services for consideration of IVF or related treatments. Level 3 centres are licensed by the Human Fertilisation and Embryology Authority (HFEA) for the provision of IVF, ICSI and donor insemination (DI) and must meet the requirements of the HFEA Code of Practice on the provision of patient information, consent and counselling. The role of the HFEA is summarised at Annex B.

2.10 Treatments requiring an HFEA licence can only be carried out in a licensed centre. Data published by the HFEA allows the outcomes for all licensed centres to be audited on an annual basis.

2.11 There are two level 3 centres in Northern Ireland: the Regional Fertility Centre at the Royal Group of Hospitals and the privately-run Origin Clinic in Belfast.

TREATMENTS FOR INFERTILITY

Ovulation Induction

Ovulation induction involves stimulating the ovaries with hormones, so that more eggs will ovulate. There are several different methods of ovulation induction, all of which have shown benefits for particular groups of women suffering infertility. If a woman is not producing eggs regularly, she may be given drugs to stimulate her ovaries.

The most common drug used for this purpose is clomiphene which is given in tablet form. Injections of follicle-stimulating hormones may also be given for the same purpose.

Surgical intervention

Surgical intervention may be undertaken to repair damage to the fallopian tubes or to reverse tubal ligation. Surgery may also be undertaken to restore fertility to a male who has had a vasectomy. Recourse to surgery has become less frequent in recent years because of the growing availability of Assisted Reproductive Technology (ART) as an alternative treatment and the fact that reversal is not successful in a lot of cases.

Surgical treatments may be used in women to treat polycystic ovaries. For women with mild endometriosis, ablation (a procedure to destroy the lining of the uterus) improves fertility - but the benefits are less clear in patients with moderate or severe endometriosis.

Artificial insemination

Artificial insemination is a potential solution for some couples where the cause of infertility cannot be found or is not amenable to treatment. The term *artificial* applies to the procedures involved, because they do not depend for their effect on sexual intercourse between the partners. Artificial insemination involves the fertilisation by artificial means of the ovum in its natural environment. There are three main varieties of this approach:

Artificial insemination (AI). This involves the injection of sperm into a woman's vagina, so that conception can take place in the fallopian tube in the normal way;

Intrauterine insemination (IUI). This is essentially the same as AI, but it includes ovulation induction and special preparatory treatment of the sperm;

Gamete intrafallopian tube transfer (GIFT). This involves the collection and mixing of eggs and sperm outside the body and their transfer to the fallopian tube before fertilisation takes place. This procedure has been mainly superseded by IVF treatment.

Assisted Conception

This involves the creation of human embryos (fertilised eggs) outside the human body for subsequent transfer to the womb. The main forms of this approach to the treatment of infertility are:

- **In vitro fertilisation (IVF)** – this uses the couple's own sperm and eggs and is an effective treatment for infertility resulting from tubal problems, or for unexplained causes. In IVF, the woman's ovaries are stimulated by drug treatments and the eggs 'harvested'. They are mixed with the male's sperm in the laboratory, where fertilisation of some eggs should occur. After an interval of some days, embryos

which develop and are considered viable are then implanted into the woman's uterus. Usually 1 or 2 embryos are implanted.

- **Intra-cytoplasmic Sperm Injection (ICSI)** – This is a useful treatment in couples with deficient sperm. The technique is similar to IVF, except that the fertilisation is undertaken by injecting a sperm into an egg with an extremely fine needle.

- **IVF using donated eggs -** Egg donation allows women who have ovarian failure to use eggs from another woman. Egg donation has proved successful, but remains limited - chiefly because of a shortage of egg donors. Egg sharing has been used recently where a woman undergoing IVF treatment may donate some of her harvested eggs to another patient.

- **Zygote intrafallopian tube transfer (ZIFT)**. This procedure is similar to GIFT, but fertilisation takes place before transfer to the fallopian tube. The distinction between ZIFT and IVF is that in ZIFT the fertilised egg is transferred as soon as fertilisation takes place, rather than after an interval of some days.

ANNEX B

ROLE OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

The Human Fertilisation and Embryology Authority (HFEA) ensures that all UK treatment clinics offering in vitro fertilisation (IVF), donor insemination (DI), stimulated intrauterine insemination (SIUI), gamete intra-fallopian transfer (GIFT) or collecting, testing or storing eggs, sperm or embryos, conform to high medical and professional standards. Every clinic in the UK that offers such treatments or services or that carries out human embryo research is required by law to be licensed by the HFEA. Licensed clinics are inspected annually.

The HFEA's other statutory functions are:

- to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;
- to keep a formal register of information about donors, treatments and children born from those treatments;
- to publicise its role and provide relevant advice and information to patients, donors and clinics; and
- to keep under review information about human embryos and any subsequent development of such embryos, and the provision of treatment services and activities governed by the HFE Act and advise Ministers if appropriate.

HFEA Members are appointed by UK Health Ministers in accordance with the guidance from the Commissioner for Public Appointments. The Members determine the HFEA's policies and scrutinise treatment and research licence applications. In order that a perspective can be maintained which is independent of the medical scientific view, the HFE Act requires that the Chairman, Deputy Chairman and at least half of the HFEA's Membership may not be doctors or scientists involved in human embryo research or providing fertility treatment. Members are not appointed

as representatives of different groups, but bring to the HFEA a broad range of expertise: medical; scientific; social; legal; managerial; religious; and philosophical.

ANNEX C

GLOSSARY

Artificial insemination - placing husband or donor sperm into the vagina with a catheter or cervical cup

Assisted reproductive technology (ART) - various methods of assisting reproduction that are accomplished with laboratory assistance

Bilateral tubal ligation - a surgical sterilization procedure in which both fallopian tubes are clamped, clipped, or cut to prevent pregnancy

Clomiphene citrate - a medication that stimulates ovulation

Endometriosis - a painful condition in which the lining of the uterus grows outside the uterus

Embryo - a fertilized egg that has begun cell division

Fallopian tubes - a pair of tubes attached to the uterus, one on each side, where sperm and egg meet in normal conception

Fertilization - the fusion of sperm and egg

Gamete intrafallopian transfer (GIFT) - the direct transfer of a mixture of sperm and eggs into the fallopian tube where normal fertilization takes place

Hormone - a substance produced by one tissue and conveyed by the bloodstream to another for metabolism and growth

Hormone replacement therapy - medication to replace oestrogen and progesterone hormones

Infertility - inability to conceive a child after one year of sexual intercourse without contraception

Intrauterine insemination - sperm is inserted into the womb at the woman's most fertile time (ovulation). The sperm will have been sorted before treatment to make sure that only the healthiest are used. It is particularly suitable if the male partner has a low sperm count or if the sperm is not surviving the journey to the womb. It is also used when a woman does not have any known fertility problems but may not have a male partner and is trying for a baby using donated sperm.

In vitro fertilization (IVF) - a method of assisting reproduction that involves surgically removing an egg from the woman's ovary and combining it with sperm in a laboratory dish. If the egg is fertilized, the resulting embryo is transferred to the woman's uterus

Ovulation - the release of a mature egg from its follicle in the ovary

Ovulation induction - to cause the ovaries to produce eggs

Ovum - a healthy egg

Sterilization - a surgical procedure to prevent pregnancy

Uterus (the womb) - the organ in which the fertilized egg develops

ANNEX D

STAKEHOLDER GROUP REPRESENTATIVES

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