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Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy:

CP38 Specialist Fertility Services

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Document History

Revision History			
Version No.	Revision date	Summary of Changes	Updated to version no.:
1.0	01/08/2005	Access Criteria agreed by the Health & Social Care Minister on 22 nd July 2005, included in first draft of full policy.	
1.0	26/09/2005	Meeting of All Wales Specialist Fertility Advisory Group agreed the following areas for further investigation: <ul style="list-style-type: none"> • Surrogacy • Frozen embryo storage and transfer • Smoking test to assess nicotine levels • Procedure with regards to suspensions from waiting list • Definition of 'living with' 	
2.0	08/09/2008	Version 1.0 was discussed at the All Wales Specialist Fertility Advisory Group meeting in September 2008. Members of the Group were informed that the Policy would be reviewed, and they were asked for any recommendations.	
2.0	17/12/2008	The review of the Policy was discussed amongst the Group including the following areas: <ul style="list-style-type: none"> • Existing Children Criterion • BMI criterion 	
2.0	February 2009	A paper outlining the conclusions of the Policy review was presented to the HCW Commissioning Business Meeting. Members were asked for feedback.	
2.0	March 2009	A paper presenting the final recommendations with regards to the Policy review was discussed by members of the HCW NCAB. The recommendations were agreed.	3.0
3.0	November 2010	A table of proposed changes was taken to the All Wales Specialist Fertility Advisory Group meeting in November 2010. The proposed changes were agreed.	4.0
4.0	August 2011	Typographical error corrected page 11 'more than three' corrected to 'three or more.' Formatting errors corrected. Review date corrected to March 2012. Removed Annex on AWFAG membership as is out of date, pending next revision. Annex on suspensions removed as not relevant to these procedures.	4.1
4.1	January 2013	Number of cycles for veterans added into criteria for treatment page 13. Paragraph on IVF for veterans added 3.2.9 page 15	4.2
4.2	January 2013	Transferred to new template minor amendments made.	4.3
4.3	March 2013	Ratified through Chair's Action on behalf of	5.0

		Management Group	
5.1	July 2013	<p>The following amendments have been made:</p> <ul style="list-style-type: none"> - reference to the Adult Gender Identity services policy on page 6 - Amendments to the waiting times section to remove the wait for unexplained fertility and ensure that patients are only listed for treatment when they have demonstrated subfertility on page 7 and 8 - Amendment to reference patients with medical conditions that affect infertility should be offered early specialist referral on page 11 - Amendment to the age of when women should be referred earlier for investigation from 35 to 36 in line with NICE guidance on page 11 - Reference to use of donor insemination with same sex couples on page 12 - Amendment to applications of cryopreservation in medical conditions where an individual will become infertile to state that the eligibility criterion for infertility treatment does not apply. However it will apply when it comes to using stored material for assisted conception in an NHS setting in line with NICE guidance on page 12 - Reference to the length of storage of eggs, sperm and embryos of 10 years and ensuring consent in line with NICE guidance on page 13 - Amendment to the definition of a full cycle of IVF treatment to include transfer of any resultant fresh and frozen embryo (s) in line with NICE guidance and to make reference that storage of frozen embryos is only funded for one year on the NHS on page 13 - Reference to embryo transfer process in line with NICE guidance on page 14 - Amendment to include where patients are referred under 40 years if the woman reaches the age of 40 during treatment complete the cycle but do not offer further full cycles in line with NICE guidance on page 14. - Addition to the age criteria to include women aged 40-42 are entitled to one cycle of IVF provided they have never had IVF treatment; there is no evidence of low ovarian reserve and there is discussions of implications of IVF and pregnancy at this age in line with NICE guidance on page 14. - Amendment to the existing children criteria to remove the reference "living with" on page 15 - Amendment to subfertility section 3.2.7 to ensure that same sex couples/single patients have attempted insemination on at least six cycles. - Addition on page 16 to include reference to change of partner whilst waiting for IVF 	5.2

		treatment - Amendment to 3.3 Referral Pathway to detail the pathway in line with NICE guidance - Amendment to 3.3.1 to remove Cardiff and Vale UHB as provider and add Abertawe Bro Morgannwg UHB as provider of Cardiff clinic - Amendment to referral pathway to remove reference to HCW and patient numbers	
5.2	July 2013	Amendments throughout the policy where single women have been referenced to also include single men. Amendments to the referral form and checklist in the annex to reflect changes in criteria and feedback from providers.	6.0
6.0	August 2015	Amendment to 2.2.1 Waiting Times, First cycle of IVF/ICSI where the previous statement regarding a mandatory wait of twelve months was omitted as a drafting error from the August 2014 revision.	6.1
6.1	October 2015	Ratified through Chair's Action on behalf of Management Group	7.0
7.1	June 2016	Amendment to -2.2.1 paragraph 4 insertion of clinical indications for expediting treatment, insertion of "Couples must have been co-habiting in a stable relationship for a minimum of 2 years." -3.2.1 insertion of minimum age of 20 for female, clarification of upper age for female and insertion of maximum age of 55 for male -3.2.2. Amendment to the existing children criteria -3.2.3 removal of couple men, insertion of caveat in relation to female with BMI below 19. Insertion of 'Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.' -3.2.9 Insertion Welfare of the child -3.5 insertion of 2 nd exclusion bullet point - insertion of Annex iv: Quality dashboard	7.2
7.2	27 November 2015	Policy amendments ratified by Management Group	8.0
8.0	26 January 2017	Reinsertion of cryopreservation Ratified by Management Group	9.0
Date of next revision		December 2019	

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All Wales Specialist Fertility Advisory Group	2 nd August 2013	5.2

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LHB Directors of Planning	15 th August 2013	5.2
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WHSSC Joint Committee	29/03/2011	3.0
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WHSSC Website	Corporate Services	26 January 2017	9.0

Policy Statement

<p>Background</p>	<p>In November 2009 the Minister for Health & Social Care announced that patients who meet the access criteria, where the woman is aged less than 40, will be entitled to two NHS cycles of treatment from the 1st April 2010.</p> <p>In 2013, in view of the NICE Guidance update for fertility services, the all Wales expert advisory group made recommendations that fertility services should be available up to a woman's 43rd Birthday</p>
<p>Summary of Access Criteria</p>	<p>The access criteria for IVF are set out in section three of this policy.</p> <p>Couples/single women/single men must satisfy all elements of the access criteria to qualify for treatment. Prior to referral, GPs and clinicians are required to ensure that patients meet the criteria.</p> <p>Cases falling outside the criteria should only be referred to the WHSSC Individual Patient Funding Panel if there are exceptional clinical reasons for consideration.</p> <p>The access criteria should be used as the basis for access to NHS funded infertility treatment. This includes all of the techniques and additional procedures outlined in section 2.1</p>
<p>Responsibilities</p>	<p>Referrers should:</p> <ul style="list-style-type: none"> • Advise patients of their ability to access treatment under this policy in order that patients can make informed decisions about their options to have a child; • Inform the patient that this treatment is not routinely funded outside the criteria in this policy; and • Refer via the agreed pathway. <p>Clinician considering treatment should:</p> <ul style="list-style-type: none"> • Discuss all the alternative treatments with the patient; • Advise the patient of any side effects and risks of the potential treatment; • Inform the patient that treatment is not

	<p>routinely funded outside of the criteria in the policy; and</p> <ul style="list-style-type: none">• Confirm that there is contractual agreement with WHSSC for the treatment. <p>Only submit an IPFR request where there are grounds for considering exceptional medical circumstances.</p>
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1. Aim

1.1 Introduction

This document has been developed as the policy for the planning of Specialist Fertility Services for Welsh patients. The policy applies to residents of all seven Health Boards in Wales.

The purpose of this document is to:

- Set out the circumstances under which patients will be able to access Specialist Fertility services;
- Clarify the referral process; and
- Define the criteria that patients must meet in order to access treatment.

1.2 Relationship with other Policies and Service Specifications

This document should be read in conjunction with the following documents:

- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR)
- Specialised Services Policy for Pre-implantation Genetic Diagnosis Services
- Specialised Services Policy for Specialised Adult Gender Identity Services
- Insert details of cryopreservation policy once approved
- Eligibility for NHS treatment in the NHS can be found at the following link <http://www.wales.nhs.uk/documents/HealthAdviceforTravellers.pdf>

2. Scope

2.1 Definition

WHSSC funds the following assisted conception techniques regulated by the Human Fertilisation and Embryology Authority (HFEA):

- In-vitro fertilisation (IVF)
- Intra-cytoplasmic sperm injection (ICSI)
- Donor insemination
- Surgical sperm retrieval methods including:
 - micro-epididymal sperm aspiration (MESA);
 - testicular sperm extraction (TESE); and
 - percutaneous epididymal sperm aspiration (PESA)
- Egg, sperm, embryo and gonadal tissue cryostorage and replacement techniques
- Other micro-manipulation techniques
- Egg donation where no other treatment is available
- IVF surrogacy

Intra-uterine insemination (IUI) is not funded by WHSSC. Funding for IUI is the responsibility of the Health Boards. Where donor sperm is needed to undertake IUI, the donated sperm will be funded by WHSSC, but not the IUI procedure.

2.2 Waiting Times

2.2.1 First cycle of IVF/ ICSI

Following referral into specialised fertility services patients should be offered an outpatient appointment within the 26 week referral to treatment target. As the normal waiting times targets do not apply to IVF treatment for clinical reasons the referral to treatment clock is stopped at the first attended outpatient consultation.

Couples with unexplained infertility will only be listed for IVF, with or without ICSI, treatment if it is demonstrated that the couple has not conceived after 2 years (this can include up to a 1 year before their fertility investigations) of regular unprotected sexual intercourse.

Couples must have been cohabiting in a stable relationship for a minimum of 2 years.

Same sex couples/single women/single men with unexplained infertility will only be listed for IVF, with or without ICSI, treatment if it is demonstrated that they have not conceived following insemination at or just prior to the known time of ovulation on at least six non-stimulated cycles.

Patients should be seen in the order they were placed on the waiting list for treatment. However patients can be expedited for treatment if there is clinical justification for doing so. Patients with the following clinical indications may expedited: Endometriosis, tubal disease, male infertility or if the female is over 36 years of age. Clinics should have a robust documented process for expediting treatment.

Patients presenting for their first IVF/ICSI cycle must wait for a minimum of twelve months before treatment as many will conceive normally during this period. This is applied by all the Clinics providing a service to Welsh patients. Couples can be expedited before the twelve month waiting time if there is a clinical justification for doing so. Further information is available to clinics with regards to expediting treatment in the "Guidance for Clinics" document.

2.2.2 Second cycle

Patients presenting for their second cycle will not be treated as a new referral. IVF, with or without ICSI, treatment is specifically excluded from the referral to treatment targets for clinical reasons, however any patient who is seen in clinic and deemed to be suitable for a second IVF cycle will be treated

in line with the referral to treatment guidance for planned procedures i.e. a maximum wait of 26 weeks following the new decision to treat being communicated to the patient.

These waiting times are applied by all the providers providing a service to Welsh patients.

2.3 Codes

ICD-10 code	Description
Z31.1	Artificial insemination
Z31.2	In vitro fertilization
Z31.3	Other assisted fertilization methods
N97	Female infertility
N97.0	Female infertility associated with anovulation
N97.1	Female infertility of tubal origin
N97.2	Female infertility of uterine origin
N97.3	Female infertility of cervical origin
N97.4	Female infertility associated with male factors
N97.8	Female infertility of other origin
N97.9	Female infertility, unspecified

OPCS-4.6 code	Description
Q13	Introduction of gamete into uterine cavity
Q13.1*	Transfer of embryo to uterus NEC
Q13.2	Intracervical artificial insemination
Q13.3	Intrauterine artificial insemination
Q13.4	Intrauterine insemination with superovulation using partner sperm
Q13.5	Intrauterine insemination with superovulation using donor sperm
Q13.6	Intrauterine insemination without superovulation using partner sperm
Q13.7	Intrauterine insemination without superovulation using donor sperm
Q13.8	Other specified
Q13.9	Unspecified
Q21	Other introduction of gamete into uterine cavity
Q21.1*	Transmyometrial transfer of embryo to uterus
Q21.8	Other specified
Q21.9	Unspecified

* **Note:** Q13.1 and Q21.1 will also have a code from Y96.- (below) to identify the method of IVF (but codes from Y96 will never appear *without* either of those two codes)

Y96	In vitro fertilisation
Y96.1	In vitro fertilisation with donor sperm
Y96.2	In vitro fertilisation with donor eggs
Y96.3	In vitro fertilisation with intracytoplasmic sperm injection
Y96.4	In vitro fertilisation with intracytoplasmic sperm injection and donor egg
Y96.5	In vitro fertilisation with pre-implantation for genetic diagnosis
Y96.6	In vitro fertilisation with surrogacy
Y96.8	Other specified
Y96.9	Unspecified
N34	Other operations on male genital tract
N34.2	Collection of sperm NEC
N34.4	Microsurgical epididymal sperm aspiration
N34.5	Percutaneous epididymal sperm aspiration
N34.6	Testicular sperm extraction

3. Access Criteria

3.1 Clinical Indications

3.1.1 IVF/ICSI

Infertility in heterosexual couples is the failure to conceive after regular unprotected sexual intercourse for 2 years. Where there is clear reproductive pathology, couples/single women/men with infertility of any duration will be considered. This will include couples that cannot achieve full sexual intercourse due to disability.

There are a number of situations where referral before two years may be appropriate:

3.1.1.1 *Medical conditions that affects fertility*

Where there is a known reason for infertility early specialist referral should be offered. Those conditions where there is potential to impact on fertility following medical or surgical treatment (e.g. prior to treatment for cancer; gender dysphoria; etc). This does not include patients that have chosen to undergo sterilisation as a contraception method.

3.1.1.2 *Pre-disposing factors*

Where a woman is 36 years or over, or there is a history of predisposing factors or disability e.g. amenorrhoea, oligomenorrhoea, pelvic inflammatory

disease or with men undescended testes. In these circumstances earlier investigation should be offered.

Same sex couples; single women and single men will be considered where subfertility is demonstrated (see criteria 3.2.7). Male same sex couples and single men should refer to the section on surrogacy (3.1.2).

People who are known to have chronic viral infections (e.g. HIV, Hepatitis B or Hepatitis C) should be referred to NHS centres that have appropriate expertise and facilities and are governed by the Human Fertilisation and Embryology Authority to provide investigation and treatment.

3.1.2 Surrogacy

Surrogacy IVF is provided to patients who meet the agreed access criteria. WHSSC will not be involved in any of the process in identifying a surrogate or any financial arrangements made between the surrogate and the genetic couple. A patient can only be placed on the IVF waiting list once a surrogate has been identified. Surrogacy IVF will only be provided where no other fertility treatment options are available to the patients, and the patients have been referred by a clinician as needing an IVF surrogacy cycle for medical reasons.

3.1.3 Donor Insemination

The use of donor insemination is considered effective in managing fertility problems associated with the following conditions:

- obstructive azoospermia
- non-obstructive azoospermia
- severe oligospermia
- infectious disease in the male partner (such as HIV)
- severe rhesus isoimmunisation
- severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection

Donor insemination should also be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring.

Donor insemination is also used for same sex couples and single patients.

Intra-uterine insemination (IUI) is not funded by WHSSC. Funding for IUI is the responsibility of the Health Boards. Where donor sperm is needed to undertake IUI, the donated sperm will be funded by WHSSC, but not the IUI procedure.

3.1.4 Use of Donor Eggs

Egg donation may be offered where no other treatment is available. The patient must be able to identify and provide a donor, either through altruistic egg donation or through an individual agreement (e.g. with a friend or relative). WHSSC will not fund IVF for patients participating in the egg sharing schemes that may operate within fertility clinics.

Egg donation may be available to women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause or to avoid transmission of inherited disorders to a child where the couple meet the other access criteria.

3.1.5 Applications of cryopreservation in medical conditions where an individual will become infertile

Clinicians should inform people that are undergoing medical or surgical treatment that will affect fertility that the eligibility criteria for infertility treatment does not apply for fertility cryopreservation provided by the NHS. This does not include patients that have chosen to undergo sterilisation as a contraception method.

However, patients should be informed that the eligibility criteria will apply when it comes to using stored material for assisted conception in an NHS setting.

Clinicians should be aware of conditions for which treatment is available and facilities for cryopreservation of gametes and /or embryos. Patients should be fairly advised of the efficacy of IVF treatment relative to the patient's health status and age and the eligibility criteria for IVF on the NHS.

3.1.5.1 Egg and Sperm Storage

Local protocols should exist to ensure that health professionals are aware of the value of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively.

Men and adolescent boys preparing for medical or surgical treatment that is likely to make them infertile should be offered semen cryostorage because the effectiveness of this procedure has been established. This does not include patients that have chosen to undergo sterilisation as a contraception method.

Women preparing for medical or surgical treatment that is likely to make them infertile should be offered oocyte or embryo cryostorage as appropriate if they are well enough to undergo ovarian stimulation and egg collection, provided that this will not worsen their condition and that sufficient time is

available. This does not include patients that have chosen to undergo sterilisation as a contraception method.

The decision to proceed with this treatment must be made jointly by the fertility clinician and referring clinician following a thorough review of the patient's individual circumstances. Patients should consent to the storage of their egg/sperm/embryo and what they would like to happen to this in the event that they die.

Cryopreserved material should be stored for an initial period of 10 years. After which the IVF provider should review patients and consider continued storage of cryopreserved sperm, beyond 10 years, to men who remain at risk of significant infertility.

Before commencing chemotherapy or radiotherapy likely to affect fertility, or management of post-treatment fertility problems, the procedures recommended by the Royal College of Physicians and the Royal College of Radiologists should be followed.

3.2 Criteria for Treatment

The access criteria should be used as the basis for access to NHS funded infertility treatment. This includes all of the techniques and additional procedures outlined in section 3.1

On the 1 April 2010 the entitlement was increased from one full cycle of IVF to two for all women who meet the WHSSC access criteria, with the exception of Armed Forces Compensation Scheme (AFCS) recipients who are entitled to three cycles (see 3.2.9).

A full cycle of IVF treatment, with or without ICSI, should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). This will include the storage of any frozen embryos for one year following egg collection. Patients will need to be advised at the start of the treatment that this is the level of service that is available on the NHS and that the NHS will not fund storage following this period. Patients must be counselled, and agree that storage of any frozen embryos following this period will need to be funded by themselves, or allowed to perish.

Providers should follow the embryo transfer guidance as defined by NICE and audited by the HFEA. The aim of this guidance is to promote the use of single embryo transfer to reduce the risk of multiple pregnancies. No more than 2 embryos should be transferred during any one cycle of IVF treatment.

3.2.1 Age

Criteria – Due to the associated risks with teenage pregnancies patients will need to be at least 20 years old to access IVF treatment. Women who are

aged less than 40 years and who meet the access criteria are entitled to two cycles of IVF with or without ICSI. However if the woman reaches the age of 40 during the first cycle of treatment they will not be entitled to a second cycle of IVF.

Women aged between 40 and 42 years (up to their 43rd birthday) who meet the access criteria are entitled to one cycle of IVF with or without ICSI provided the following 3 criteria are also fulfilled:

- They have never previously had IVF treatment
- There is no evidence of low ovarian reserve
- There has been a discussion of the additional implications of IVF and pregnancy at this age.

Male age

Criteria – Men must be aged 55 years or younger in order to access IVF treatment

3.2.2 Existing Children

Criteria – IVF on the NHS is available for:

- (1) couples where one of the partners does not have any living children (biological or adopted)
- (2) single women or men who do not have any living children (biological or adopted)

3.2.3 Body Mass

Criteria – Women accessing IVF treatment must have a body mass index (BMI) of between at least 19 and up to and including 30. Female patients with a BMI below 19 that are ovulating normally may be treated at the discretion of the treating clinician. Patients outside this range will not be added to the waiting list and should be referred back to their general practitioner for management where required.

Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.

3.2.4 Sterilisation

Criteria – Sub-fertility is not the result of a sterilisation procedure in either partner/single woman/single man (this does not include conditions where sterilisation occurs as a result of another medical problem). Couples/single women/single men who have undertaken a reversal should not be referred for treatment.

3.2.5 Smoking

Criteria – Where either of the couple/single woman/single man smokes the patient is not eligible. Only patients who agree to take part in a supported

programme of smoking cessation will be accepted on the IVF treatment waiting list and must be non-smoking at time of treatment.

3.2.6 History of previous treatment

Criteria – For single patients, three or more IVF cycles by the patient will exclude any further NHS IVF treatment. For couples, three or more IVF cycles by either partner will exclude any further NHS IVF Treatment. Previous cycles whether NHS or privately funded will be taken into account.

3.2.7 Sub-fertility

Criteria – Sub-fertility must be demonstrated before there can be access to NHS funded IVF treatment. Sub-fertility for heterosexual couples is defined as inability to conceive after 2 years unprotected intercourse or a fertility problem demonstrated at investigation. Sub-fertility for same sex couples/single women/single men is defined as no live birth following insemination at or just prior to the known time of ovulation on at least six non-stimulated cycles or a fertility problem demonstrated at investigation.

For same sex couples/single women/single men, the non-stimulated cycles may be achieved through a private arrangement or through NHS-provided IUI with donor sperm. Intra-uterine insemination (IUI) is not funded by WHSSC. Funding for IUI is the responsibility of the Health Boards. Where donor sperm is needed to undertake IUI, the donated sperm will be funded by WHSSC, but not the IUI procedure.

In women aged 40-42 years there is also no evidence of low ovarian reserve.

3.2.8 HFEA

Criteria – Patients not conforming to the Human Fertilisation and Embryology Authority (HFEA) Code of Practice will be excluded from having access to NHS funded assisted fertility treatment.

3.2.9 Welfare of the child

The couple/ single woman/ single man should be assessed as meeting the requirement contained within the HFEA appendix entitled 'Welfare of the child'. Details can be found at <http://www.hfea.gov.uk/index.html>

3.2.10 Change of Partner whilst waiting for IVF treatment

NICE Guidance states that "Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment." Couples sign consent for treatment together so if the relationship breaks down then it follows that the consent then breaks down.

Criteria – If a couple consent to treatment but during the waiting period for treatment the couple break up then treatment cannot commence. If one or

both of the partners wish to proceed with treatment with either a new partner or by themselves then the clinic that is providing the treatment needs to be notified. The new couple/individual will need to attend a consultation where the fertility history of the couple/individual needs to be reviewed, treatment options explained and discussed and if the couple/individual still meet the eligibility criteria consent to proceed with treatment.

3.2.11 IVF for Veterans

Criteria - Armed Forces Personnel who have become infertile as a result of military action and are Armed Forces Compensation Scheme (AFCS) recipients are entitled to 3 full cycles of IVF treatment. All applications for this should be forwarded to Welsh Health Specialised Services via the All Wales IPFR process for consideration in line with guidance from the Independent Medical Expert Group.

3.3 Referral Pathway

Patients who experience problems with fertility will attend their GP practice to discuss their options. The patients will normally be assessed within primary and secondary care.

A woman of reproductive age who has not been conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be referred to secondary care fertility services for further clinical assessment and investigation along with her partner.

Patients with unexplained infertility who have not conceived after two years (this can include up to 1 year before their fertility investigations) should be referred for IVF treatment.

However there are a number of situations where referral before two years may be appropriate. Where investigations show there is no chance of pregnancy with expectant management and where specialised fertility services are the only effective treatment, refer the patient directly to a specialist team for IVF treatment. This can include:

3.3.1 Medical conditions that affect fertility

Where there is a known reason for infertility or potential impact on fertility following medical or surgical treatment (e.g. prior to treatment for cancer; gender dysphoria; etc) early specialist referral should be offered. This does not include patients that have chosen to undergo sterilisation as a contraception method.

3.3.2 Pre-disposing factors

Where a woman is 36 years or over, or there is a history of predisposing factors or disability e.g. amenorrhoea, oligomenorrhoea, pelvic inflammatory

disease or with men undescended testes. In these circumstances earlier investigation should be offered.

A decision to refer a patient for specialised fertility services will be based on:

- The access criteria contained in this policy and the NICE guidelines which underpin them.
- Individual clinical assessment against clinical guidelines and patient suitability. The generic referral form, which assesses the patient's eligibility against the access criteria must be used by the referring clinician and countersigned by the tertiary centre. The referral form is attached as Annex (ii).
- The referral pathway flowchart is attached as Annex (i).

3.4 Providers

There are three providers of specialist fertility services for Welsh patients. These are:

- Liverpool Womens NHS Foundation Trust (The Hewitt Centre at the Liverpool Womens' Hospital);
- The Shrewsbury and Telford Hospital NHS Trust (Shropshire and Mid-Wales Fertility Centre at Shrewsbury Hospital);
- Abertawe Bro Morgannwg University Health Board (Wales Fertility Institute at Neath Port Talbot Hospital and Wales Fertility Institute at University Hospital for Wales)

Funding for specialist fertility services does not follow the individual patient but through to the designated tertiary centres for them to provide services for their catchment population. Funding will only be provided for individuals to access providers other than those listed above if there are exceptional clinical reasons for doing so. If this is the case then the referring consultant should complete an IPFR form. Private providers will not normally be considered.

3.5 Exclusions

Patients who do not meet the access criteria are excluded from accessing NHS funded specialist fertility services.

Referral under this policy does not cover the following group:

- Pre-implantation and genetic diagnosis (PGD) – although PGD is not covered within this policy, it is subject to a separate commissioning policy.
- Patients undergoing medical or surgical treatment which may impact on fertility. Access to cryopreservation of eggs, sperms and embryos is subject to a separate commissioning policy.

3.6 Exceptions

If the patient does not meet the criteria for treatment, but the referring clinician believes that there are exceptional clinical grounds for treatment an

Individual Patient Funding Request (IPFR) can be made to WHSS under the All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR).

If the patient wishes to be referred to a provider out of the agreed pathway, an IPFR should be submitted. Guidance on the IPFR process is available at www.whssc.wales.nhs.uk

3.7 Responsibilities

Referrers should:

- advise patients of their ability to access treatment under this policy in order that patients can make informed decisions about their options to have a child;
- Inform the patient that this treatment is not routinely funded outside the criteria in this policy; and
- Refer via the agreed pathway.

Clinician considering treatment should:

- Discuss all the alternative treatments with the patient;
- Advise the patient of any side effect and risks of the potential treatment
- Inform the patient that treatment is not routinely funded outside of the criteria in the policy;
- Confirm that there is contractual agreement with WHSSC for the treatment; and

Only submit an IPFR request where there are grounds for considering exceptional circumstances.

4. Putting Things Right: Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided. The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for

the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board;

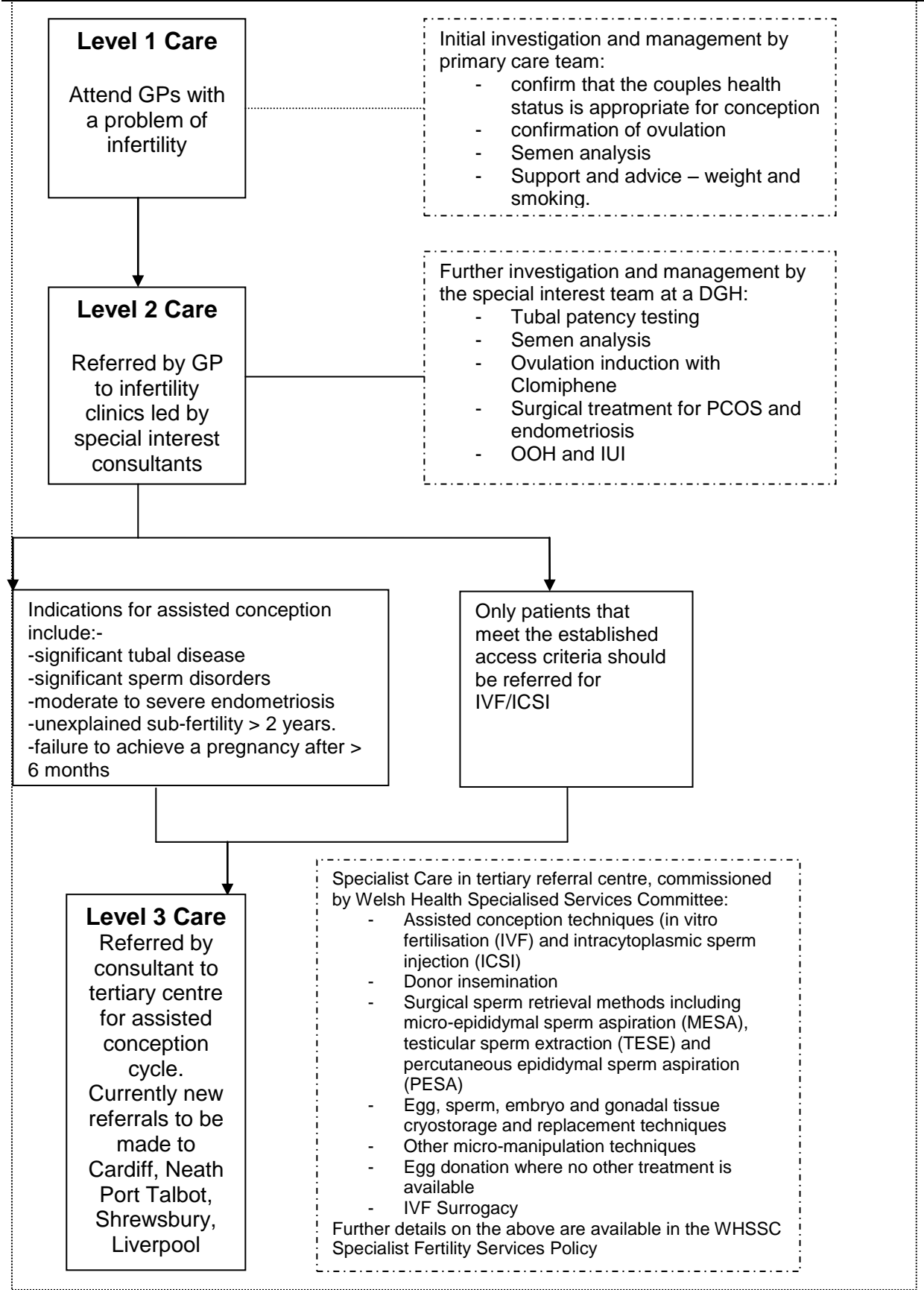
- When a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (welsh).

This policy has been subjected to an Equality Impact Assessment. The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex (i) Referral Pathway for Specialist Fertility Treatment for Welsh Residents



Annex (ii) IVF Referral Form

To: Administrator, XXXXX Unit
I wish to refer the patient(s) below onto the NHS waiting list for IVF treatment.
I have completed the details below and parts A & B. I believe to the best of my knowledge that the appropriate NHS eligibility criteria have been met.
Yours sincerely

(Referring Clinician signature)
(Referring Clinician name)

Address

Postcode:

Date:
Countersigned by:

(Tertiary Centre)

Date:

The information requested on this form is required to ensure that referrals meet the appropriate eligibility criteria for NHS funding.

In order for couples to be eligible for one cycle of NHS funded IVF or ICSI all criteria must be met. All preliminary investigation tests should be undertaken prior to referral. Results should be available in part B of this form.

PLEASE ENSURE THAT THE FEMALE PATIENT'S NHS NUMBER IS INCLUDED ON THE BOTTOM OF EACH SHEET

Female partner's details:		Male partner's details	
NHS No.	_____	NHS No.	_____
Full name:	_____	Full name:	_____
Date of birth:	_____	Date of birth:	_____
Address:	_____ _____ _____	Address:	_____ _____ _____
Postcode	_____	Postcode	_____

Telephone _____ Telephone _____
(Home) _____ (Home) _____
Telephone _____ Telephone _____
(mobile) _____ (mobile) _____

This information is used to contact you regarding your treatment. Please inform the IVF centre as soon as possible if any of your contact details change.

I declare that the information above and within Part A of this form is correct, and I accept that should it come to light that false information has been provided, I may be liable for the costs of my treatment:

Signed: _____

Signed: _____

PART A

In order for couples to be eligible for NHS funded specialist fertility services all criteria must be met. All preliminary investigation tests should be undertaken prior to referral and results attached. If this form is incomplete the referral will be returned.

Criteria		Female Partner	Male Partner
Age at time of referral			
Weight			
Height			
BMI			
Number of previous IVF, with or without ICSI, cycles	NHS		
	PRIVATE		
Date first seen by GP for fertility reasons			
Please tick reasons for referral			
Unexplained fertility and evidence attempted to conceive for 2 years prior to referral			
Male factor infertility			
Tubal Disorders			
Multiple Factors			
Ovalutory disorders			
Ovarian failure			
Endometriosis			
Uterine problems			
No male/female partner			
Menopausal			
Please answer yes or no to the following elements			
Any children from:	1. This relationship		
	2. Previous relationship		
Previous Sterilisation/vasectomy			
Smoker			
Ex-smoker (If Yes Date of Cessation)			
Veteran that is a recipient of Armed Forces Compensation Scheme (AFCS)			

PART B

All preliminary investigation tests should be undertaken prior to referral and all results attached to this form. If this form is incomplete the referral will be returned.

Preliminary Investigations Results

Female:	Date:	Result:
Rubella serology		
Chlamydia serology		
Hepatitis B & C serology (<i>within the last 3 years</i>)*		
HIV Screening (<i>within the last 3 years</i>)*		
Serum LH (<i>Day 2-4 of menstrual cycle</i>) [<i>within the last 3 months</i>]		
Serum FSH (<i>Day 2-4 of menstrual cycle</i>) [<i>within the last 3 months</i>]		
Serum TSH (<i>within the last 5 years</i>)		
Prolactin		
Hb/basic haematology (<i>within the last 6 months</i>)		
Haemoglobinopathy screen by Hb electrophoresis (if non-Caucasian)		
Smoke Screen test		
Details of any surgical treatment/investigations undertaken		
Male:	Date	Result
Hepatitis B & C serology (<i>within the last 3 years</i>)*		
HIV Screening (<i>within the last 3 years</i>)*		
Previous Semenology (if applicable)		Vol:
		Density:
		Motility:
		Normals:
Previous Semenology (if applicable):		Vol:
		Density:
		Motility:
		Normals:
Previous Semenology (if applicable):		Vol:
		Density:
		Motility:
		Normals:

Smoke Screen test		
Details of any surgical treatment/investigations undertaken		

*** NB: PLEASE ATTACH PHOTOCOPIES OF HEPATITIS B & C AND HIV TEST RESULTS. PHOTOCOPIES OF ALL RESULTS SHOULD BE ATTACHED.**

Any other medical information of relevance or significant medical/surgical illness: (i.e. tubal patency tests, previous gonadotrophin stimulation, details of laparoscopy)

If previous infertility treatment has been undertaken please include any significant information including any reaction to fertility drugs:

Any details of any significant psychiatric illnesses or social issues:

Annex (iii) Checklist

To be completed by the referring gatekeeper or treating clinician

PRIOR APPROVAL

Please tick the appropriate boxes:

Patient NHS No:			
Patient is Welsh Resident	Post Code		
Patient is English Resident	GP Code:		
		Yes	No
Patient meets following access criteria for treatment:			
Female Age (<43 at time of treatment) AND			
At least one of the couple does not have any existing children AND			
Body Mass of patients is between 19 and 30 AND			
No evidence of planned sterilisation AND			
Patients are no longer smoking AND			
Where unexplained fertility attempted to conceive 2 years prior to referral AND			
Confirms with HFEA code of practice			
Patient wishes to be referred to non-contracted provider			
<i>An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided as an exception. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&id=181455</i>			
Patient does not meet access criteria but is exceptional			
<i>An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided as an exception. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&id=181455</i>			

Name: _____ **Designation:** _____

Signature: _____ **Date:** _____

	Name (printed):	Signature:	Date:	Yes	No
Authorised by Gatekeeper					
Authorised by Patient Care Team					
Authorised by Other (please state)					
Patient Care Team/IPFR TRM Reference number:					

Annex (iv) Annual IVF QUALITY DASHBOARD

Unit Name

Name of person submitting dashboard return

Reporting Period:

Quarter	Period	Report by:
1	Apr-June	End of July
2	July- Sept	End of Oct
3	Oct- Dec	End of Jan
4	Jan- Mar	End of Apr

To be completed for Welsh NHS patients treated in each centre

For each quarter please indicate for the patients treated:

	Please enter unit data here for quarter 1	Please enter unit data here for quarter 2	Please enter unit data here for quarter 3	Please enter unit data here for quarter 4
The number of embryo transferred				
Number of cycles started				

Please indicate how many patients have undergone treatment are in the following categories:

		Please enter unit data here for quarter 1	Please enter unit data here for quarter 2	Please enter unit data here for quarter 3	Please enter unit data here for quarter 4
Cycle	Number of patients undergoing first cycle				
	Number of patients undergoing second cycle				
Age	Number of patients less than 35				
	Number of patients aged 35-37				
	Number of patients aged 38-39				
	Number of patients aged 40-42				
IVF/ICSI and fresh/frozen embryos	Number of IVF with fresh embryos				
	Number of IVF with frozen embryo transfers				
	Number of ICSI with fresh embryo transfer				
	Number of ICSI with frozen embryo transfer				

Please indicate how many patients have undergone treatment are in the following categories:

Quality Dimension	Quality Indicator	Numerator	Please enter unit data here for quarter 1	Please enter unit data here for quarter 2	Please enter unit data here for quarter 3	Please enter unit data here for quarter 4
Clinical Effectiveness	Pregnancy Rate	Number of clinical pregnancies				
	Cancelled cycles	Number of cycles cancelled before egg collection				

		Number of cycles cancelled between egg collection and embryo transfer				
	Proportion of single embryo transfers	Number of single embryo transfers				
	Multiple pregnancy rate	Number of cases where more than 2 fetal hearts detected				
	Live birth rate	Number of live births in the previous years quarter				
Patient Safety	Number of adverse incidents	Number of adverse incidents reported to the HFEA				
	Nature of reportable incidents					
	Proportion of severe ovarian hyperstimulation syndrome	Number of severe OHSS reported to HFEA				
Patient Experience	Number of Complaints	Number of complaints				
	Number of Compliments	Number of compliments				