Number 18 *of* 2024

HEALTH (ASSISTED HUMAN REPRODUCTION) ACT 2024

CONTENTS

PART 1

Preliminary and General

Press release

Minister for Health establishes Assisted Human Reproduction Regulatory Authority

From: Department of Health

Published on: 13 October 2025

Last updated on: 13 October 2025

Minister for Health Jennifer Carroll MacNeill today established the Assisted Human Reproduction Regulatory Authority (AHRRA). The Minister has appointed Professor Deirdre Madden, of the School of Law, University of Cork (UCC), as the first Chairperson of the Board.

INFERTILITY MANAGEMENT: AN UPDATE FOR PHARMACISTS

David Fitzgerald, Pharmacist Executive Manager

The National Maternity Hospital, Holles Street

IIOP Presentation 2025

LEARNING OUTCOMES

Define infertility and its common causes

Outline pharmacological management options

Discuss pharmacist roles in fertility management and ART

Explore ethical, legal and counselling aspects of fertility care

Further Reading:

- ESHRE (European Society of Human Reproduction and Embryology)
- NICE Clinical Guideline 156
- The Fertility Handbook – Professor Mary Wingfield; 2017

OVERVIEW OF INFERTILITY IN IRELAND

Affects 1 in 6 couples

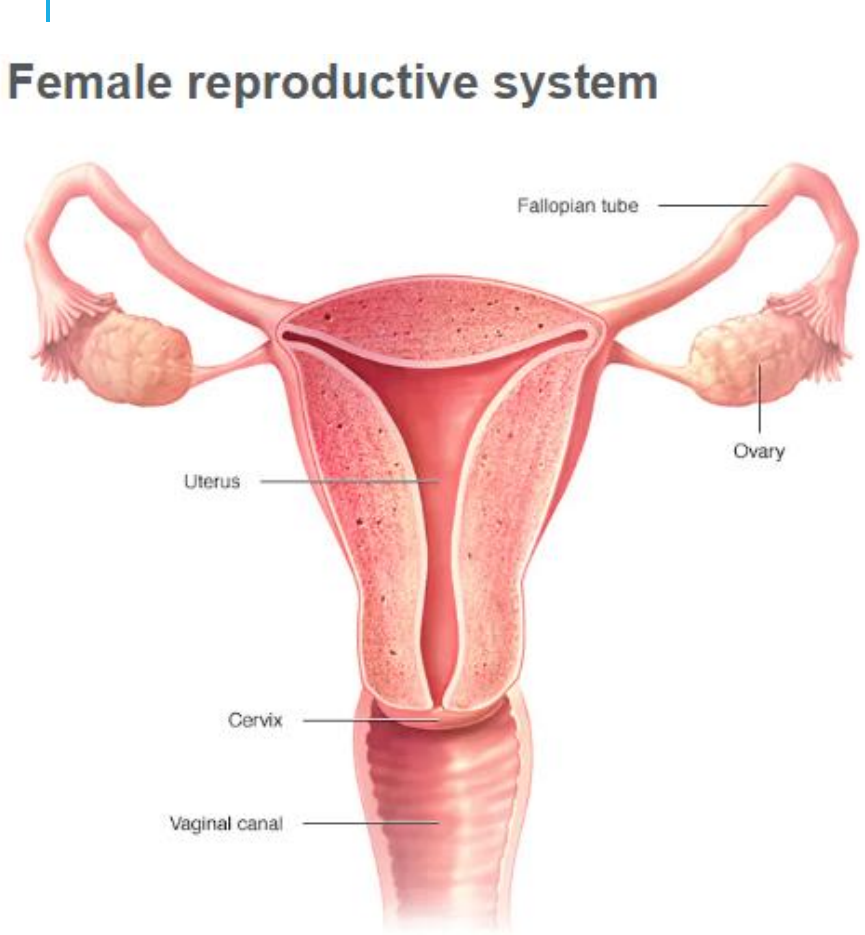
Infertility is defined as a disease characterised by the failure to conceive a pregnancy within 12 months of regular, unprotected sexual intercourse or due to the inability to reproduce, either as an individual or with a partner

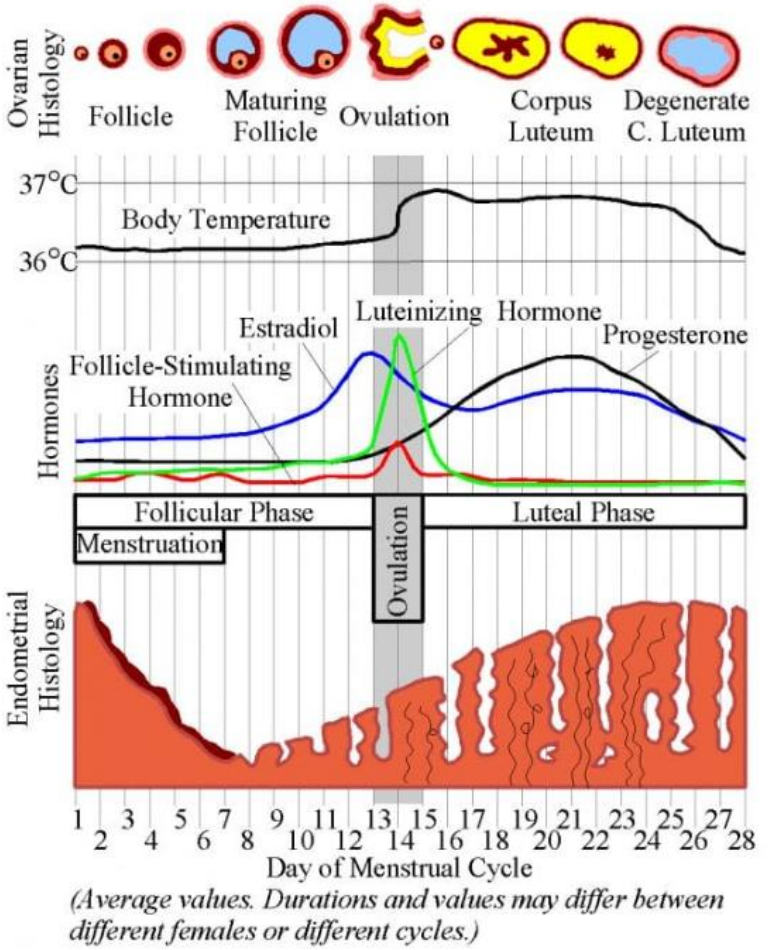
Approx. 30,000 couples affected in 2022

Ability to conceive declines with age

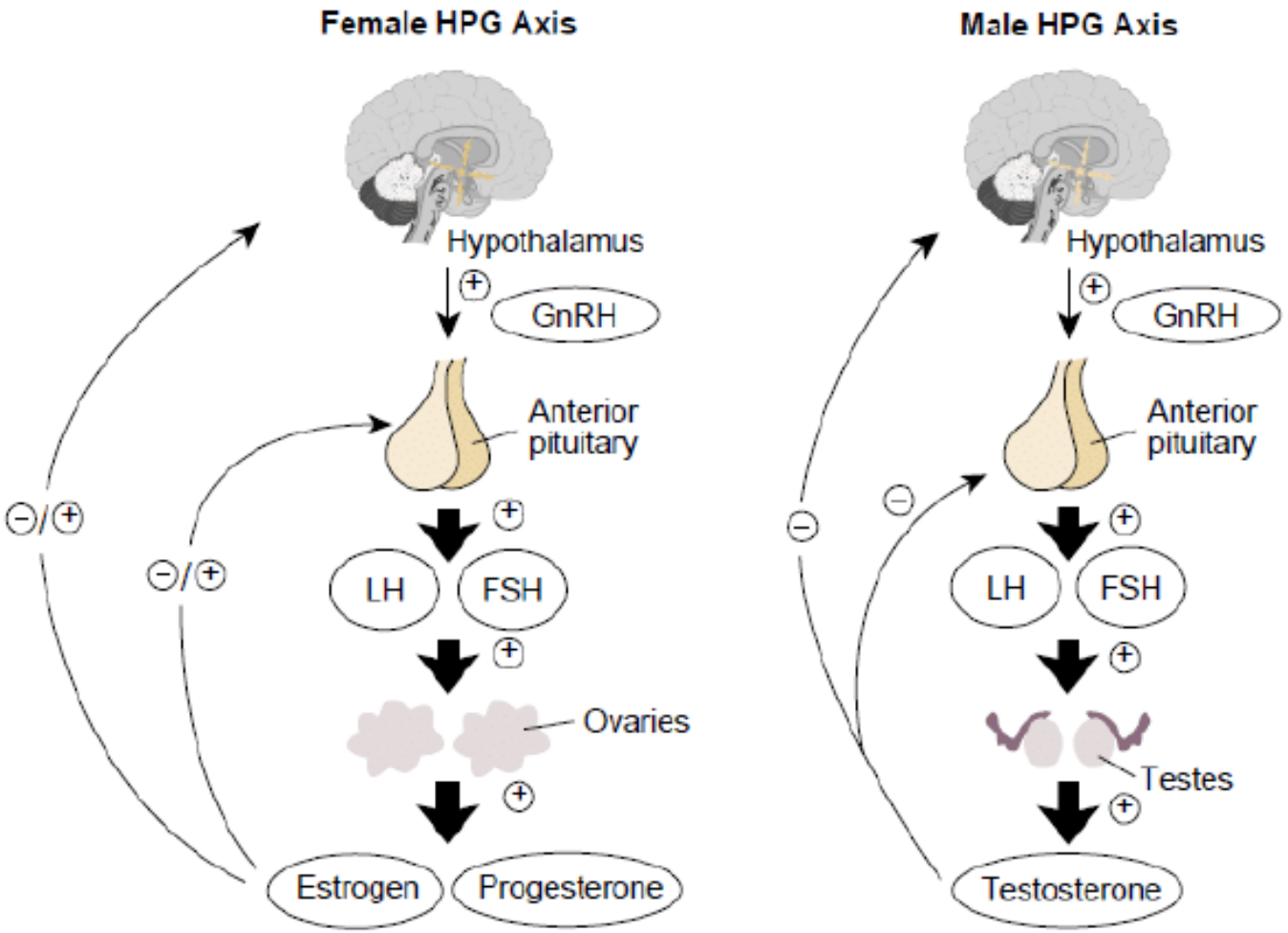
Historically lack of legislation, regulation, access and public funding in Ireland

REPRODUCTIVE BIOLOGY





HPG AXES

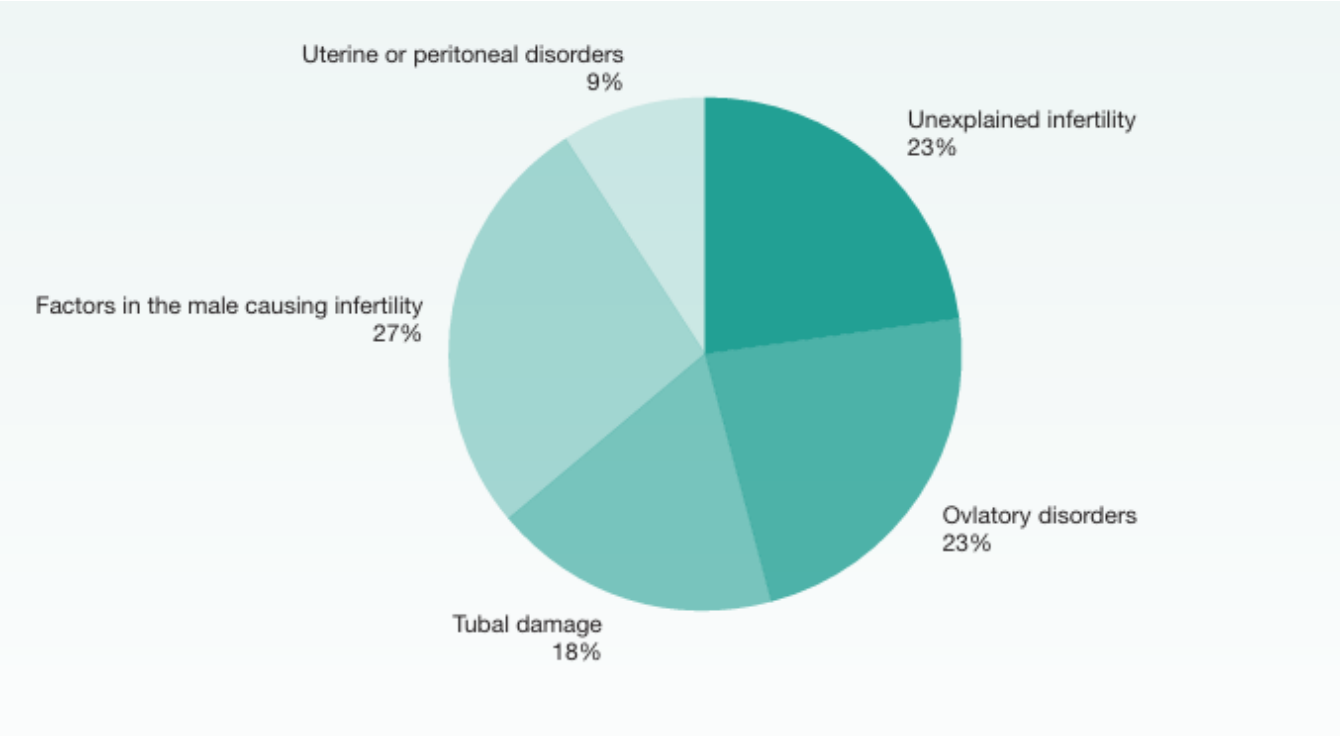

Female HPG Axis
Hypothalamus
GnRH
Anterior pituitary
LH
FSH
Ovaries
Estrogen
Progesterone
Male HPG Axis
Hypothalamus
GnRH
Anterior pituitary
LH
FSH
Testes
Testosterone

CAUSES OF INFERTILITY

Female: ovulatory disorders, endometriosis, tubal dysfunction

Male: sperm quality, hormonal factors, STIs, mumps, medical conditions

Shared and unexplained causes



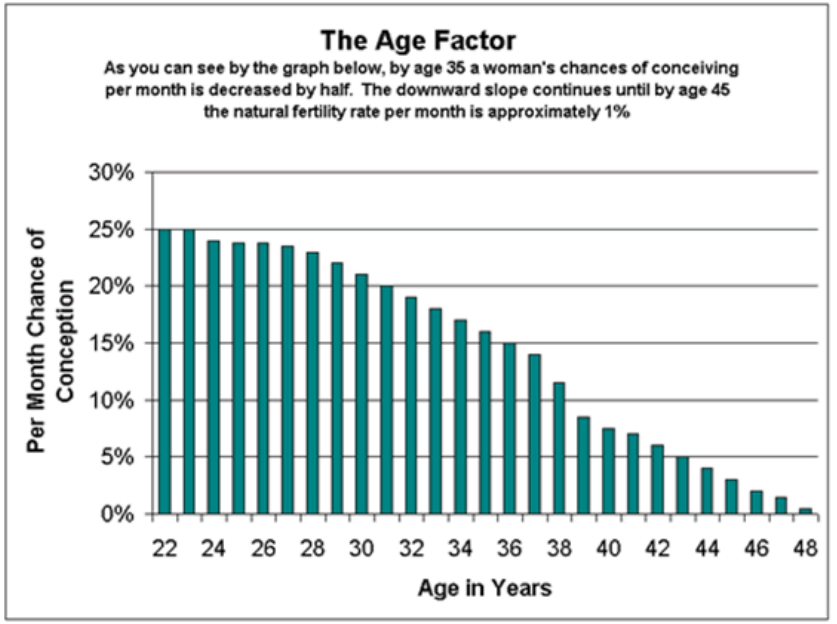
EFFECT OF AGE AND OTHER RISK FACTORS

Female age remains the most critical factor for conception & successful pregnancy

↓ Ovarian reserve – AMH / US scan

↓ Egg quality

Also ↓ sperm quality in men > 45



Both Women and Men	Women	Men
Obesity	Caffeine *(2 cup limit)*	Anabolic Steroids
Excessive Exercise	Vaping	Cocaine
Smoking		Saunas, heated car seats
Alcohol		
Stress		
Marijuana, Heroin, MDMA		

MEDICATION-INDUCED INFERTILITY

Both Women & Men	Women	Men
Chemotherapy	Anti-psychotics	Exogenous Testosterone
	Spironolactone	Sulfasalazine
	NSAIDs	CCBs
	Herbal Supplements	Anti-depressants

INVESTIGATIONS AND DIAGNOSIS

Women

Physical Exam

Ovarian Reserve – AMH, AFC

Hormonal profile – FSH, LH, progesterone, oestrogen, TFTS, prolactin – *only if irregular cycle*

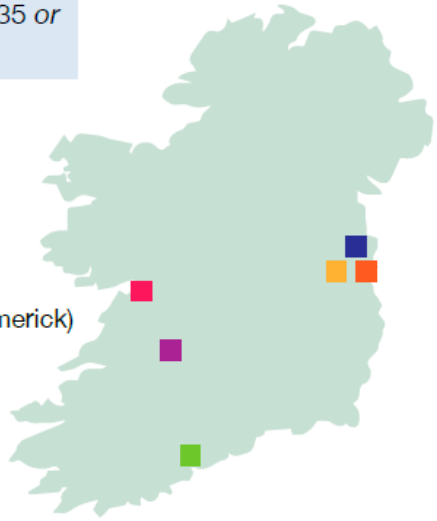
Rubella antibodies

STI check

Female Age	18 – 42 + 364 days
Male Age	18 – 59 + 364 days
Female BMI	18.5 – 35.0
Fertility History/ Diagnosis	Risk factors which affect fertility *or* Trying to conceive 12 months if female aged 18-35 *or* Trying to conceive 6 months if female aged ≥36

Regional Fertility Hubs

- Rotunda Hospital, Dublin
- National Maternity Hospital, Dublin
- The Coombe Hospital
- Cork University Maternity Hospital
- Nenagh Women's Health Hub (University Maternity Hospital Limerick)
- University Hospital Galway



Men

Semen Analysis

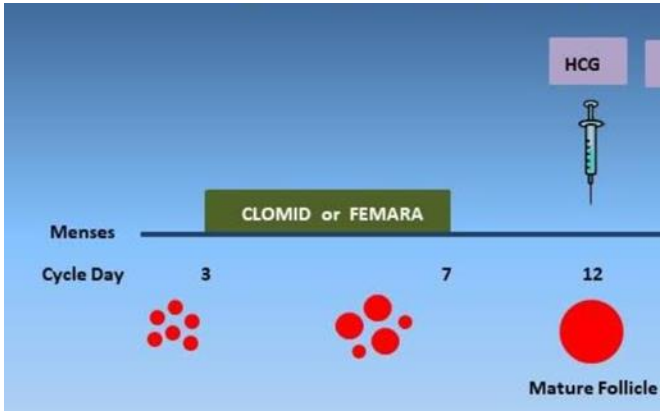
Hormonal profile – FSH, LH, Prolactin, testosterone – *only if abnormal semen analysis*

ASSISTED REPRODUCTIVE TECHNOLOGY

Definitions

Ovulation induction (OI) - Use of medicines to stimulate ovaries to release egg(s) in women who do not ovulate spontaneously

- 6 cycles before moving on to IUI/IVF/ICSI



Intrauterine Insemination (IUI) – sperm placed directly in uterus around time of ovulation

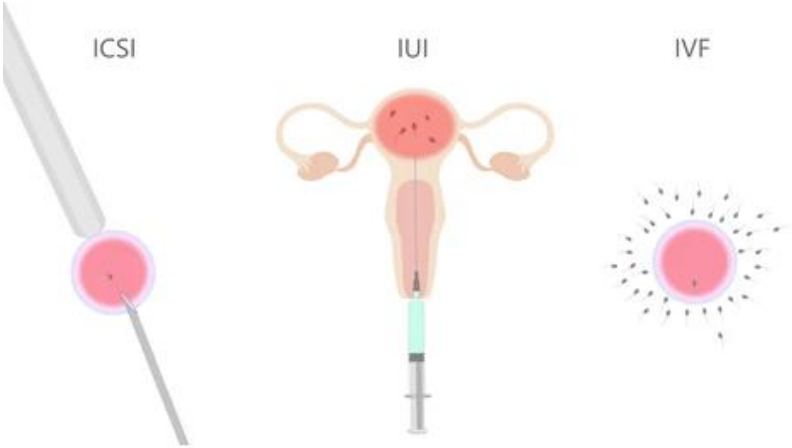
- Least invasive

In-Vitro Fertilisation (IVF) - Eggs and sperm combined in-vitro (in glass), fertilized egg transferred to uterus

- Standard ART

Intracytoplasmic Sperm Injection (ICSI) – Each egg injected with a single sperm in-vitro

- For severe male factor, or failed IVF



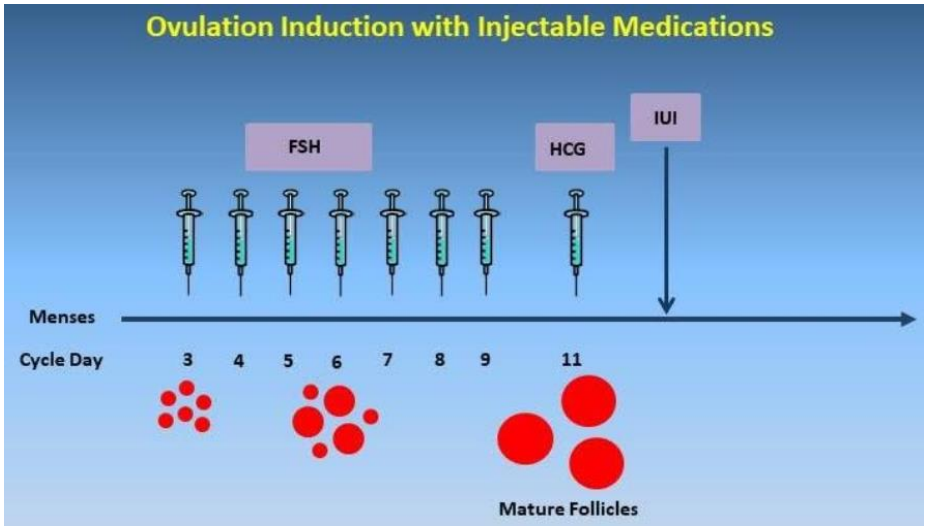
OVULATION INDUCTION – ORAL AGENTS

Medication	Mechanism	Dose	Adverse Effects
Letrozole (1st Line)	Aromatase inhibitor ↓ oestrogen production in ovaries → FSH ↑ from pituitary	2.5 – 5mg OD on D2 to D6 of cycle	Low oestrogen: hot flushes, mood swings, headaches, difficulty sleeping
Clomifene	Oestrogen receptor antagonist in hypothalamus → FSH ↑ from pituitary	25 – 50mg OD on D2 to D6 of cycle	Worse than letrozole ↑ risk of multiple pregnancy
Tamoxifen	Same as clomifene	20 – 60mg OD for 5 days at start of cycle	Similar to clomifene
Metformin	PCOS: improves insulin sensitivity → ovaries ↓ of testosterone	500 – 2000mg daily	GI upset
Cabergoline	Hyperprolactinaemia: Dopamine agonist ↓ prolactin secretion; induces normal ovulation	0.25 – 2mg per week	GI upset Valvulopathy with cumulative doses

OVULATION INDUCTION – INJECTABLE AGENTS

Gonadotrophin FSH ± LH act directly on ovaries to induce ovulation

hCG trigger injection to release egg once follicle of certain size on US



Fewer side effects than oral agents – still cause bloating, mood swings

Higher risk of multiple pregnancy - ↑ requirement for US monitoring

Risk of Ovarian Hyperstimulation Syndrome (OHSS)

OVULATION INDUCTION – INJECTABLE AGENTS

Gonadotrophins FSH / LH

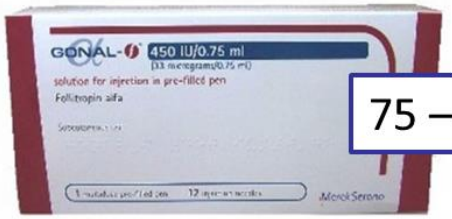
FSH with LH (> 35 years; common)

- Pergoveris® (900iu FSH / 450iu LH)

150/75iu daily

FSH Only (< 35 years; less common)

- Gonal-F® "originator": follitropin-α
- Bemfola®:generic of Gonal-F
- Rekovelle®: ↓ risk OHSS



75 – 150iu daily

Trigger

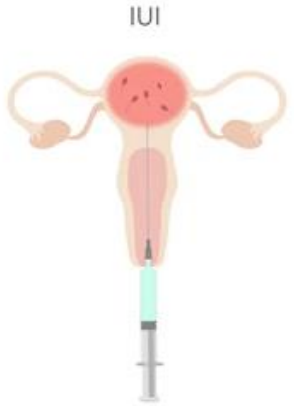
Recombinant hCG

- Ovitrelle® 6,500 units

Naturally derived hCG

- Gonasi® 5,000 units
- Pregnyl® discontinued

INTRAUTERINE INSEMINATION (IUI)



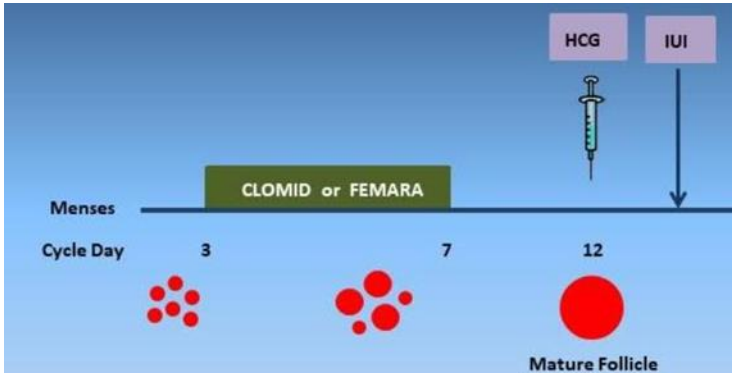
"Artificial insemination"

Ovulation induction + hCG trigger

Sperm processed in lab and inserted into uterus after ovulation

Used in younger couples

- IVF for older couples



Less expensive than IVF

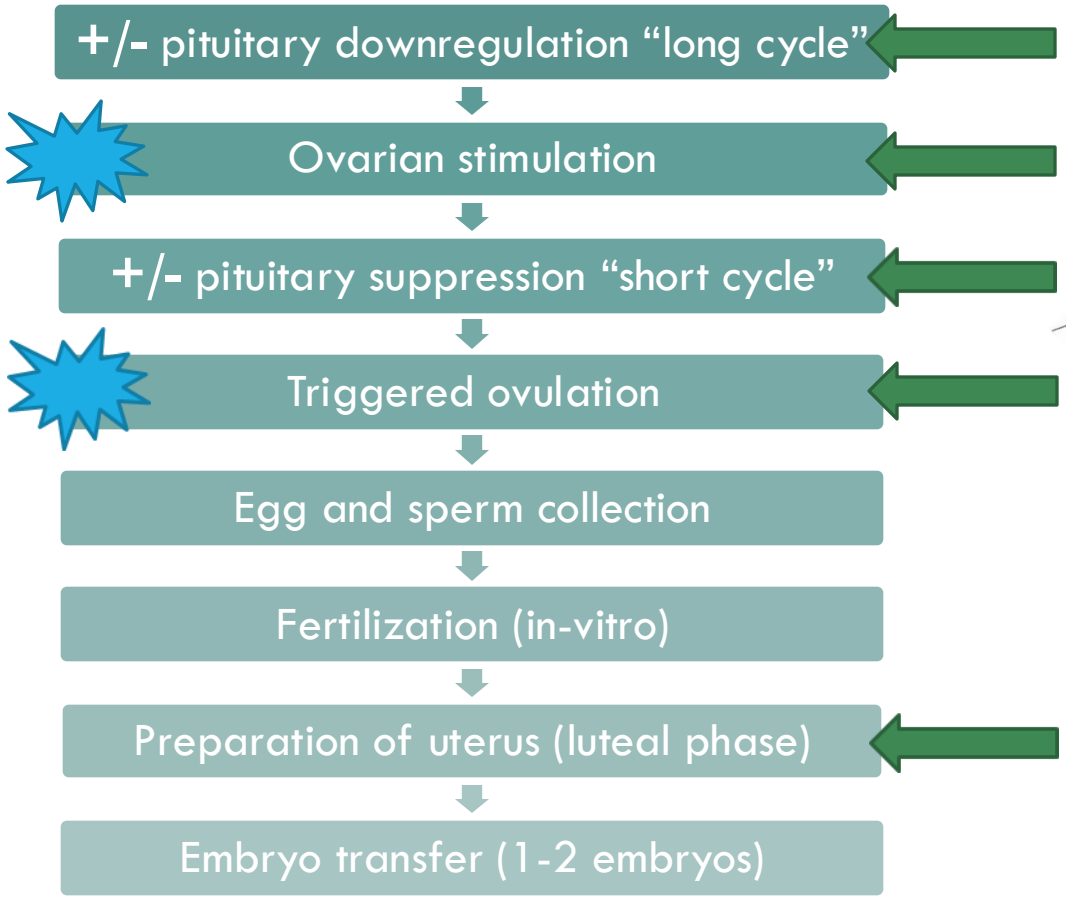
- IUI €1000 per cycle if paying

Indications: psycho-sexual issues, physical disability, previous surgery to cervix, donor sperm for single women, lesbians, HIV^+

IN-VITRO FERTILISATION (IVF)

Indications: male factor infertility, blocked fallopian tubes, unsuccessful OI / IUI cycles, unexplained female infertility

7 stages



IVF: PITUITARY SUPPRESSION OR DOWNREGULATION

"Short Cycle" with GnRH antagonist / suppression

- Control oestrogen levels to prevent early LH surge and ovulation
- Cetrorelix, Ganirelix
- Started on 5th day of FSH/LH "stims" – continue 4 -10 days until egg collection
- Tx of choice; usually tried 1st, patient-friendly, ↓ risk OHSS
- Preferred in PCOS

"Long Cycle" with GnRH agonist / downregulation

- Prolonged course; started 2 – 3 weeks before FSH/LH "stims" and continue until egg collection
- Buserelin, nafarelin, triptorelin, luprorelin, goserelin
- Less patient-friendly, symptoms of low oestrogen
- Used in endometriosis, ovarian cysts, fibroids
- ↑ risk OHSS
- Similar success rate to "short cycle"

IVF: OVARIAN STIMULATION & TRIGGERED OVULATION

Goal of IVF to produce multiple follicles (aim for 8 – 14 eggs)

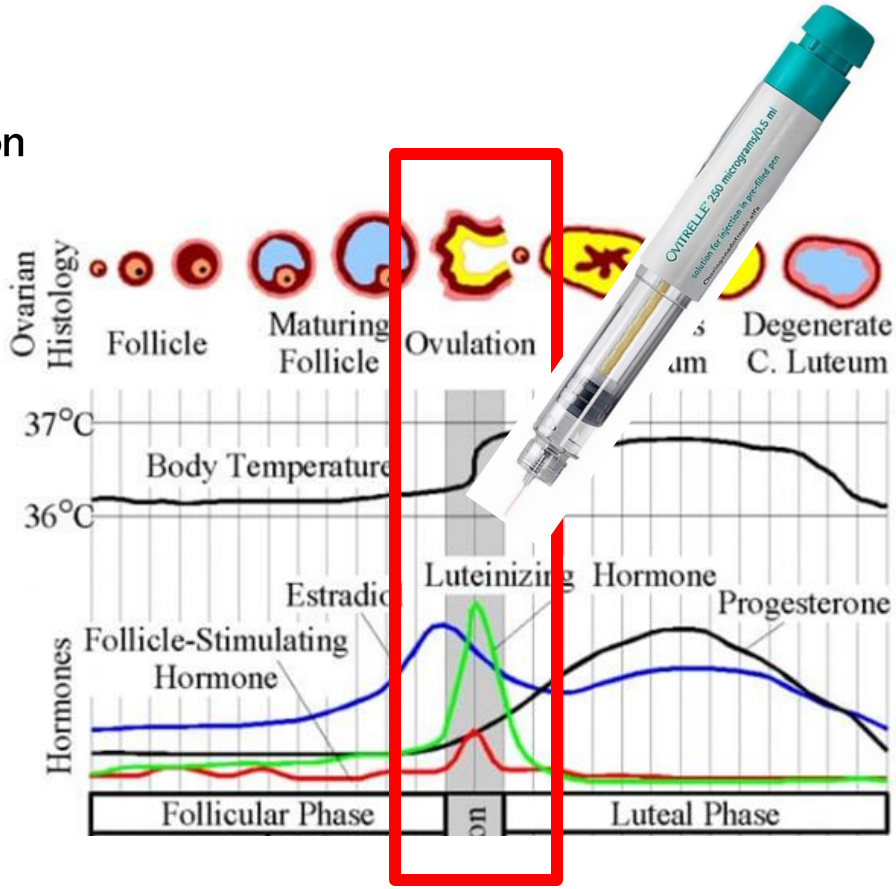
- Compared to ovulation induction aim of 1 egg

Dose of FSH in IVF vs ovulation induction

- IVF: 150 – 225 units per day (max 450 units)
- OI: 75 – 150 units per day (max 225 units)

hCG "trigger" to mimic LH surge for maturation and release of eggs

- S/C injection 36 hours before egg collection



IVF: EGG RETRIEVAL AND TRANSFER

Egg collection 36 hours after hCG trigger; US-guided minor surgical procedure

- Use paracetamol for pain
- Avoid NSAIDs

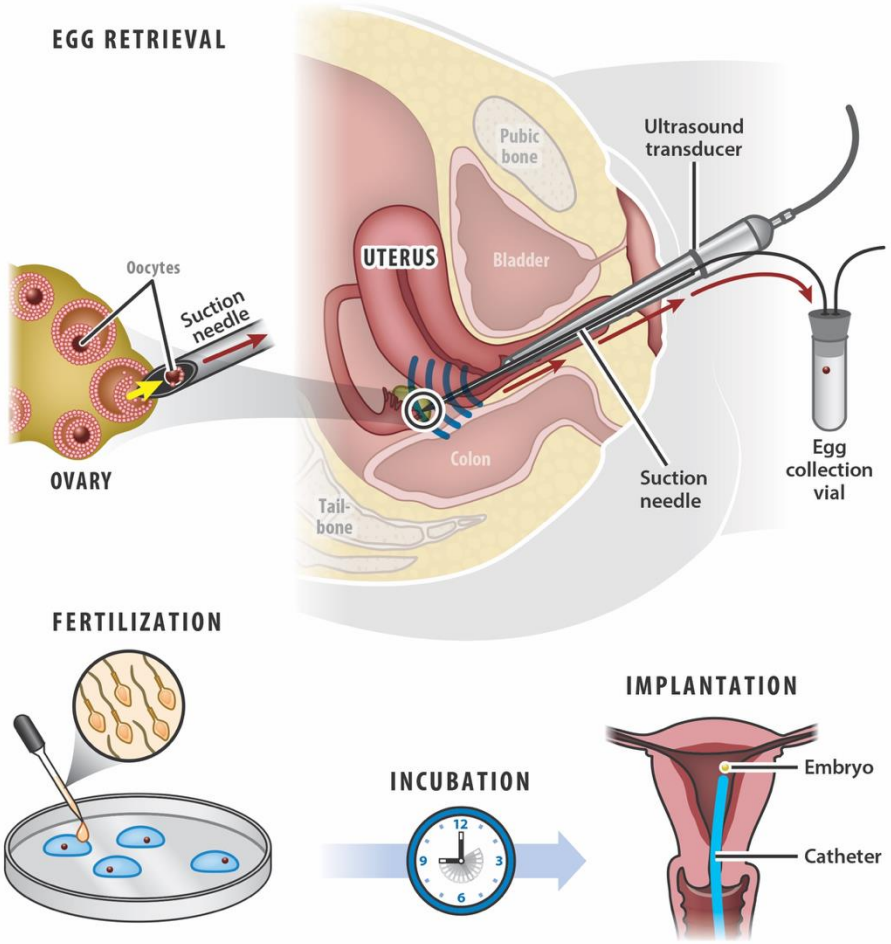
Sperm collection same day as egg collection

Fertilisation "in-vitro"

- 2/3rds eggs form embryos

Embryo transfer on Day 3 – 5

- Highest grade transferred to uterus



IVF: LUTEAL PHASE SUPPORT

Progesterone used to prepare the uterus for pregnancy

Suppression / downregulation regimen depletes endogenous progesterone

Started after egg collection

Continue until 8 weeks gestation or if previous miscarriage or bleed in current pregnancy then until 12 – 16 weeks gestation

1st line Cyclogest® 400mg BD pv

Crinone® 8% Gel OD pv

Utrogestan® pv capsule, Lutinus® pv tablet

Duphaston® 10mg TDS po

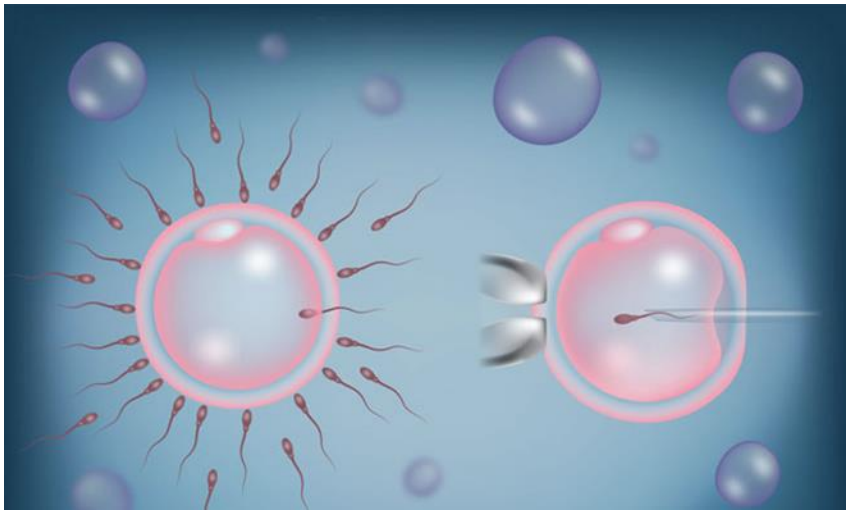
"Double progesterone" – pv plus s/c injection

- Prolutex® or Lubion®

INTRACYTOPLASMIC SPERM INJECTION (ICSI)

Variation of IVF where sperm are very compromised

- Severe deficit of sperm quality
- Azoospermia (absence of sperm)
- Previous IVF failure



Each egg injected with a single sperm

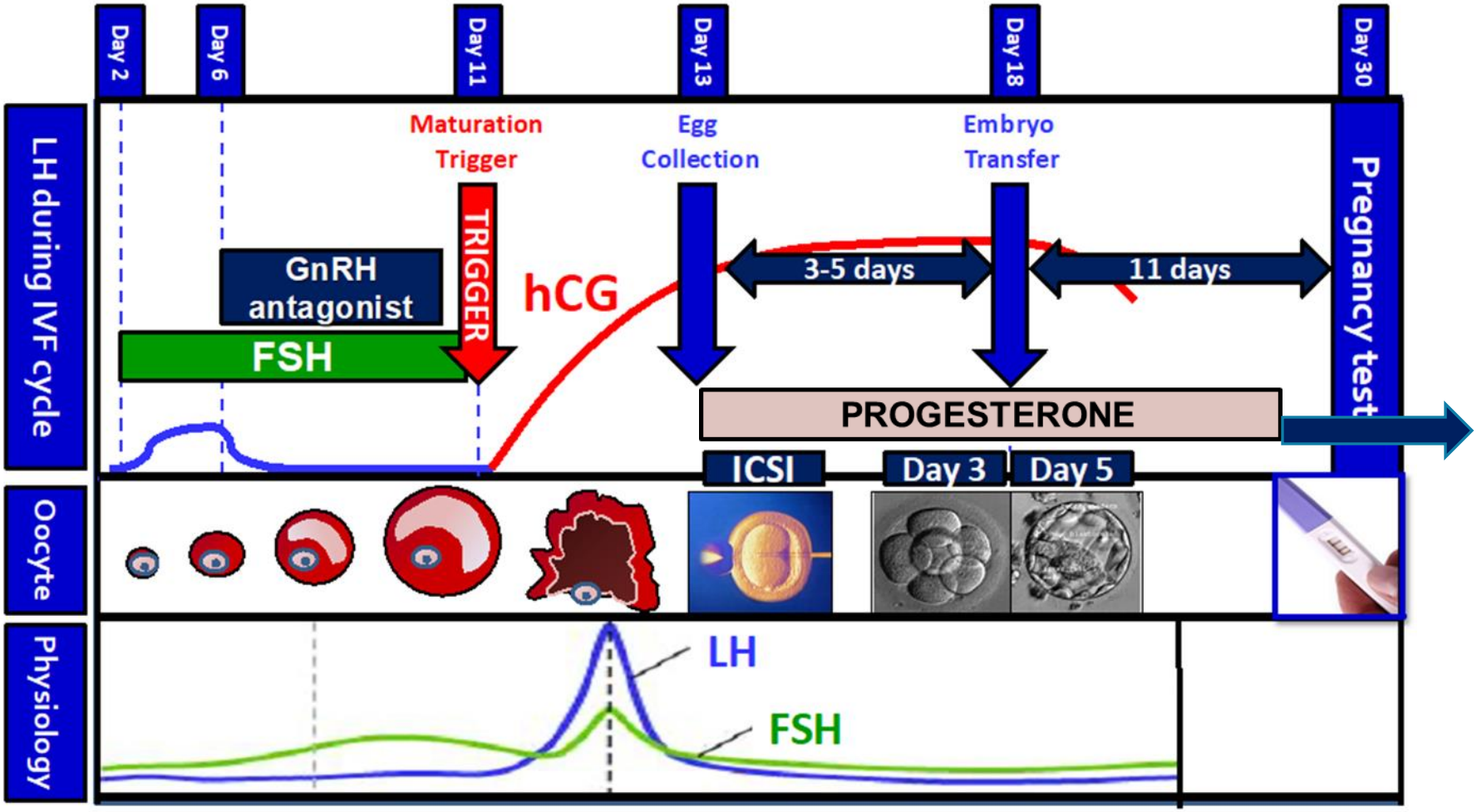
All other stages of cycle identical to IVF

↑ risk of congenital abnormality

- Background rate 2 – 3%
- IVF 3 – 4%
- ICSI 4.5%

Male genetic fertility; male child may have same genetic fertility problem as father

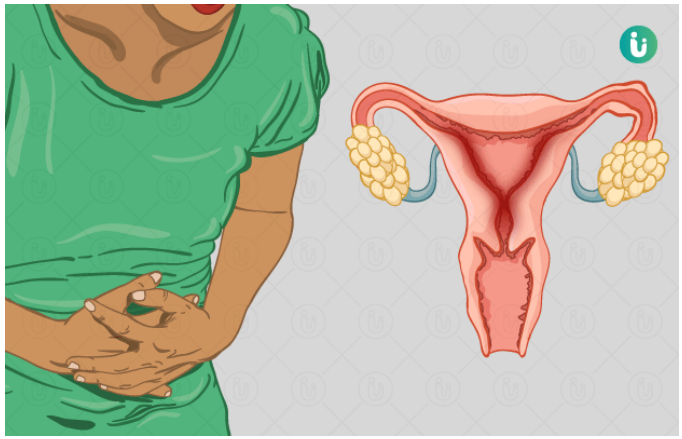
IVF / ICSI RECAP



IVF: ADDITIONAL MEDICATIONS

Medication	Use
OCP	Time the natural cycle to the clinic's timetable
HRT	Endometrial preparation, cycle timing
Testosterone	Follicular development and better quality eggs
Thyroxine	Hypothyroidism linked to risk of miscarriage
Vitamin D3	Higher pregnancy and live birth rates
Folic Acid	Embryo development, neural tube defects
Co-enzyme Q10	Better quality eggs
Aspirin	Reduce risk of miscarriage
Prednisolone	May improve implantation rates; *limited evidence*
LMWH	Decrease VTE risk due to elevated hormone levels
Naltrexone	Lowers uterine inflammation; *limited evidence*
Doxycycline	Prophylaxis before egg retrieval / embryo transfer
Azithromycin	To clean sperm

RISKS OF ART



Ovarian Hyper-stimulation Syndrome (OHSS)

- ↑ Oestrogen affects integrity of small blood vessels
- Fluid leaks to abdomen, ankles and can leak to heart/lungs
- Less common now due to antagonist regimens and ability to freeze embryos
- Encourage patients to report persistent nausea, vomiting, severe pain, thirst, abdominal swelling or reduction in passing urine
- Mild OHSS in 33% of IVF/ICSI cycles; moderate to severe in 3 – 8% of cycles

Multiple Births - ↑ risk with ovulation induction vs IVF/ICSI

Fetal abnormalities – likely genetic as opposed to drug-related

↑ risk of prematurity

Lifetime cancer risk

- Study in Netherlands – no ↑ risk of breast cancer
- NICE: no association with cancer in women or in children born by ART

Medication Side Effects

- Abdominal bloating, headache, mood changes, menopausal symptoms

PHARMACIST PRACTICE POINTS

Timing is essential – ensure sufficient supply in advance of administration dates

Medications left over from previous cycles – often have FSH/LH "stims", progesterone, preparatory medications left over from failed cycle

Needle quantity and type

- Reconstitution 21G green
- IM administration 23G blue
- SC administration 25G orange

Consumables – cold chain/coolbox, alcohol wipes, sharps disposal

Counselling – most fertility clinics will counsel patient on timing and administration

- Manufacturer provides support materials / videos via QR codes on products

Drug interactions with SSRIs – impaired conversion of Clomifene / Tamoxifen to active metabolites

High Tech Medicines

- Agonists / Antagonists - Cetrotide®, Synarel®, Decapeptyl®
- FSH/LH "Stims" – Pergoveris®, Gonal-F®, Bemfola®, Rekovelle®
- hCG trigger - Ovitrelle®
- EU prescriptions valid
- High-tech must be transcribed by GP / fertility clinic
- Submit original prescription and copy of transcription to high-tech hub who will issue a reference number

PRACTICAL EXAMPLE 1

Rx

Pergoveris 150 units FSH / 75 units LH daily x 10/7

Ovitrelle 250mcg x 1

Crinone 8% gel PV nocte x 15/7

FSH / LH "stims"

hCG trigger

Luteal support

PRACTICAL EXAMPLE 2

Rx

Gonal-F 300 units daily x 14/7

Cetrotide 0.25mg daily x 11/7

Ovitrelle 250mcg x 1

Cyclogest 400mg pv nocte x 1/12

FSH "stims"

GnRH antagonist – pituitary suppression

hCG trigger

Luteal support

LEGISLATIVE CHANGES

"There is at present a serious disconnect between what developments in science and medicine have rendered possible on one hand, and the state of the law on the other" – Judge Hardiman 2014

In 2021 Ireland ranked 39th out of 40 in European Atlas of Fertility Treatment

- Now ranked 12th

Health (Assisted Human Reproduction Act) approved in summer 2024

- Put in place regulatory framework for provision of AHR
- Establishment of Assisted Human Reproduction Regulatory Authority (AHRRA)
- Sets out general criteria for provision of AHR treatments
- Use of donor sperm, eggs and embryos
- Sets out circumstances in which surrogacy permitted

AHR REGULATORY AUTHORITY (AHRRA)


Press release

Minister for Health establishes Assisted Human Reproduction Regulatory Authority

From: Department of Health

Published on: 13 October 2025

Last updated on: 13 October 2025

New statutory, regulatory agency established under the 2024 Act

To protect, promote and ensure wellbeing of children born as a result of AHR, persons undergoing AHR and intending parents

Prohibition of unlicensed person providing AHR treatment

- No more unregulated private consultant clinics
- Will ensure compliance of license holders with the Act
- Will regulate treatment guidelines, age limits for treatment, consent, number of embryos to transfer, surrogacy, post-humous AHR
- Consensus approach to treatment e.g. management of hypothyroidism - ↑ risk of miscarriage yet no streamlined approach to treatment based on TSH levels

FERTILITY HUBS

6 regional hubs started in 2022

3 stage Model of Care

1. GP – first point of contact
2. Fertility Hub following initial GP consult
3. Private fertility clinics for IVF and advanced AHR

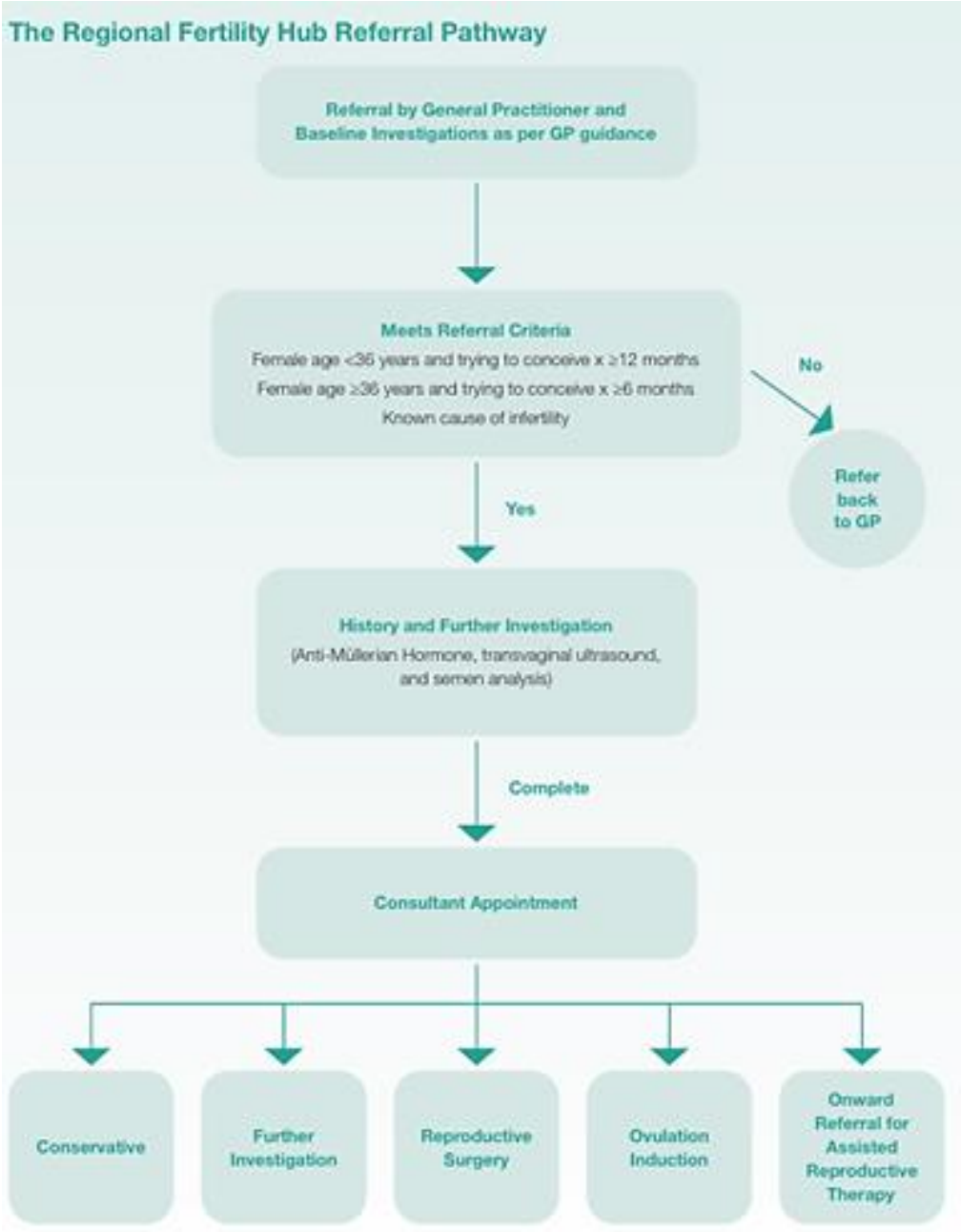
Public funding for unlimited OI cycles, and one IVF cycle

- Referral to private IVF clinic
- 2 hubs now offering IUI

Patients pay €80/month DPS

Couples only

Now both primary and secondary infertility



FERTILITY HUBS

Referrals now averaging

525 per month

Referral form available on

standard GP healthlink

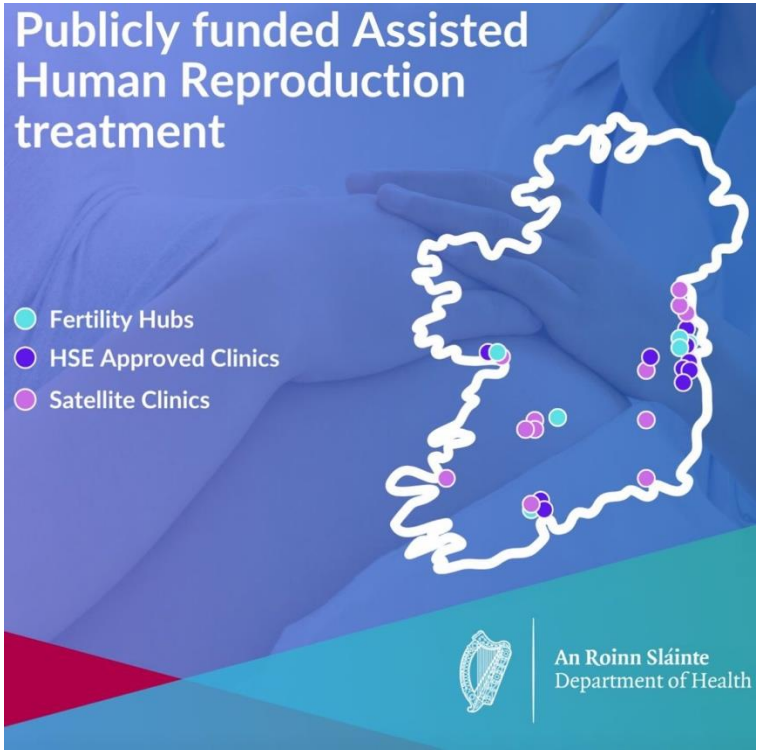
38% success rate in patients who have

been referred in past 2 years

4.2.2 Total Number of Referrals per month per Treatment Type September 23-August 24

	Sept 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	April 24	May 24	Jun 24	Jul 24	Aug 24	Total
IUI	0	6	12	7	11	16	14	19	17	25	15	24	**166**
IVF	3	8	16	24	36	37	32	38	46	54	53	51	**398**
ICSI	10	23	45	29	44	34	50	38	50	45	60	63	**491**
ICSI plus Tese	0	0	1	0	4	3	2	3	1	2	2	10	**28**
Total	**13**	**37**	**74**	**60**	**95**	**90**	**98**	**99**	**114**	**126**	**130**	**148**	**1,084**

In terms of treatments for which patients are referred, as would be expected the majority of patients are referred for either IVF or ICSI.



SUMMARY – KEY TAKEAWAYS

Prevalence of both male and female infertility risen over past 20 years

Female age is most important predictor

Types of ART:

- OI - Use of medicines (oral or injectable) to stimulate ovaries to release egg(s) in women who do not ovulate spontaneously. Natural conception
- IUI – sperm placed directly in uterus around time of ovulation. Same medications used as OI
- IVF - Eggs and sperm combined in-vitro (in glass), fertilized egg transferred to uterus. Additional medications used to suppress pituitary to avoid early ovulation, along with progesterone to maintain endometrium
- ICSI – Each egg injected with a single sperm in-vitro. For severe male factor. Same medications as IVF

Timing is essential – ensure all medications available on time

Calculate quantity and combination of FSH, FSH/LH pens required along with needles if necessary

AHRRA to begin regulation and licensing – will lead to standardisation

Public funding and access via fertility hubs expanding – currently OI, some IUI, and referral for 1 cycle of IVF in private clinic – funding will expand in future

Q&A

Questions and discussion