National Women & Infants Health Programme

HSE Fertility Services Report

September 2023-August 2024

Acknowledgements

In publishing this report, I would like to thank HSE colleagues who have worked with NWIHP to deliver this inaugural public Assisted Human Reproductive service. Specifically, I would like to acknowledge the commitments and contributions of Ms Claudia Manning and her team working in HSE procurement, Brian Mc Carthy and his team from the HPO office, Aoibheann Ni Shuilleabhain and her communications team, Eilish O'Connor from the Office of National Director of Capital and Estates, and Chris Meehan from the Office of the Chief Information Security Officer. Their expertise and input has been invaluable in developing and implementing the public AHR service.

Furthermore, I wish to acknowledge the hard work and unfaltering dedication staffs working in the regional fertility hubs have displayed so as to ensure patients receive consistent, evidence-based high-quality fertility care. All regional fertility hub staff and hospital managements have been unwavering in their support for the advancement of AHR services and their support enables NWIHP to drive forward in terms of expanding the service.

Finally, I would like to thank Prof Mary Wingfield for her clinical leadership during the set up phase of the process.

NWIHP very much looks forward to ongoing collaboration with all stakeholders so as to action the Minister's commitment in Budget 2025 to expand the public AHR access criteria.

Kilian McGrane,

Director of National Women and Infants Health Programme

Contents

AHR	Assisted Human Reproductive
BMI	Body Mass Index
CNS	Clinical Nurse Specialist
DoH	Department of Health
GP	General Practitioner
HSE	Health Service Executive
HYCOSY	Hysterosalpingo-contrast-sonography
ICGP	Irish College of General Practitoners
ICSI	ICSI is a type of IVF. With the difference being the manner in which the eggs are fertilised in the laboratory. In standard IVF, the eggs are placed in a dish with thousands of sperm and one sperm fertilises the egg. With ICSI, a single sperm is chosen and injected directly into the centre of the egg. The resulting embryo will then be placed in the woman's uterus where it will hopefully implant and lead to a pregnancy.
IUI	IUI is a fertility treatment that involves inserting the man's sperm directly into the woman's uterus at the most fertile point in the menstrual cycle
IVF	IVF is a fertility treatment where sperm and eggs are collected and carefully combined in a laboratory. The resulting embryo will then be placed in the woman's uterus where it will hopefully implant and lead to a pregnancy.
MoC	Model of Care
NWIHP	National Women and Infants Health Programme

1.0 Introduction

The HSE's National Women and Infants Programme (NWIHP) is responsible for managing and overseeing the development of reproductive medicine services in the public health service. This work is guided and underpinned by the Model of Care (MoC) for Fertility Services in Ireland which was developed by the Department of Health (DoH) in collaboration with NWIHP.

This report will commence by providing a brief summary of the development of reproductive medical services in the public sector in Ireland further to the development of the MoC. Thereafter, the report will focus on providing an overview of data held at national level since the introduction of publicly funded, privately provided Assisted Human Reproductive (AHR) Services as of 25th September 2023. A synopsis will then be provided as to the next steps planned for the further development of public reproductive medical services in Ireland.

2.0 Model of Care for Fertility – Overview

The MoC for public fertility services in Ireland was designed around three keys stages in a patients' care pathway starting in primary care with their GPs, then into secondary care in the acute hospital sector and then,where necessary, AHR treatment inclusive of in-vitro fertilisation (IVF) and intra-cytoplasmic sperm injection (ICSI), with patients being referred through these stages via structured pathways. A key principle underpinning the MoC is that clinical intervention will be provided at the lowest level possible in line with the patient's clinical indication and requirements.

Phase One of the MoC, envisaged the establishment of designated regional fertility hubs within the six maternity networks in Ireland, in order to facilitate and enable the management of a significant proportion of patients presenting with fertility-related challenges at secondary care level. Patients are referred by their GPs to their local Regional Fertility Hub, which can provide a range of medical treatments and surgical interventions to assist with natural conception, depending on the clinical presentation.

Phase Two of the roll-out of the MoC focused on the development and provision of AHR inclusive of IUI, IVF and ICSI through the public health system at tertiary level.

3.0 Implementation of MoC to date

3.1 Phase One Implementation

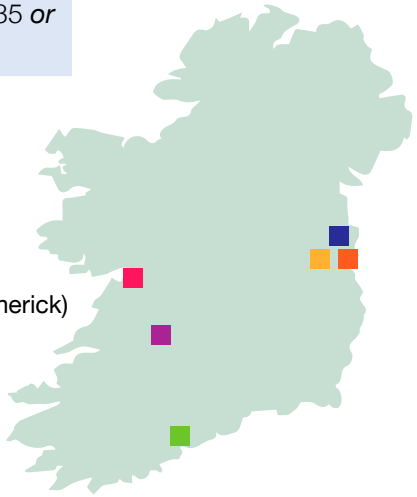
Phase one of the implementation of the MOC for fertility saw the development and implementation of six regional fertility hubs located strategically across Ireland so as to provide an equitable service in each of the maternity networks. The regional fertility hubs are located in the Rotunda Hospital, the National Maternity Hospital, the Coombe Hospital, Nenagh Hospital, Galway University Hospital and Cork University Maternity Hospital. Each of the hubs are led by consultants with expertise in reproductive medicine supported by teams of specialist fertility nurses.

The six regional fertility hubs offer secondary level care comprising of a comprehensive fertility assessment for both females and males. Depending on the outcome of these investigations further diagnostic and/or medical and/or surgical management may be indicated and undertaken. The treatment capacity at secondary level at present does not extend to providing assisted fertility treatment such as IUI or IVF. In order for a GP and/or Consultant to initiate a referral to a regional fertility hub the following patient criteria must be met:

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



3.2 Phase Two Implementation

Following the Government announcement and commitment to publicly fund the provision of AHR services in Budget 2023, the HSE was tasked with the delivery of a publicly funded AHR service to commence in September 2023. In the absence of a publicly delivered AHR facility and service it was determined that in the short to medium term, access to AHR services would be secured for public patients through the private sector in Ireland, whilst in parallel public capacity to directly deliver an AHR service was developed.

A national procurement process was undertaken under the auspices of NWIHP and HSE Procurement further to which eight private AHR Providers were formally authorised by the HSE to provide 12 defined care packages of AHR services (Appendix A) to identified public patients with the price per package of care set by the HSE. Details of the eight private AHR Providers authorised by the HSE, inclusive of their primary AHR centres and approved satellite clinics, are provided in Appendix B. This procurement process was completed within a 6-month timeframe so as to deliver on the Minister's commitment to commence publicly funded AHR service by September 2023.

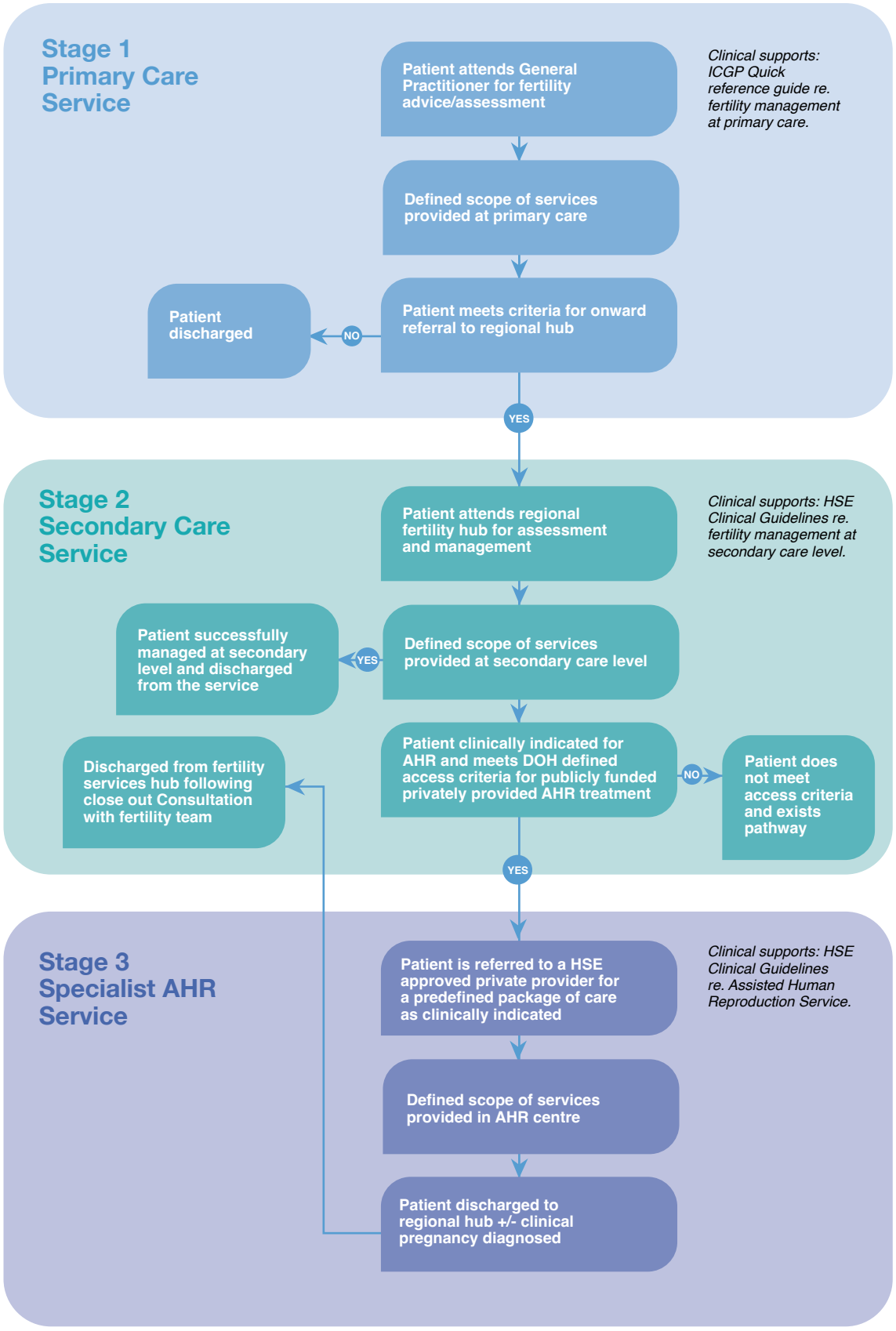
To manage the process of referrals being made by six regional fertility hubs to eight private Providers and the associated claims process for care packages delivered, NWIHP partnered with colleagues in the HSE Health Pricing Office to adapt the existing Access to Care IT System so as to meet the unique needs of the fertility services. The Access to Care IT system has been pivotal in the operational success of the AHR service as it provides an electronic platform for which the referral and discharge of patients and associated claims and payment processes can be managed robustly. This system also supports the HSE in its oversight role of this outsourcing arrangement.

In parallel to the identification and selection of private AHR Providers, the development of a national suite of access criteria determining the eligibility of public patients for publicly funded AHR services was undertaken. This work was led by the Department of Health, with NWIHP formally supporting and inputting into these criteria which are both clinical and non-clinical in nature. The criteria as developed were presented by the Minister of Health to the Government for agreement on 24th July 2023. The access criteria as defined and agreed are set out in Appendix C of this document.

As of 24th September 2023, the six regional fertility hubs have been enabled to refer couples clinically indicated for assisted treatments such as IUI or IVF *and* who meet the national access criteria as defined by the Department of Health for treatment to one of the eight HSE authorised private AHR providers. The couples themselves choose which Provider they wish to attend.

3.3 Patient Pathway from Primary Care to Secondary Care to Tertiary Care

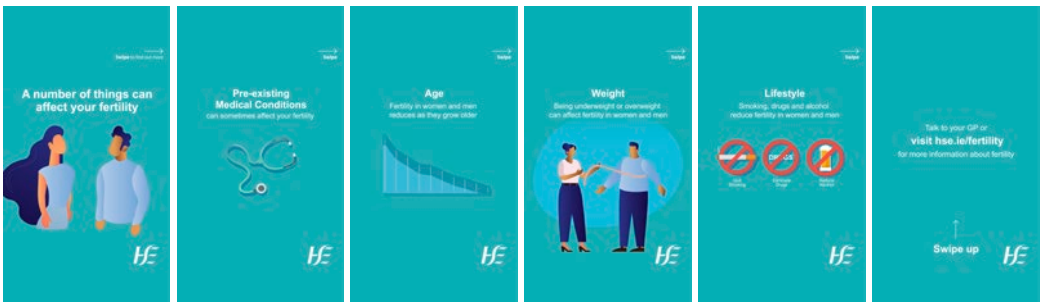
Assisted Human Reproduction – Care Pathway



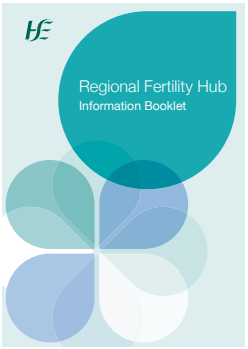
3.4 Communication Strategy

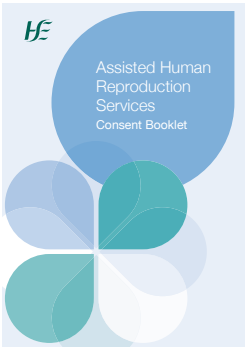
The HSE is committed to ensuring that both healthcare providers and the public are informed regarding the new public fertility services pathway. In this regard a multi-pronged communication strategy and campaign was devised in collaboration and consultation with HSE Communication colleagues. Key strands of this strategy included the following:

- The launch of a social media outreach campaign in early 2024, detailed the new fertility AHR service, the associated patient pathways and provided pertinent information for the public regarding optimisation of their fertility health.



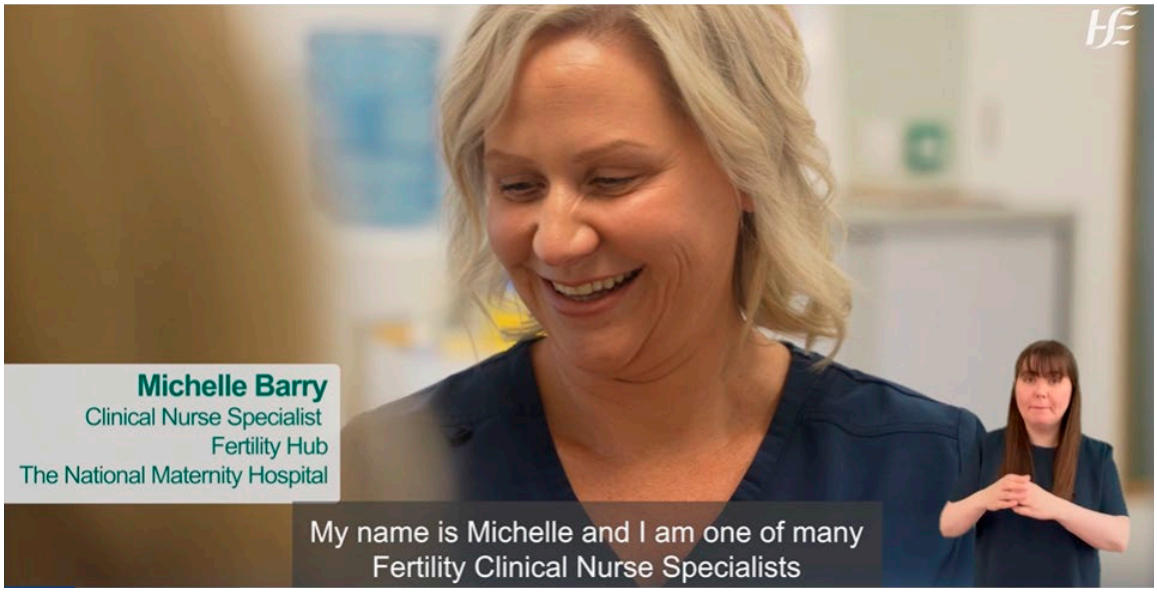
- The development, design and dissemination of specific information booklets for use at regional fertility hub level with key information relating to the regional and AHR fertility public services alongside information regarding fertility and optimising individual lifestyle for natural conception. These booklets are provided in hardcopy to every patient/couple prior to attending the reginal fertility hub.





- An extensive review and update of the HSE website was undertaken so as to reflect developments and changes in public fertility services, Fertility Q&A sessions were undertaken on social media, a fertility podcast was recorded with colleagues in HSE Health and Wellbeing division and specific videos were produced with fertility experts from the regional fertility hubs explaining the patient pathway in the regional hubs. These videos were launched online on the HSE website in 2024.

https://www2.hse.ie/pregnancy-birth/trying-for-a-baby/your-fertility/expect-regional-fertility-hub/



3.5 Clinical Practice Guidelines

A new national Clinical Practice Guideline entitled *Fertility – Investigation and Management in Secondary Care* was developed and published late in 2023 under the auspices of the Institute of Obstetrics and Gynaecology and the NWIHP. Working is on-going regarding the development of a national Clinical Practice Guideline entitled – In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI), with it anticipated that document will be signed off and published early in 2025.

In parallel to the above work streams, the Irish College of General Practitioners published a Quick reference guide for fertility '*Fertility Assessment in General Practice*' and released a suite of information videos for College members and patients attending general practice regarding the management and care of fertility in primary care and the public fertility pathways available in the hospital sector.

https://www.irishcollegeofgps.ie/Home/Clinical-Hub/Patient-Resources/Womens-Health

Collectively this work supports and enables healthcare providers operating at both primary and secondary level care to deliver quality reproductive medicine service grounded in evidence-based medicine.

4.0 Trends and Data Overview

Since the introduction of referral pathways for eligible public patients from the six regional fertility hubs to a HSE authorised private AHR Provider, data at national level has been collated and reviewed by NWIHP to inform its role in overseeing the development of reproductive medicine in Ireland.

Presented in this report is an overview of key data sets held in relation to the development of reproductive medical services in Ireland, with particular focus on the provision of publicly funded, privately provided AHR services to eligible public patients. This data has been collected from two primary sources, namely:

- A. The six regional fertility hubs
- B. The Access to Care IT system.

4.1 Regional Fertility Hub Activity

The data represented in this section is derived directly from the fertility hubs who submit key metrics to NWIHP on a monthly basis. Please note the activity metric proforma was updated as of January 2024 and as such, some data metrics have data available YTD only. Data is verified at local level and thereafter submitted to NWIHP for analysis of service demand and delivery.

4.1.1 Referral Activity Nationally 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
Referrals Received	454	708	581	403	496	507	478	547	565	449	587	513	**6,288**

With the commencement of the availability of publicly funded AHR care pathway late in September 2023, a surge of referrals across the six regional fertility hubs was experienced in October 2023. As the new care pathway embedded, it is noted that the referral numbers have begun to level off somewhat in 2024, with an average of 525 fertility referrals being received per month across the six regional fertility hubs. It is important to note that from a referral counting perspective, a referral to a regional fertility hub is counted by the female who is referred as the primary patient. However, in reality a referral represents the couple who are experiencing fertility challenges, such that 525 referrals equates to circa 1,050 individuals on average being referred per month to one of the six regional fertility hubs.

Year to date (January-August 2024) 35% of referrals received have been redirected back to source. The primary reasons informing such redirection is that:

- The patient does not meet the access criteria for the six regional fertility hubs;
- A critical piece of information is missing from the referral e.g. patient's age and/or BMI such that the receiving hospital is unable to triage the referral; and
- Patients being referred are outside the catchment area for the regional fertility hub. In these instances, the referrer is advised to redirect the referral to the patient's nearest regional fertility hub.

Of all referrals received to the regional fertility hubs, 91% of referrals originated from GPs with the remainder being comprised of consultant-to-consultant referrals.

4.1.2 Clinic Activity

	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
Number of Consultant Clinics	56	60	61	46	73	61	56	68	75	67	62	64	**749**
Number of CNS Clinics*	71	90	117	78	108	91	101	141	132	128	129	107.5	**1,293.5**

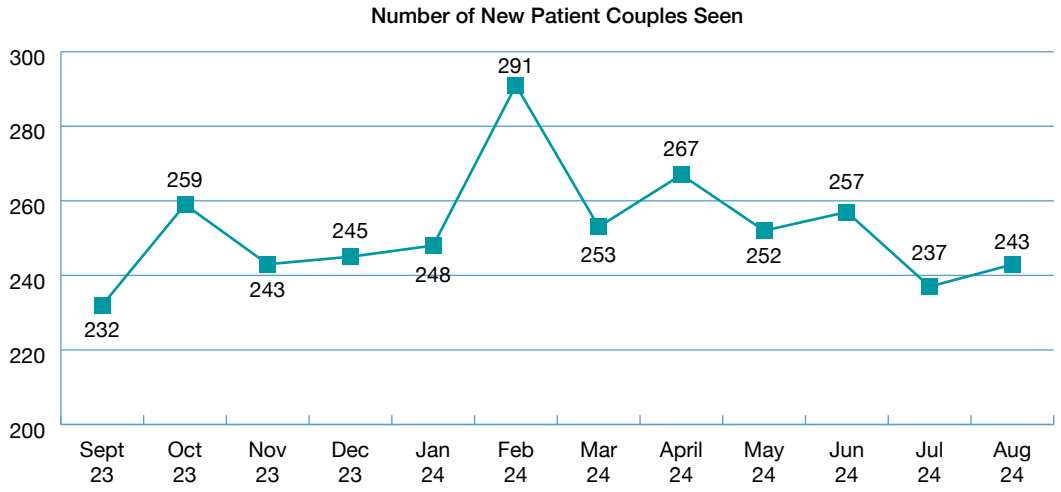
** Sept 23-May 24 represents CNS activity from five sites. From June 24 onwards all regional fertility sites are represented.*

The data above represents the number and type of structured clinics provided across the six regional fertility hubs. The patient pathways within the regional fertility hubs are designed such that there is early engagement with patients further to a referral being received and accepted.

Once a referral is accepted a patient health questionnaire is posted out to patients with a view to obtaining early in the care pathway a suite of standardised information regarding the health status and medical history of each patient. Upon receipt of the returned paperwork, the nursing team will coordinate a suite of baseline investigations for the presenting couple inclusive of bloodwork, ultrasound scans and semen analysis with the average approximate time to be seen by a specialist nurse at nine weeks.

Once all results are available, a plan of care appointment is offered by the nursing team to see the Consultant specialist within the hub so as to review all findings and to determine and identify the next appropriate clinical steps whether that be further secondary level care or consideration of assisted fertility treatment. Over 90% of patients are seen by the Reproductive Medical Consultant for this plan of care consultation within a 6-month timeframe.

4.1.3 Number of New Patients seen in Consultant Clinics, September 23-August 24



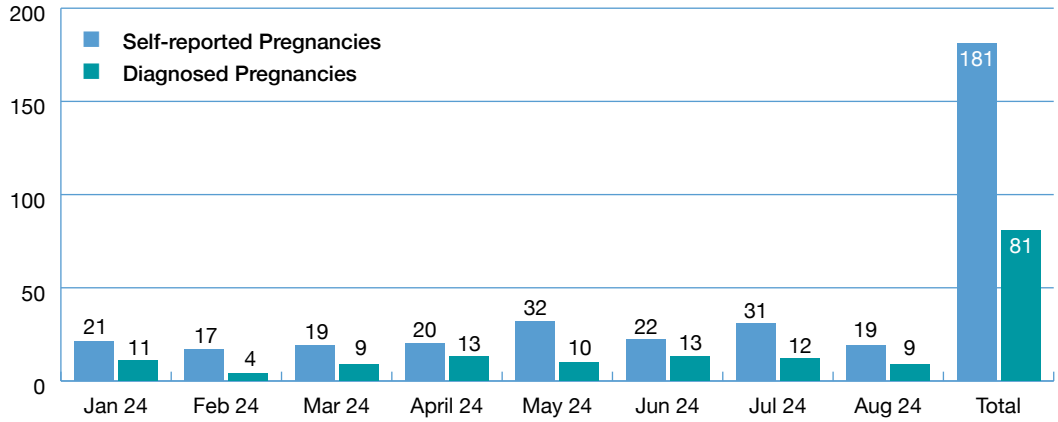
For the period above, the access criteria defined for publicly funded, privately provided AHR services currently did not allow for treatments that required the use of donor material. As such, the six regional fertility hubs for this period have primarily if not exclusively managed heterosexual couples.

Therefore, as previously mentioned in relation to referral data above, within this report patient activity is counted by the primary patient referred but, in fact, each referral represents a male-female couple. As such it is very important to note that the six regional fertility teams manage new and review patients within the context of them being a couple. This means that both the female and the male are active patients of the hubs and both are assessed and managed with a view to determining the best plan of care for them with reference to the care needs of both the female and the male combined.

In line with all other clinical services, the six regional fertility hubs are managing both new and review patients. Between the period September 2023 to August 2024, a total of 2,997 new couples have had a consultation with a specialist across the six regional fertility hubs. This equates to an average of 42 new couples being seen per hub per month over the 12 months.

Furthermore, since January 2024, the six regional fertility hubs have reported that 2,550 couples have had further review consultations with a specialist in the hubs.

4.1.4 Outcomes at Regional Hub Level



The data presented in this graph represents activity metrics returned for five sites for the period January to August 2024. It is advised to interpret this data with caution as this data is predominately reliant on regional fertility hub patient couples self-reporting their pregnancies to the fertility teams further to care and management and discharge at secondary level.

Regional fertility hub services do not routinely conduct pregnancy scans for conservative management of care and pregnancies which are diagnosed at hub level are for the most part identified via ovulation induction progress scans.

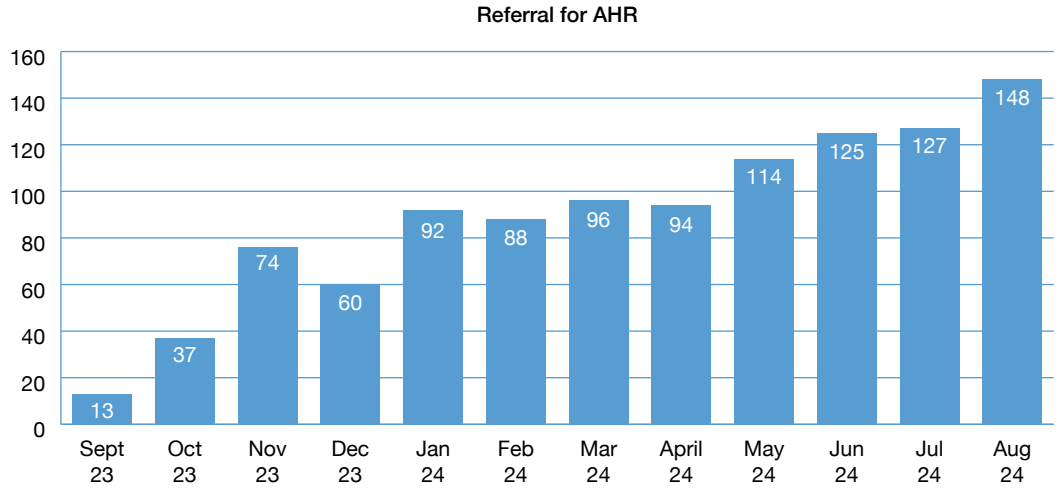
Overall, the five hubs returning this data have reported a total of **262 clinical pregnancies**, of which 181 were self-reported by patients, whilst the remaining 81 were diagnosed further to scanning within a regional fertility hub. It is reasonable to assume that this is an under representation of the number of couples achieving pregnancy further to attending a public regional fertility hub given the challenges associated with collecting this data.

This data, limited as it may be, clearly demonstrates that not all patient couples experiencing fertility challenges will require AHR with many managed successfully at secondary level.

4.2 AHR Referral Data

The data set out below in the following section is derived from the Access to Care IT system. In reviewing this data, it is important to bear in mind the nature of AHR services and the prolonged period over which a couple may remain under the active clinical management and care of a private AHR Provider before they are finally discharged.

4.2.1 Total Number of Referrals per month for AHR Treatment September 23-August 24



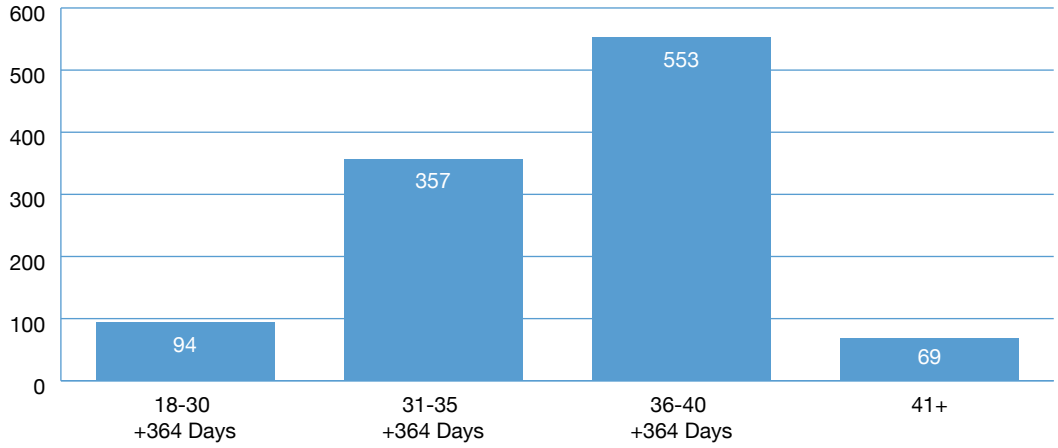
The referral pathway for AHR treatment became available to regional fertility hubs as of 24th September 2023. The number of patients being referred has grown month on month as patients continue to move through the six regional fertility hubs and exhaust treatment options available at secondary level care. Eligible patients who meet the DOH access criteria are consented at regional level and referred on average within 5 working days to one of the patients chosen HSE approved private fertility provider. The ability for patients to choose their preferred provider is a key principle of the patient pathway. Under the service agreements in place, the chosen provider must provide their initial consultation with the patient within six weeks of receipt of referral, if not earlier.

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.

4.2.3 Breakdown of the Female Age of Patients Referred for AHR September 23-August 24



As presented above, female patients aged between 36- 40 years of age represented the largest cohort of patients (50%) referred to an AHR Private Provider by one of the six regional fertility hubs. Female patients aged 41 year plus represented 6% of referrals made, whilst those in the youngest age bracket, 18 to 30 years of age, represented 9% of all referrals made. In relation to the older cohort, it is important to note that as part of the access criteria for publicly funded AHR services, females must be aged less than 41 years of age at the point of their GP referral to the regional hub so as such a cohort of women can and will attain the age of 41 years during the course of their care and management in the regional fertility hub prior to a referral being made for assisted treatment.

4.3 AHR Treatment Outcomes

It is noted that the pathway of care for assisted fertility treatment through publicly-funded treatment has only been in place for just over 12 months minimum. In the context of fertility treatment, this is a relatively short period of time, with it not uncommon for treatments to extend up to 12 months and beyond. Additionally, the calculation and provision of robust and comparable outcome data for assisted fertility treatment is complex in terms of how data is calculated, presented and interpreted. Within the current reporting period, this complexity is exacerbated by the data set held being too small and not of sufficient size to enable robust reporting. It is expected that it may take a further 12 months minimum for this data set to grow to a sufficient size to review and report on outcomes across a range of metrics.

For the purposes of this current report, of the 206 couples recorded as discharged to date, a total of 79 couples were discharged with a confirmed clinical pregnancy, diagnosed by the relevant Private Provider via a scan at the 6-to-8-week gestational period. Overall, this represents a 38% clinical pregnancy success rate. It is important to note however, that this is an overall pregnancy rate for **all couples** discharged and must be viewed in the context that variations in the rate of clinical pregnancies between age groups is not accounted for nor for example is the clinical treatment provided to yield a clinical pregnancy indicated, e.g., IUI versus IVF, fresh embryo transfer versus frozen embryo transfer etc.

As the dataset grows it is planned that future reports in this area will provide richer outcome data.

5.0 Next Phase of Service Delivery

5.1 Building Public Capacity for Delivery of Public AHR Service

Building public capacity for the delivery of a public AHR service is being undertaken in a phased approach with the initial development of public IUI services in select regional fertility hubs underway in parallel to the development of the first public AHR unit providing the full suite of AHR services.

It is anticipated that over the course of 2025, three of the regional fertility hubs will commence delivering IUI services. Rotunda, Nenagh and Cork have been identified as the sites with sufficient infrastructural capacity to facilitate the provision of a public IUI service.

Ireland's first public AHR centre will be based in Cork in the Lee Road Clinic under the governance of the Cork University Maternity Service. The development of this service is in active progress, with a project team in place overseeing the development and operationalisation of the service. Significant work programmes are underway in terms of the design, equipping and refurbishment of the designated location with recruitment of required additional personnel to commence in late 2024 into 2025. This first of its kind public AHR Centre is anticipated to commence service provision in late 2025, early 2026.

5.2 Broadening of AHR Access Criteria

The Minister of Health in line with his commitment to review the national access criteria for publicly funded AHR 12 months after the commencement of the pathway in September 2023, announced in Budget 2024 that the access criteria for AHR will be extended to include couples experiencing secondary infertility and those requiring donor gametes. The HSE very much look forward to working with the DoH regarding the expansion of the access criteria and will endeavour to apply the learning from the previous 12 months of operating the new AHR care pathway.

Expanding the access criteria will invariably increase the demand for service across the six regional fertility hubs. It remains an imperative that waiting times to access public service in the six fertility hubs are not extended on foot of a broader set AHR access criteria. As such, NWIHP will continue to actively engage and collaborate with the six regional fertility hubs so as to support the provision of fertility services in a consistent manner across all six hubs.

5.3 Funding and Resourcing

The Government has committed an annual €30 million budget for the provision of fertility services. The AHR service and associate care pathways in the public sector is in its infancy with the service in its totality not yet reaching 'steady state'. The provision of AHR services, as has been well documented, began modestly with a narrow set of eligibility criteria for AHR. This approach was strategic so as to ensure that the new care pathways were developed in a controlled and staged manner such that the system did not become overwhelmed and moreover the funding available would be sufficient to accommodate eligible individuals referred for AHR.

The cost of public funded assisted fertility treatment per couple varies greatly between patients as treatment plans are bespoke and determined by the individual needs of the couple. Based on the level of referrals made for assisted treatment between the period September 2023 to August 2024, a financial liability in the region of €12 million was incurred with a proportion of these liabilities actively maturing during this period or being managed on an expectant basis.

It is important to note that with increasing rates of referrals to the six regional fertility hubs and the expected broadening of access criteria, that the cost of delivery of this service will also increase. However, it is anticipated that in the first instance that the expansion of access criteria announced in Budget 2025 will be managed within the existing budget allocation of €30 million and as such increased funding will not be required.

6.0 Conclusion

The HSE was tasked with a clear objective from the Minister of Health and the DoH to establish a publicly funded AHR service. NWIHP working with multiple stakeholders and colleagues implemented and operationalised a public AHR service within the allocated timeframe.

Overall, the progress and development of the service to date is satisfactory with most importantly clinical pregnancies reported at both secondary and tertiary level care. This progress is reflected by the recent publication by the European Atlas of Fertility Treatment which now ranks Ireland 12th out of 43 countries in 2024 compared to 39th in 2021. Undoubtedly, demand is increasing for the service and further work is needed in terms of access at regional fertility hub level, specialist referral pathways for fertility patients including genetics and urology, development of the first public AHR centre and broadening of the AHR access criteria. It is intended over the course of 2025 that progress will be made in these areas as NWIHP continue to engage with all relevant stakeholders so as to progress the development of this valuable health service in Ireland.

Appendix A

Care Package – Title	Care Package – Full Details
1: Complete IUI Cycle	▶ Pre-treatment consultation service, including accurate and objective patient information leaflets and patient education. This patient education must provide training for the patient regarding the management of injectables where necessary. ▶ Completion of structured consenting process by suitably qualified personnel per IUI cycle i.e. clinical nurse specialist or medical specialist. ▶ Management and organisation of IUI treatment plan including issuing of required medication prescription. ▶ Provision of all required clinically indicated ultrasound scans including baseline scan and required follicle tracking scans. On average, this is anticipated to involve a minimum of two scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ Sperm collection, processing and preparation. ▶ Provision of IUI procedure to female patient. ▶ Pregnancy bloods after two weeks. ▶ Pregnancy scan after 7-8 weeks where clinically indicated.
2: IUI Procedure	▶ Completion of structured consenting process by suitably qualified personnel per IUI procedure i.e. clinical nurse specialist or medical specialist. ▶ Sperm collection, processing and preparation on day of procedure. ▶ Provision of IUI procedure to female patient and immediate post procedure aftercare. Notes re package of care two: Pre and post procedure care regarding IUI provision will be provided by public health service, with private provision required specifically re provision of IUI procedure. The delivery of this specific care package will require co-ordination with relevant public sites to enable appropriate patient scheduling.
3: Cancelled IUI Cycle	▶ Pre-treatment consultation service, including accurate and objective patient information leaflets and patient education training for the patient regarding the management of injectables. ▶ Completion of structured consenting process by suitably qualified personnel i.e. clinical nurse specialist or medical specialist. ▶ Management and organisation of IUI treatment plan including issuing of required medication prescription. ▶ Provision of all required clinically indicated ultrasound scans including baseline scan and required follicle tracking scans. On average, this is anticipated to involve a minimum of two scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ Documented clinical determination to terminate IUI cycle prior to sperm collection and provision of IUI procedure arising from over or under stimulation of female patient and associated risks of same.

Care Package – Title	Care Package – Full Details
4: IVF Cycle encompassing Fresh Embryo Transfer	▶ Pre-treatment consultation service, including accurate and objective patient information leaflets and patient education. This patient education must provide the necessary training for the patient regarding the management of injectables. ▶ Completion of overarching structured consenting process by medical reproductive medicine specialist. ▶ Structured overarching consenting process to address and include, but not necessarily limited to, the following areas: treatments, medication, clinical and general risks, collection of sperm, oocyte retrieval, culture and manipulation of embryos, embryo grading, embryo transfer, elective freezing and thawing of embryos, storage of collected samples, action to be undertaken regarding unused gametes and/or embryos if intending parent(s) dies or lacks capacity, of if there is a change in circumstances, e.g., legal separation, divorce, or in the event of a post factum difference in opinion between intending parent(s). ▶ Further procedure specific consents to be undertaken as patient(s) move through care pathway for oocyte retrieval procedures and embryo transfer procedures. ▶ Management and organisation of IVF treatment plan including issuing of required medication prescription. ▶ One cycle of IVF treatment to include all medication management, scans, sedation, ovarian stimulation and retrieval, IVF lab technique, collection of sperm, fertilisation, culturing and grading of any resultant blastocysts up to Day 6, one fresh embryo transfer and one year storage of any surplus blastocysts. ▶ In relation to scans, it is required that this would encompass all required clinically indicated ultrasound scans including baseline scan and required stimulation scans to track the development of follicles. On average this is anticipated to involve a minimum of three such scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ A review consultation with the patient(s) with the relevant team lab team, including immediately after IVF cycle, with regard to grading of embryos and management of storage. ▶ Pregnancy bloods after two weeks. ▶ Pregnancy scan after 7 – 8 weeks where clinically indicated.

Care Package – Title	Care Package – Full Details
5: IVF Cycle not encompassing Fresh Embryo Transfer	▶ Pre-treatment consultation service, including accurate and objective patient information leaflets and patient education. This patient education must provide the necessary training for the patient regarding the management of injectables. ▶ Completion of overarching structured consenting process by medical reproductive medicine specialist. ▶ Structured overarching consenting process to address and include, but not necessarily limited to, the following areas: treatments, medication, clinical and general risks, collection of sperm, oocyte retrieval, culture and manipulation of embryos, embryo grading, embryo transfer, elective freezing and thawing of embryos, storage of collected samples, action to be undertaken regarding unused gametes and/or embryos if intending parent(s) dies or lacks capacity, of if there is a change in circumstances, e.g., legal separation, divorce, or in the event of a post factum difference in opinion between intending parent(s). ▶ Further procedure specific consent to be undertaken as patient(s) move through care pathway for oocyte retrieval procedures. ▶ Management and organisation of IVF treatment plan including issuing of required medication prescription. ▶ One cycle of IVF treatment to include all medication management, scans, sedation, ovarian stimulation and retrieval, IVF lab technique, collection of sperm, fertilisation, culturing and grading of any resultant blastocysts up to Day 6 and one year storage of blastocysts. ▶ In relation to scans, it is required that this would encompass all required clinically indicated ultrasound scans including baseline scan and required stimulation scans to track the development of follicles. On average this is anticipated to involve a minimum of three such scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ A review consultation with the patient(s) with the relevant team lab team, including immediately after IVF cycle, with regard to grading of embryos and management of storage. ▶ Documented clinical determination as to why fresh embryo transfer not proceeded with.

Care Package – Title	Care Package – Full Details
6: ICSI encompassing Fresh Embryo Transfer	▶ Pre-treatment consultation service, including accurate and objective patient information leaflets and patient education. This patient education must provide the necessary training for the patient regarding the management of injectables. ▶ Completion of overarching structured consenting process by medical reproductive medicine specialist. ▶ Structured overarching consenting process to address and include, but not necessarily limited to, the following areas: treatments, medication, clinical and general risks, collection of sperm, oocyte retrieval, culture and manipulation of embryos, embryo grading, embryo transfer, elective freezing and thawing of embryos, storage of collected samples, action to be undertaken regarding unused gametes and/or embryos if intending parent(s) dies or lacks capacity, of if there is a change in circumstances, e.g., legal separation, divorce, or in the event of a post factum difference in opinion between intending parent(s). ▶ Further procedure specific consents to be undertaken as patient(s) move through care pathway for oocyte retrieval procedures and embryo transfer procedures. ▶ Management and organisation of ICSI treatment plan including issuing of required medication prescription. ▶ One cycle of ICSI treatment to include all medication management, scans, sedation, ovarian stimulation and retrieval, ICSI lab technique, collection of sperm, fertilisation, culturing and grading of any resultant blastocysts up to Day 6, one fresh embryo transfer and one year storage of any surplus blastocysts. ▶ In relation to scans, it is required that this would encompass all required clinically indicated ultrasound scans including baseline scan and required stimulation scans to track the development of follicles. On average this is anticipated to involve a minimum of three such scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ Inclusive in the above is a review consultation with the patient(s) with the relevant team lab team, including immediately after ICSI cycle, with regard to grading of embryos and management of storage. ▶ Pregnancy bloods after two weeks. ▶ Pregnancy scan after 7 – 8 weeks where clinically indicated.

Care Package – Title	Care Package – Full Details
7: ICSI not encompassing Fresh Embryo Transfer	▶ Pre-treatment consultation service, including accurate and objective patient information leaflets and patient education. This patient education must provide the necessary training for the patient regarding the management of injectables. ▶ Completion of overarching structured consenting process by medical reproductive medicine specialist. ▶ Structured overarching consenting process to address and include, but not necessarily limited to, the following areas: treatments, medication, clinical and general risks, collection of sperm, oocyte retrieval, culture and manipulation of embryos, embryo grading, embryo transfer, elective freezing and thawing of embryos, storage of collected samples, action to be undertaken regarding unused gametes and/or embryos if intending parent(s) dies or lacks capacity, of if there is a change in circumstances, e.g., legal separation, divorce, or in the event of a post factum difference in opinion between intending parent(s). ▶ Further procedure specific consent to be undertaken as patient(s) move through care pathway for oocyte retrieval procedures. ▶ Management and organisation of ICSI treatment plan including issuing of required medication prescription. ▶ One cycle of ICSI treatment to include all medication management, scans, sedation, ovarian stimulation and retrieval, ICSI lab technique, collection of sperm, fertilisation and culturing and grading of any resultant blastocysts up to Day 6 and one-year storage of blastocysts. ▶ In relation to scans, it is required that this would encompass all required clinically indicated ultrasound scans including baseline scan and required stimulation scans to track the development of follicles. On average this is anticipated to involve a minimum of three such scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ Inclusive in the above is a review consultation with the patient(s) with the relevant team lab team, including immediately after ICSI cycle, with regard to grading of embryos and management of storage.
8: Cancelled IVF/ ICSI Cycle	▶ In relation to the provision of both IVF and ICSI, it is acknowledged by the HSE that based on clinical determinations, an IVF/ICSI cycle may be cancelled. ▶ The HSE has defined such a cancelled cycle as one where an egg collection procedure has not proceeded further to ovarian stimulation. ▶ The HSE will permit such cycle cancellations on a maximum of two occasions and will require the Provider to have made a documented clinical determination that such cancellations (with alterations in the stimulation regime) will improve the ultimate outcome of treatment.

Care Package – Title	Care Package – Full Details
9: Frozen Embryo Transfer Procedure	▶ Pre-treatment consultation service including accurate and objective patient information leaflets and/or patient education. It is acknowledged that the extent and depth of this consultation service will be dependent on the level of information and education provided as part of the overarching consent process for the previously undertaken IVF or ICSI cycle. ▶ Completion of structured consenting process specific for FET procedure by medical reproductive medicine specialist. ▶ Management and organisation of FET Treatment plan including issuing of required medication prescription. ▶ One frozen embryo transfer cycle to include all clinically required medication management, scans, thawing and transfer of embryo previously created, graded and selected further to publicly funded IVF or ICSI cycle. Note, in circumstances whereby the first embryo thawed on the day of transfer does not survive, it will be expected by the HSE that as per normal practice, where available a second stored embryo will be prepared for transfer on the same day. ▶ In relation to scans, it is required that this would encompass all required clinically indicated ultrasound scans including baseline scan and endometrium monitoring scans. On average this is anticipated to involve a minimum of two such scans, however where additional scans are indicated as clinically necessary it will be expected by the HSE that these are provided to the patient at no further cost. ▶ Pregnancy bloods after two weeks. ▶ Pregnancy scan after 7 – 8 weeks where clinically indicated.
10: Male Patients Requiring Uncomplicated Testicular Sperm Extraction (TESE), i.e. managed via local anaesthetic/ sedation	▶ Pre-treatment consultation service including patient information leaflets and patient education. ▶ Completion of structured consenting process for procedure by medical specialist. ▶ One TESE care package to include provision of required pain medication/sedation, sperm extraction, analysis and preparation for fresh use or storage for future use for up to one year.
11: Storage Arrangements	▶ Annual cost of storage arrangement for gametes and blastocysts.
12: Virology Screening Bloods	▶ Provision of virology screening bloods to include HIV 1 and 2, Hepatitis B core antibody and surface antigen, Hepatitis C and syphilis.

Appendix B

Name of Provider	Location(s) of Primary AHR Centre	Satellite Clinic Locations	Website Details	Preference Number for Treatment
Beacon Care Fertility	The Concourse, Beacon Court, Dublin 18	Drogheda Limerick	www.beaconfertility.ie	
First IVF	Abbeyhall, Abbeylands, Clane, Co. Kildare		www.firstivf.ie	
Merrion Fertility Clinic	Lower Mount Street, Dublin 2		www.merrionfertility.ie	
ReproMed Dublin	5th Floor, North Block, Rockfield, Dundrum, Dublin 16	Drogheda	www.repromed.ie	
ReproMed Galway	Brooklawn House, Galway West Business Park, Rahoon, Galway		www.repromed.ie	
SIMS IVF Clonskeagh	Clonskeagh Road, Clonskeagh, Dublin 14	Carlow Dundalk Limerick	www.sims.ie	
SIMS IVF Swords	Swords Business Campus, Unit5/6a, Balheary Road, Swords, Co. Dublin	Carlow Dundalk Limerick	www.sims.ie	
SIMS IVF Cork	City Gate, Mahon, Co. Cork	Carlow Dundalk Limerick	www.sims.ie	
Thérapie Fertility	The Park, Carrickmines, Dublin 18	Limerick Dundalk Galway	www.therapiefertility.ie	
Waterstone Clinic	Lotamore House, Tivoli, Cork	Waterford Kildare Limerick	www.waterstonesclinic.ie	

Appendix C

Non-Clinical Access Criteria

Access Criteria – "Non-Clinical"	Recommendation
Residency	Individuals must be ordinarily resident in the State and referred through their GP to a Regional Fertility Hub.
Number of existing children	Eligible couples must have no living children from the existing relationship and include at least one partner with no living child.
Number of previous IVF cycles	Access to publicly funded IVF is available for those individuals who have previously undertaken a maximum of one previous IVF cycle and where all embryos created as part of that cycle have been used.
Voluntary sterilisation	A couple/ individual will not be eligible for publicly funded IVF treatment if either partner/individual has had voluntary sterilisation.
Welfare of the child	An assessment will be carried out, based primarily upon a self-declaration form.
Duration of couple's relationship	There shall not be more than two intending parents of a child born as a result of AHR treatment and, they shall be in a relationship for at least one year.

Clinical Access Criteria

Access Criteria – "Clinical"	Recommendation
Heterosexual couple	▶ Known clinical cause of infertility or ▶ Where there is no known clinical cause, patients will be treated, on referral by a GP, at regional fertility hubs and provided with all appropriate advice, screening testing and procedures and then, if still unresolved, will be offered referral to AHR/IVF/ICSI or AHR/IUI as appropriate, in accordance with clinical guidelines.
Age (at referral by GP to Regional Fertility Hub)	Female – max. age 40 plus 364 days Male – max. age 59 plus 364 days
Body Mass Index (BMI)	Females – Minimum 18.5, Maximum 30.0

Advised Clinical Criteria

Advised Clinical Criteria	Recommendation
Alcohol consumption	Intending birth mother: no more than 1 or 2 standard drinks once or twice per week; Males: no more than 3 to 4 standard drinks per day, ideally targeting a consumption of 10 standard drinks or less over a week.
Smoking	All intending parents non-smoking for at least 3 months.
Recreational/Illegal Drugs	All intending parents non-users of recreational drugs for at least 3 months.