NWCI'S RESPONSE TO THE GENERAL SCHEME OF THE ASSISTED HUMAN REPRODUCTION BILL 2017

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National Women's Council of Ireland

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Executive summary

The National Women's Council of Ireland (NWCI) welcomes the publication of the General Scheme of the Assisted Human Reproduction (AHR) Bill. NWCI supports legal regulation of AHR services to safeguard the interests of women, couples, children and healthcare professionals. The development of a regulatory framework will further support the state to fulfil its commitment to provide publicly-funded access to AHR.

Summary of recommendations

NWCI's comments on the General Scheme reflect our focus on the promotion and protection of women's health within the treatment of infertility and the provision of AHR services. Our comments centre on the need for:

- Inclusion of patient and women's representation on the board of the Assisted Human Reproduction Regulatory Authority and in the carrying out of its functions.
- Development of public education, information and research functions for the Authority to: inform the public about infertility prevention; provide impartial information on AHR treatments and providers to patients; and develop data on AHR use and patient experience.
- Provision of counselling for patients throughout the treatment process.

NWCI does not make recommendations on the Heads addressing surrogacy, as the organisation does not have an official position on surrogacy. However, we raise issues for consideration in relation to surrogate mothers.

NWCI recognises that the regulation of AHR is only one of the elements required to reduce the distress caused by infertility. A range of actions must be taken to ensure we support people to start their families, reduce the numbers of people experiencing infertility and provide equitable access to AHR treatments for those who require it. Thus, looking at issues beyond the scope of the General Scheme, NWCI's submission also highlights the need for:

- Supportive policies and benefits for people seeking to start a family (e.g., affordable childcare, paid parental and paternity leave, affordable housing).
- Provision of quality infertility care across health service through the roll-out of a Model of Care for Infertility.
- Public funding of AHR to ensure equitable access.

Introduction

NWCI welcomes the development of legislation on AHR, which when implemented can have a significant positive impact on women's reproductive healthcare, on women and couples seeking to conceive and on the provision of AHR in Ireland. Our response to the General Scheme centres on the promotion and protection of women's health within the treatment of infertility and the provision of AHR services.

NWCI recognises the provision of AHR is just one element required to reduce the suffering caused by infertility in Ireland. Action must be taken on a range of areas to ensure we support people to start their families, reduce the numbers of people experiencing infertility and provide AHR treatments for those who require it:

- Government must introduce social and economic policies which support people to have families at a time of their choosing and to combine family and work commitments.
- We must increase information about infertility, its causes and prevention.
- We must undertake research on causes and cures of infertility which could significantly reduce the need for AHR treatment.
- We must reduce stigma about infertility so that people seek support quickly.
- We must ensure that AHR providers and treatments are regulated to provide the best quality of care.
- We must ensure that all those who require AHR can access public treatment.

Submission structure

- Part 1 provides an overview of NWCI's work on reproductive health and our role in promoting women's perspectives and the perspectives of our membership in legislative developments. It outlines why a gender perspective, which responds to women's health needs, is important in the context of the development of AHR legislation and provides an overview of current AHR provision in Ireland.
- Part 2 details our comments on specific Heads of the General Scheme. *NWCI does not propose to comment on all aspects of the General Scheme, our comments are confined to areas where we believe the Bill can be revised or strengthened for the benefit of women's health.*
- Part 3 discusses the importance of the legislation to the development of publicly-funded AHR treatments on an equitable basis.

NWCI's submission was developed following consultation with NWCI's membership, engagement with academics and health researchers working on AHR and with individuals with experience of infertility and AHR treatment.

PART 1: Women's Health and AHR

NWCI is acutely aware of the distress experienced by women who experience infertility. For many women their decision to seek AHR treatment will have been preceded by a series of negative events, such as multiple miscarriages, pelvic pain, endometriosis and/or gynaecological surgery.

The AHR Bill represents a significant first step in addressing the difficulties faced by women and couples seeking AHR services in Ireland. These difficulties include: lack of independent information about AHR providers and treatment; limited public understanding of infertility and how infertility may prevented; and lack of public access to treatment.

The AHR Bill will provide a necessary framework to regulate services and standardise practice across providers. Once regulation is in place it will then be possible to address the lack of equity in access to AHR in Ireland, which remains primarily a private service, unaffordable to many.

NWCI's work on reproductive health

NWCI is Ireland's leading women's membership organisation, representing 180 member groups and a growing number of individual members. We work to ensure women's equal access, participation, and recognition in Irish society. One way in which women's equality is realised is through women's control of their reproductive and maternal health. This is why reproductive health has been a core area of NWCI's work for many years. We are closely involved in improving women's access to contraception, increasing maternity entitlements, advocating for affordable, quality childcare and for the ongoing development of women-centred maternity care. NWCI has a unique role in communicating the health concerns of women in Ireland through ongoing consultation with our membership base and other organisations. Our work on women's health over the last 40 years has highlighted women's experiences of healthcare services and has drawn attention to the various barriers different groups of women may experience accessing health services.

NWCI advocates for reproductive healthcare services which are based on best medical practice and which reflect the lived experiences of women. We engage with the issue of infertility from a broad perspective, reflecting the diversity of experiences women face and the different decisions women make about reproduction and family formation. Thus, in addition to seeking regulation and public provision of AHR, NWCI recognises the need for much more significant focus on the prevention of infertility and on family-friendly supports and policies for people seeking to start a family.

Our comments on the General Scheme are grounded in NWCI's *Every Woman*[1] model for reproductive healthcare for women and girls.

Every Woman model of reproductive healthcare

In 2017, NWCI launched our *Every Woman* model for quality, universal, lifelong reproductive healthcare for women and girls.

The model recognises that women have a life-long need for reproductive healthcare services across six priority areas, which should be available through the health system:

1. Relationship and sexual health education;
2. Affordable and accessible contraception;
3. Sexual and reproductive health services;
4. Comprehensive pregnancy care, **including fertility treatment**;
5. Reproductive cancer care; and
6. Menopause services

Reflecting the fact that some women and couples may need assistance to conceive and have children, NWCI advocates for access to fertility treatment as a key component of reproductive healthcare for women.

Every Woman further describes key principles which should underpin the provision of all reproductive healthcare services, including AHR:

- Services should be private, with confidentiality between the doctor and patient protected.
- Services should be accessible through public funding.
- Services should be comprehensive.
- Services should be of high quality, complying with best medical practice and standards.
- Services should be adequately funded to ensure timely access.

In examining the General Scheme, NWCI has considered how the legislation can support access to AHR in way which upholds the *Every Woman's* principles for reproductive healthcare.

Women's health and AHR

In this section we provide an overview of why a women's health perspective should inform the AHR Bill. An in-depth discussion of AHR and women's health in an Irish context are provided in two 2009 reports produced by the Women's Health Council (the statutory body, since dissolved, with responsibility for women's health): *Infertility and Treatment a*

[1] NWCI (2017) 'Every Woman – affordable, accessible healthcare options for women and girls in Ireland'. http://everywoman.nwci.ie/

review of pyscho-social issues[2] and *Infertility Treatments for Women - A Review of the Bio-medical Evidence*[3].

The female body is the primary site of most AHR treatments[4,5] and this necessitates careful consideration of AHR provision from a women's health perspective. This is not to imply that AHR and infertility treatment is a 'woman's issue'. Infertility results from both male and female causes and infertility results in significant distress both for women and men.

Infertility is a complex issue which intersects with biological and medical concerns and with social issues related to family formation and women and men's gender roles. Historical and cultural beliefs have tended to inextricably link women's identity with procreation and caring. This can have very negative impact on women who are having difficulty having a child and also ignores the suffering infertility causes to men and men's role in raising families.

While the devastating effects of infertility are felt by both women and men, the evidence points to a much more negative effect on women's lives.[6,7] There are many reasons why women have a more negative experience of infertility, which are linked to women's biological and social role as mothers.[8] In most cases, women will undergo the majority of AHR procedures, regardless of whose infertility (female or male) is impaired. As women undergo the bulk of invasive procedures, they are responsible for daily monitoring of their menstrual cycles and experience disruption in their work/life schedules to accommodate rigid treatment regimes.[9] Treatment cycles can also negatively affect women's career progression and financial security.[10,11]

More attention should be paid to assessing male infertility, which is much less invasive than the assessment for women. Investigation of males could lead to significantly better outcomes given that in a third of cases infertility is caused by male reproductive issues.[12] Early, basic testing for men could identify infertility issues at an early stage and resolve them at the lowest level of complexity.

In addition to the physical impacts, infertility can lead to a range of psycho-social impacts, from emotional effects, feelings of loss of control, effects on self-esteem and identity, impacts on relationships and grieving of the loss of a future parent-child relationship.[13] These psycho-social impacts can also be affected by gender, with women

[2] Available at: http://health.gov.ie/wp-content/uploads/2014/03/infertPsychosocial.pdf
[3] Available at: http://health.gov.ie/wp-content/uploads/2014/03/infertBiomedEvid_Full.pdf
[4] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[5] Institute of Public Health in Ireland (2017) 'Submission to a new National Women's Strategy 2017-2020'.
[6] Greil, A. L. (1997). "Infertility and Psychological Distress: a critical review of the literature." Social Science and Medicine 45 (11): 1679-1704.
[7] Peterson, B. D., L. Gold and T. Feingold (2007). "The experience and influence of infertility: considerations for couple counsellors." *The Family Journal* 15 (3): 251-257.
[8] Klock, S. (2008) 'Psychological Issues Related to Infertility'. http://www.glowm.com/?p=glowm.cml/section_view&articleid=412
[9] For experiences in the Irish context, see: Mahon, E. and Cotter, N. (2014) 'Assisted reproductive technology – IVF treatment in Ireland: A study of couples with successful outcomes'. *Human Fertility*, 17(3), 165-169. DOI: 10.3109/14647273.2014.948498
[10] Redshaw, M., C. Hockley and L. L. Davidson (2007). 'A qualitative study of the experience of treatment for infertility among women who successfully became pregnant.' *Human Reproduction* 22 (1): 295-304.
[11] Deech, R and Smajdor, A (2007) *From IVF to Immortality: Controversy in the Era of Reproductive Technology* Oxford University Press.
[12] Eunice Kennedy Shriver National Institute of Child Health and Human Development. 'How common is male infertility, and what are its causes?' https://www.nichd.nih.gov/health/topics/menshealth/conditioninfo/infertility
[13] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council

finding counselling services useful in supporting a sense of belonging and validating their reactions.[14]

To help reduce the negative impact of infertility on individuals, it is essential that society recognises women's contribution to society outside of procreation and caring, as well as the contribution which men can and do make to raising families.

Policies and appropriate supports for people seeking to start a family

The issue of infertility directly relates to how Irish society supports women and couples who wish to form families.

Maternal age is considered one of the key determinants of conception, and much public attention has been dedicated to the increasing age of first-time mothers. Women are often criticised for 'waiting too long' to start their families. This narrative of maternal delay does not recognise the constraints which women and their partners make decisions about family formation. Research[15],[16] clearly indicates the impact of societal factors on family formation, including the high cost of housing, economic and employment uncertainty and the absence of supportive family policies.

Fear of discrimination in the workplace and the unequal distribution of care work can impact on women's pregnancy decisions. Many women (and couples) will want to have some financial security before starting their family. This indicates that much greater emphasis should be placed on how people wishing to start a family can be supported through economic and social policies which increase people's ability to combine work and family responsibilities.[17],[18] NWCI has consistently advocated for social and economic policies which support women's choices for family formation and child-bearing, including access to affordable, secure housing and flexible working arrangements.[19]

- *NWCI recommends implementation of policies and benefits to support people seeking to start a family, including access to affordable childcare and improvements in paid parental and paternity leave.*

[14] Schmidt, L. *et al.* (2003). "Patients' attitudes to medical and psychosocial aspects of care in fertility clinics: findings from the Copenhagen Multi-centre Psychological Fertility (COMPI) Research Programme." *Human Reproduction* 18 (3): 628-637.
[15] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[16] Morgenworth, E. (2018) *Prospects for Irish Regions and Counties – scenarios and implications.* ESRI Research Series No. 70
[17] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[18] Women's Health Council (2005). Submission to the European Commission's Green Paper: "Confronting demographic changes: a new solidarity between generations" (COM 2005). Dublin: The Women's Health Council.
http://www.whc.ie/publications/EU_Submission_Demographic_Changes.pdf
[19] For example, see NWCI (2017) 'Value for Money and Money for Values – Pre-Budget Submission' http://www.nwci.ie/index.php/learn/publication/value_for_money_and_money_for_values_making_the_national_budget_work_for_wo; NWCI (2009) ' Who cares? Challenging the myths about gender and care in Ireland'. http://www.nwci.ie/download/pdf/who_cares_october_2009.pdf; NWCI (2005) 'An Accessible Childcare Model'. https://www.nwci.ie/images/uploads/nwci-childcare_report.pdf

Prevention of infertility

More must also be done to prevent people experiencing infertility, thereby reducing the need for AHR treatment.

A substantial proportion of infertility may be preventable. For example, untreated sexually transmitted infections are a preventable risk factor for infertility in both women and men. Established and possible causes of infertility include genetic abnormalities, aging, certain acute and chronic diseases, lifestyle risk factors such as smoking and body weight and exposure to environmental, occupational, and infectious agents.[20]

Prevention of infertility should be integrated into reproductive health promotion for both women and men, including:

- Comprehensive approaches to STI screening, treatment, prevention
- Clear public health messages on how to prevent infertility
- Chronic disease prevention to reduce the incidence and severity of conditions such as diabetes and polycystic ovary syndrome
- Health promotion campaigns to address lifestyle factors that may affect infertility

➢ *NWCI recommends an increased emphasis on the prevention of infertility and on efforts to increase public awareness of infertility, its causes and treatments.*

AHR in Ireland

There are two major overarching concerns in relation to the AHR provision in Ireland - there has been no legal regulation of AHR providers & services and AHR treatment is only available privately.

Infertility is recognised by the World Health Organisation as a disease[21], yet access to infertility treatment is not available in the Irish public health system. This is despite the reality that infertility is a common public health issue with one in six couples in Ireland experiencing problems conceiving a child.[22] Reflecting patient demand, AHR has been available in Ireland since 1987 and the number of people privately accessing AHR treatments and services has increased over time.

Surveys indicate that the Irish public supports better access to and regulation of AHR. In 2002, a survey by the Commission on Assisted Human Reproduction (CAHR)[23] found that 68% of people agreed with the availability of AHR services. A 2013 survey of Irish public

[20] Centers for Disease Control and Prevention (2014) *National Public Health Action Plan for the Detection, Prevention, and Management of Infertility*. https://www.cdc.gov/reproductivehealth/infertility/pdf/drh_nap_final_508.pdf
[21] http://www.who.int/reproductivehealth/topics/infertility/definitions/en/
[22] Report of the Commission on Assisted Human Reproduction (2005) http://health.gov.ie/wp-content/uploads/2014/03/Report-of-The-Commission-on-Assisted-Human-Reproduction.pdf
[23] Report of the Commission on Assisted Human Reproduction (2005)

opinion[24], led by researchers in the Royal College of Surgeons in Ireland, also showed public approval for AHR. Most participants (77%) agreed that any fertility services offered internationally should also be available in Ireland and 63% agreed the Government should introduce AHR legislation.

Legal Regulation of AHR Provision

The need for legal regulation of AHR has been a concern for many years[25], with statutory regulation proposed by the Department of Health's CAHR in 2005.[26] The only progress in developing a legal framework – in advance of the publication of the General Scheme – was the Children and Family Relationships Act 2015 which includes un-commenced provisions on donor-assisted AHR.[27]

In the absence of regulation, people are availing of services in a legal vacuum[28] and clinics are operating without adequate regulation.[29] AHR services have been largely reliant on physician self-regulation through their professional bodies.[30] There are no nationally-approved guidelines for counsellors working in AHR, or for other health professionals in areas such as liaison and follow-up care for both successful and unsuccessful treatment.[31] In the absence of statutory regulation, professionals or clinics may interpret best practice in different ways, leading to inconsistency in treatment and patient experience.

Regulation is essential to standardise practices across clinics. Regulation can be used to ensure a range of positive outcomes for patients, including that clinics:

- Undertake clinically-indicated treatment
- Provide the least invasive treatment first
- Manage and clearly identify risks to patients
- Provide information on success rates in a format which is accessible to patients

[24] DJ Walsh, ES Sills, Gary S Collins, CA Hawrylyshyn, P Sokol, APH Walsh (2013) 'Irish public opinion on assisted human reproduction services: Contemporary assessments from a national sample'. *Clinical and Experimental Reproductive Medicine* 2013;40(4):169-173https://epubs.rcsi.ie/cgi/viewcontent.cgi?article=1029&context=obsgynart

[25] Allison, J. (2016) 'Enduring politics: the culture of obstacles in legislating for assisted reproduction technologies in Ireland'. Reproductive Biomedicine and Society Online, 3, 134-141.

[26] Report of the Commission on Assisted Human Reproduction (2005) http://health.gov.ie/wp-content/uploads/2014/03/Report-of-The-Commission-on-Assisted-Human-Reproduction.pdf

[27] UL (2017) Information booklet on Donor Assisted Human Reproduction (DAHR) and the Law in Ireland https://www.ul.ie/engage/sites/default/files/2017,%20No%2013%20Information%20booklet%20on%20Donor%20Assisted%20Human%20Reproduction%20DAHR%20and%20the%20Law%20in%20Ireland.pdf

[28] Department of Health (2017) General Scheme of the Asissted Human Reproduction Bill. Accessed at http://health.gov.ie/blog/publications/general-scheme-of-the-assisted-human-reproduction-bill-2017/

[29] Walsh, D. *et al.*(2013) 'Irish public opinion on assisted human reproduction services: Contemporary assessments from a national sample'. Clin Exp Reprod Med, 40(4):169-173

[30] Allison, J. (2016) 'Enduring politics: the culture of obstacles in legislating for assisted reproduction technologies in Ireland'. *Reproductive Biomedicine and Society Online*, 3, 134-141.

[31] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues.* Dublin: The Women's Health Council.

Access to AHR

The second major concern in relation to AHR is the lack of public access to treatment, making AHR inaccessible to many in Ireland. This is because AHR services are overwhelmingly provided by private clinics and paid for by patients themselves (some clinics may offer services to public patients on a discretionary basis and there is some public provision for cancer patients[32]). The only financial support provided by the state comes through subsidisation of the purchase of drugs and tax relief on health expenditure. Yet, even this limited support is inaccessible to many who cannot afford to meet the up-front costs of treatment. NWCI welcomes the Government's intention to provide public funding for fertility treatments[33] so that AHR can be provided as universal service within the publicly-funded health system. The AHR Bill will provide the long-required regulation to underpin state services.

PART 2: Comments on the General Scheme

NWCI recognises the many positive elements in the General Scheme, particularly in relation to the establishment of a Regulatory Authority to license and monitor AHR treatments and service providers. In this section we make comments on specific Heads of the Bill which we believe require clarification or amendment to best support women's health.

Representation of patient and women's interests

Head 76 Membership of the Board

As has been outlined above, infertility is a public health issue which impacts a significant number of women, men and families in Ireland. It is crucial that the lived experiences of those undergoing fertility treatments are integrated into the process of regulation and the structures of the Assisted Human Reproduction Regulatory Authority (the Authority).

Head 76 (2) states that all the members of the Board of the Authority shall be appointed by the Minister and must be people who have experience or expertise in matters connected with the functions of the Authority, or in corporate governance and management generally.

Head 76 (5) states that the Minister 'may' request relevant stakeholders to nominate appropriate candidates for consideration for appointment to the Board. The explanatory

[32] Currently, cancer patients can access publicly-funded fertility preservation *prior to cancer treatment* (funded by the National Cancer Control Programme). However, cancer patients who need fertility preservation post treatment must pay privately.
[33] Dept. Health Press Release, 3rd October 2017 'Government approves the drafting of the Assisted Human Reproduction Bill'. http://health.gov.ie/blog/press-release/government-approves-the-drafting-of-the-assisted-human-reproduction-bill/

note elaborates on this by highlighting a number of examples, such as the Institute of Obstetricians and Gynaecologists, the Royal College of Physicians in Ireland, the Nursing and Midwifery Board of Ireland, the National Infertility Support Group, Legal representation and Scientific, Research and Ethicist representation.

NWCI would draw the attention of the Committee to Schedule 1 of the UK's Human Fertilisation and Embryology Act 1990[34], which outlines the requirements to be a member of the Human Fertilisation and Embryology Authority. Of particular note this Authority must comprise of a mixture of the following:

> (a) any person who is, or has been, a registered medical practitioner;
>
> (b) any person who is, or has been, concerned with keeping or using gametes or embryos outside the body; and
>
> (c) any person who is, or has been, directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so.

In making nominations for appointments to the Authority, the Minister should have regard to the need for diversity of expertise and experience and to the need to appoint persons who have the expertise to carry out the functions of the Authority or to ensure that those functions are carried out. The UK approach ensures that the members of the UK Authority are as representative as possible.

- *NWCI recommends that AHR patients (individuals with experience of AHR treatment) should be represented on the Authority's Board.*
  NWCI recommends a clear commitment in legislation to this effect, so that the word 'may' be replaced with 'shall'. We further recommend that consideration be given to the formulation of the composition of the UK Authority.

Given that women's interests are central to the regulation of AHR treatments, it is essential that women's voices form part of the Authority. Such an undertaking forms part of the UK Human Fertilisation and Embryology Act 1990, which states in section 5, schedule 1(4)(2) in making appointments regard shall be had to 'the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women'. A more prescriptive provision for the composition of the Irish Human Rights and Equality Commission forms part of the Irish Human Rights and Equality Act 2014.[35]

- *Given that women's interests are central to the regulation of AHR treatments, NWCI recommends the Board of the Authority shall comprise of at least 40% of the underrepresented sex.*

The patient/user perspective should also be integrated into the workings of the Authority. Ongoing engagement with patients using AHR can ensure that the monitoring and licensing of services meets the identified needs of patients, as well as those of clinicians and

[34] The Human Fertilisation and Embryology Act of the United Kingdom was passed in 1990, leading to the formation of the Human Fertilisation and Embryology Authority (HFEA), the first statutory body to regulate and control assisted conception anywhere in the world.
[35] Section 12(2) of the Irish Human Rights and Equality Act 2014 states: Of the members of the Commission, not less than 6 of them shall be men and not less than 6 of them shall be women, and in a case where there are 14 or more members, not less than 7 of them shall be men and not less than 7 of them shall be women.

service providers. It is evident that good practice in AHR clinics encompasses more than medical care. A more holistic approach to patient care is believed to improve health outcomes, increase patient and team satisfaction, reduce negative psychosocial reactions and help patients better come to terms with their experience.[36] Patients can provide insight into how services are provided and suggest how services can better meet patient need – how their care options are described, how the planning process for treatment is shared between the clinical staff and the patients and how alternative options, such as adoption, are discussed. The health service has developed a range of mechanisms to engage patients in regulation and service development. The Authority should seek to engage patients in reference panels and through the undertaking of research on patient experience.

- *A core function of the Authority should be to engage with people who have personal experiences of AHR and to conduct research to ensure patient experiences inform the development of regulation and AHR services.*

Raising public awareness about causes and prevention of infertility

Head 71 Duty of the AHRRA to provide information

Considering the widespread nature of infertility more attention should be given to its prevention and to raising public awareness of its causes and cures.

While infertility is a relatively common problem, people often feel isolated in their experience. Better public awareness of infertility and information on where to seek support would ensure individuals feel better supported. Awareness would also reduce the stigma which often surrounds infertility, supporting individuals to seek early investigation by health services. People experiencing infertility should also be directed towards the supports available to them, including counselling and support groups.

All information should be provided in a form that is accessible to people who have additional needs, such as people with disabilities and people who do not speak or read English.[37]

- *Provision of public education about infertility should be a core function of the Authority. The Authority should be responsible developing and disseminating information on the main known causes of fertility problems, preventative measures and supports available (support groups).*

[36] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council
[37] NICE (2017) Fertility Overview. Accessed at https://pathways.nice.org.uk/pathways/fertility

Informed choice and the provision of independent information

Head 9 Consent; Head 67 Functions of the AHRRA; Head 71 Duty of the AHRRA to provide information

Informed choice is integral to the process of AHR treatment and can only be made with accurate, accessible information.

AHR treatment options are complex and patients need to understand their options properly to be able to make informed choices. While there is a large amount of medical and academic research on AHR treatment it is difficult for patients at a vulnerable time in their lives to be able to access reliable, clear information.[38] Access to independent information would further benefit health professionals caring for those seeking infertility advice and treatment.

Currently, there is a lack of comprehensive independent information on AHR treatments available in Ireland. In particular, there is no independent information on Irish clinic success and failure rates.[39] As outlined by the Women's Health Council[40], success rates in relation to the various treatments may be confusing for the lay population as they are reported in clinical language and there is no standard format that allows for comparison between clinics.

According to Head 9(3)(b), '[p]rior to giving his or her consent …. the person in question shall have been provided with relevant information about the proposed AHR treatment or treatments, as the case may be'. Relevant information is left undefined.

Head 71 of the Bill outlines the duty of the Authority to provide information. Head 67 (6) states, 'to the extent [AHRRA] considers appropriate, advice and information on activities governed by this Act'. The explanatory note that accompanies this provision recognises that this information is best provided by an independent organisation.

NWCI considers that provision of accurate and up-to-date information on AHR practices should be an integral function of the Authority. The Bill should designate specific responsibility to the Authority for provision of all independent information on AHR treatments and related matters. The UK's Human Fertilisation and Embryology Authority (www.hfea.gov.uk) is the Government's independent regulator overseeing AHR treatment (licensing, inspections and standard setting). The UK Authority also provides impartial information on all aspects of the AHR process and treatments via its website.

- *Given that informed choice has been raised as integral to the process of AHR treatment, the Authority should be responsible for providing free, clear and impartial information to all affected by fertility treatment.*
- *Given the significance attached to the provision of 'relevant information', it should be defined to include at a minimum the physical risks and psychological repercussions involved in proceeding with AHR treatment.*
- *Given that access to accurate and up-to-date information on success rates is essential to making an informed choice, the Authority should ensure reported*

[38] Women's Health Council (2009) *Infertility Treatments for Women - A Review of the Bio-medical Evidence.* http://health.gov.ie/wp-content/uploads/2014/03/infertBiomedEvid_Full.pdf

[39] Institute of Public Health in Ireland (2017) 'Submission to a new National Women's Strategy 2017-2020'.

[40] The Women's Health Council (2009) *Infertility and its Treatments A Review of Pyscho-social Issues,* para. 3.3.1.

success rates in relation to the various treatments are accessible for a lay population and are provided in a standardised format enabling comparison between clinics.

Research function of the Authority

Head 67 Functions of the AHRRA

This is a crucial period for the development of AHR services in Ireland. In the coming years AHR services will be subject to regulation and will be provided as a universal service. Yet, we know very little about the current operation of AHR services and the level of demand, or the experiences of patients receiving AHR treatments.[41] The most recent data from the European Society of Human Reproduction and Embryology (ESHRE) reported that in 2011, Ireland had 3,040 AHR treatment cycles resulting in 680 infants (0.9% of national births).[42] While this provides some indication of the number of AHR cycles (not all clinics in Ireland provide data to ESHRE), we do not know the overall numbers seeking treatment.

A programme of ongoing research is needed to document AHR demand and use in Ireland and patient experience of AHR services. The Authority should collect regular health intelligence on AHR in Ireland, with data analysed by gender, age, socio-economic and ethnic categories. Disaggregation will provide information on AHR use and outcomes for different groups of women, such as women with disabilities or LGBTQ women, who may experience multiple discriminations in access to treatment. It is important that significant attention is given to research which documents the experiences of people who have previously, or are currently using AHR services.

- *Given the paucity of domestic data in this area, the Authority should be explicitly mandated to study and report on the broad social, ethical, health, legal and economic implications of AHR on a periodic basis.*

Access to quality counselling

Head 8 Counselling

Head 8 provides for the provision of 'pre-treatment counselling' for AHR patients.

Infertility and the process of undergoing AHR treatment can cause significant distress and psycho-social impacts. Patients abroad and in Ireland have continually expressed a need for more emotional advice and support throughout the process. In its 2005 report, the CAHR recommended that counselling be available from appropriately qualified counsellors

[41] Evelyn Mahon and Noelle Cotter , Assisted reproductive technology- IVF treatment in Ireland: A study of couples with successful outcomes , Human Fertility , Vol 17, (3), 2014, p165 - 169

[42] M.S. Kupka, T. D'Hooghe, A.P. Ferraretti, J. de Mouzon, K. Erb, J.A. Castilla, C. Calhaz-Jorge, Ch. De Geyter, and V. Goossens(2011) Assisted reproductive technology in Europe, 2011: results generated from European registers by ESHRE† The European IVF-Monitoring Consortium (EIM)‡ for the European Society of Human Reproduction and Embryology (ESHRE) Human Reproduction, Vol.31, No.2 pp. 233–248, 2016

before, during and after treatment as an integral part of the service offered by AHR clinics.[43]

Counselling and psychological support is important throughout the whole treatment process, particularly at stressful times, such as implantation, waiting for a pregnancy test, or dealing with an unsuccessful outcome. When treatment is coming to an end, counselling support can support patients to consider other options such as adoption, or to accept that that they will not have a child.

- *Counselling should be provided before, during and after treatment to those considering AHR treatment so that they are properly supported and are adequately informed of the risks involved, the potential benefits that may be obtained and the possibility of success in their particular situation.*[44]

According to Head 8, all intending parents wishing to undergo AHR treatment shall be provided with counselling from a counsellor who delivers services on behalf of the AHR treatment provider. It is important that counsellors are trained to provide AHR counselling and are in a position to provide impartial support to their patients. Work is ongoing in the Department of Health in relation to implementing provisions for the designation and regulation of counsellors under the Health and Social Care Professionals Act 2005. Any subsequent regulatory developments in this area must be taken into consideration as the Bill progresses.

- *Counselling should be provided by suitably qualified professionals who should adequately convey the complex medical and scientific ramifications of different treatment approaches in verbal and written form.*[45]

Age restrictions

Covered in a number of Heads

A number of age restrictions to treatment are outlined in the General Scheme. For example, Head 6(3) states AHR treatment shall not be provided to persons under the age of 21 years and Head 6(4) that AHR treatment shall only be provided to women who are 47 years and under. Comparable age restrictions are not provided for men. This appears to be discriminatory and requires explanation.

While setting a female age limit for treatment is part of many countries' criteria for publicly-funded AHR treatment, there is significant variation in these age limits. In countries with no age limits, discretion to determine access rests with the clinic or doctor, who may rely upon other clinical indications, such as the patient's ovarian reserve and hormonal levels.[46]

[43] Commission on Assisted Human Reproduction, Report, (2005), xv, recommendation 12.
[44] Exact extract from the Commission on Assisted Human Reproduction, Report, (2005), xv, recommendation 12.
[45] Extract from the Commission on Assisted Human Reproduction, Report, (2005), xv, recommendation 12.
[46] Keane, M. *et al.* (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.

- *Consideration should be given to the removal of specified age restrictions for AHR treatments in favour of a provision by which clinicians can determine a patient's eligibility for treatment based on agreed clinical criteria set down by the Authority.*

Functions of the Regulatory Authority

Head 67 Functions of the AHRRA

Given that AHR has not been regulated in Ireland to-date, it is vital that the new Authority has the designated functions and power to speedily create a robust regulatory system.

NWCI would draw the Committee's attention to the detailed legislation (Health Act 2007) governing the Health Information and Quality Authority (HIQA). This Act sets out HIQA's regulatory powers in considerable detail. For example, the sections governing inspections and investigations and concerning designated centres articulate matters such as a right of entry. Schedule 3B of the UK's Human Fertilisation and Embryology Act 1990 also makes provisions in relation to inspection, entry, search and seizure.

- *The powers of the Authority, including inspections and investigations, should be articulated in detail.*

Complaints procedure

No current Head

It is important for patients to understand what, if any power, the Authority has to intervene in complaints against licensed centres.

The Authority should have a specific statutory duty to investigate patient complaints. Complaints made by patients about the treatment or service that they have received at a centre licensed by the Authority may impact on the Authority's duty to provide advice and information to patients. Depending on the matters raised, complaints may also give rise to a duty to investigate serious adverse events.

- *The Authority should have the power to investigate complaints and concerns raised by patients and to censor clinics or practitioners where necessary.*

Review Clause

No current Head

AHR technologies have rapidly advanced in the last decade. It is essential that this Bill not only responds to present AHR provision but can regulate developments over time.

While a structured process of post-enactment review of legislation was incorporated into parliamentary procedure in November 2013 and re-affirmed in 2016, it is not yet

conducted on a regular basis. Certain Acts stipulate that their operation must be reviewed after a period of time, a task for which the Minister is generally responsible. For example, under the *Gender Recognition Act 2015* (s.7), a review of the operation of the Act is to begin two years after its commencement and a report made to the Houses of the Oireachtas no later than 12 months after the review begins.

- *Given the continued advancement of AHR, NWCI urges the incorporation of a review clause into this Bill to ensure that the new legislation carries out its intended propose, to address any gaps in the application of the law and to ensure its ongoing relevance into the future.*

Storage time limits for childhood cancer patients

Head 22 Storage of gametes and embryos

Cancer treatment can affect fertility and a patient may need to seek fertility preservation before treatment begins. Section 22(8) states that gametes may not be stored for more than 10 years without permission of the Authority. This may have implications for adult survivors of childhood cancer who underwent fertility preservation as children and need to store gametes beyond this time limit.

- *There are a number of ways in which this issue could be addressed via amendment to the current text: including a time extension for those who have had cryopreservation as a result of cancer; giving powers to the Authority to set reasonable grounds for extension; or by stating that people who had their gametes preserved during childhood due to a medical condition would be exempted from this requirement.*

Comments on regulation of surrogacy as outlined in the General Scheme

NWCI is not in a position to make a recommendation on the surrogacy elements of the General Scheme, as the organisation does not have an official position on surrogacy. However, in considering the text of the General Scheme we would raise issues for consideration in relation to surrogate mothers.

The surrogate mother

The technological advances presented by AHR naturally give rise to ethical and legal concerns. This is particularly the case for surrogacy which intersects with issues relating both to women's reproductive health and to the need to protect women from exploitation.

There is considerable concern about the practice of surrogacy given the potential for the coercion and exploitation of surrogate mothers in Ireland and in other countries. Broadly,

there are three main concerns related to surrogacy – the commodification of women and children; exploitation of women, including of the birth mother and/or of intending parents; and child protection. Individual women's, human rights and health organisations have taken different positions on surrogacy – calling for its prohibition, for strong regulation of practices, or supporting surrogacy in a range of forms.

NWCI believes that any consideration of altruistic surrogacy should place a particular focus on the potential experience and position of the surrogate mother, who would typically be the most vulnerable party in any arrangement. Any potential surrogate mother would bear any negative emotional, physical or lifestyle risks of the pregnancy. Further, a surrogate mother would face significant additional risks, such as the intending parents reneging on the surrogacy arrangement and she is left as parent of the child, or alternatively she may wish to keep the baby and the prior surrogacy agreement is held against her.

In the case that the Irish Government decides to regulate altruistic surrogacy in Ireland, significant attention must be given to legal, economic and health safeguards to protect surrogate mothers from exploitation.

PART 3: Development of Equitable Access to AHR

NWCI's *Every Woman* model advocates for women in Ireland to have access to all elements of reproductive and sexual healthcare services. NWCI welcomes the Government's intention to provide public funding for fertility treatments so that AHR can be provided as universal service within the publicly-funded health system. The WHO (2016) *Action plan for sexual and reproductive health*[47] recommends states include diagnosis and treatment of infertility as a standard component of basic health care packages. The all-party Sláintecare model for reform of the health system recommended that 'maternity care, including IVF'[48] would be part of healthcare entitlements in a universal healthcare system.

Universal access to AHR requires mechanisms of public oversight and transparency, including data on the use, practices, and outcomes of AHR treatments. Thus the introduction of the AHR Bill is essential to underpin the development of public provision of AHR. It is important that in tandem with the development of the AHR Bill, steps are taken to prepare for universal access to treatment, including development of care pathways for patients and clinical criteria for access.

Currently, women in higher socioeconomic groups are proportionally more likely to use AHR services in Ireland.[49] Public funding is essential to achieve equitable access for all women requiring treatment. Private-only AHR provision is likely to have created

[47] WHO (2016) *Action plan for sexual and reproductive health: towards achieving the 2030 Agenda for Sustainable Development in Europe – leaving no one behind.* Copenhagen: WHO.
http://www.euro.who.int/__data/assets/pdf_file/0018/314532/66wd13e_SRHActionPlan_160524.pdf
[48] P.59, Houses of the Oireachtas Committee on the Future of Healthcare (May 2017) *Sláintecare Report.*
https://www.oireachtas.ie/parliament/media/committees/futureofhealthcare/Oireachtas-Committee-on-the-Future-of-Healthcare-Slaintecare-Report-300517.pdf
[49] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.

suppressed demand by those who require AHR treatment but cannot afford it. Evidence also suggests that in countries such as Ireland which do not have public access to AHR, people wait longer to receive treatments as they save to meet the costs.[50]

Public funding can also bring additional benefits. It can ensure quicker access to AHR for eligible patients, which is significant given the impact of age on fertility. In other countries public funding for AHR has been used to establish safer embryo transfer practices, reducing incidence of complicated pregnancies.[51]

Current costs

Currently, AHR costs are prohibitive for many. Some individuals will stretch their finances to the limit to pursue treatment and many others are not able to access treatments at all.[52] For example, a single in vitro fertilization (IVF) cycle in a private Irish fertility clinic ranges from €4,100 to €5,900, while intracytoplasmic sperm injection costs between €5,200 and €6,400.[53] Patients will also incur additional costs such as initial consultations, testing, investigations and counselling fees.

Patients who access fertility treatments may claim 20% tax relief on the costs involved under the tax relief for medical expenses scheme. To avail of tax credit the patient must have the resources to pay for the service to then claim the tax relief in the future, making this process inequitable for many who cannot afford initial costs. The Medical Card, High Tech Drug Scheme and Drug Repayment Scheme provide some relief from drug costs. Some private health insurers[54] offer some coverage for assisted reproductive services, but this is only available for those who can pay privately for insurance.

Public funding of AHR

Following enactment of the AHR legislation, the Government has said it will provide public funding for AHR.[55] As identified by the Health Research Board's review of funding[56], internationally AHR is primarily funded via three mechanisms – full funding, partial, or no funding from public health system. The Health Research Board review[57] indicated that the

[50] Keane, M. *et al.* (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[51] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[52] Women's Health Council (2009b) *Infertility and Treatment a review of pyscho-social issues*. Dublin: The Women's Health Council.
[53] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[54] Laya covers up to a maximum of €1,000 per female recipient and Voluntary Health Insurance covers infertility treatment at an approved centre up to €2,500 per lifetime for members of the VHI PMI 0411 plan, which is only one of its many plans. See, Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[55] Dept. Health Press Release, 3rd October 2017 'Government approves the drafting of the Assisted Human Reproduction Bill'. http://health.gov.ie/blog/press-release/government-approves-the-drafting-of-the-assisted-human-reproduction-bill/
[56] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[57] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.

overall economic cost to society of AHR treatment is relatively modest – even for countries offering generous public funding, AHR represents 0.25% of the national health budget.

Internationally, publicly-funded AHR is subject to eligibility criteria and the number of publicly-funded cycles also varies by jurisdiction.[58],[59] The criteria adopted in Ireland should be based on safety, clinical evidence, equity and the likelihood of successful outcome.

- *NWCI recommends the development of a mechanism for public funding of AHR to ensure equitable access, while ensuring providers provide safe and cost-effective services.*

Care pathways for universal access

The creation of public access to AHR necessitates the urgent development of a Model of Care for Infertility. This model of care will coordinate care across all of the healthcare providers a woman will interact with during her treatment, including primary care, gynaecology, hospital services and AHR providers. As outlined in the UK's National Institute for Health and Care Excellence quality standard for fertility[60], a person-centred, integrated approach is vital to deliver high quality care.

- *The Model of Care for Infertility in Ireland should address all areas of infertility care, including: provision of information; initial advice; investigation; medical and surgical management of male/female and unexplained fertility; access to IVF and other procedures; counselling; and access to fertility preservation for patients with cancer.*
- *In providing for a system of universal access to AHR treatments, the state should also consider the psycho-social supports which will be required by individuals before, during and after such treatments. This should include mechanisms to plan with patients for when treatment will end, and the provision of supports, particularly for those who have an unsuccessful outcome.*

[58] Keane, M. et al. (2017) *Assisted reproductive technologies: International approaches to public funding mechanisms and criteria. An evidence review.* Dublin: Health Research Board.
[59] NICE UK Press Release, 31st October 2014, 'The importance of 3 full cycles of IVF'. https://www.nice.org.uk/news/blog/the-importance-of-3-full-cycles-of-ivf
[60] NICE (2014) *Fertility Problems – quality standard.* nice.org.uk/guidance/qs73

Conclusion

NWCI welcomes the opportunity to respond to this consultation on the General Scheme of the AHR Bill. NWCI, as the national women's membership organisation, is committed to the regulation of AHR treatments to protect women's health.

While the legislative basis represented by the General Scheme is an essential step, much more will be required to ensure infertility care in Ireland achieves best practice for women and couples in Ireland, including:

- Policies and benefits to support family formation
- Increased emphasis on prevention of infertility and pre-conceptual health
- Public awareness of fertility problems and treatments
- Equitable access to AHR

As the AHR Bill progresses, NWCI will continue to bring forward evidence-based proposals, the perspectives of our members and the lived experience of women on all elements of AHR. In this way we will work with the Department of Health, the HSE and the future Assisted Human Reproduction Regulatory Authority to ensure the provision of AHR supports women's health and advances equality for women in Ireland.

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