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Assisted human reproduction legislation: Acknowledging the voice of health care professionals

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ABSTRACT

Objective: Ireland is one of 5 European countries which currently lacks specific legislation on Assisted Human Reproduction (AHR). Draft legislation was introduced in 2017 and revised in 2022 with a view to enacting legislation this year (2022). This study sought to ascertain the views of healthcare professionals to proposed AHR legislation, prior to the implementation of that legislation.
Study design: A survey questionnaire based on all clinically relevant aspects of the Irish draft AHR Bill 2017 was distributed to relevant healthcare professionals using an online platform.
Results: Over 200 healthcare personnel indicated strong support for the availability of AHR techniques, access to treatment for all patient populations regardless of relationship or gender status, and appropriate legislation and regulation in the field. Views of respondents are at variance with several proposals surrounding surrogacy, with 84 % favouring a pre-birth order to assign parentage from birth, rather than the proposed birth order 6 weeks after birth. The majority also support legislation around international surrogacy. Contrary to the draft Bill, respondents believe that men, as well as women, should be able to use posthumously any stored gametes or embryos belonging to the deceased partner or the couple. While the majority favour altruistic gamete donation, respondents support more generous compensation for donors, such as compensation for time lost at work.
Conclusion: This study has uniquely ascertained the views of healthcare professionals to imminent AHR legislation. It is hoped that the results will help inform the national legislation as it nears completion. Similar studies could help other countries, and policy bodies such as ESHRE to frame good legislation in this extremely specialised and complex field.

Introduction

The World Health Organization (WHO) notes that laws and policies regulating third party reproduction and assisted reproductive technology (ART) are critical to "ensure universal access without discrimination" and to "protect and promote the rights of all human parties involved" [1]. Legislation in ART is extremely complex, because it raises questions about the status of a human embryo and the creation of families outside the traditional male/female relationship. This requires, in contrast to other medical fields, regulation by both state law and medical guidelines [2,3]. Regulatory authorities such as the Human Fertilisation and Embryo Authority (HFEA) in U.K. have proven invaluable in this regard [4]. While most countries practising AHR have some legislation in place, this varies widely, particularly regarding gamete and embryo donation, surrogacy, pre-implantation genetic testing (PGT) and other evolving techniques [5,6]. The history of AHR legislation has been controversial in many countries. Restrictive Italian legislation introduced in 2004 was the subject of a failed national referendum in 2005, with aspects of the law overturned in 2009 when the Italian Constitutional Court deemed parts of the 2004 legislation unconstitutional [7,8]. German legislation based on the 1990 Embryo Protection Act is also restrictive and described by Leopoldina, the German National Academy of Science, as "outdated and incompatible with the new diagnostic and therapeutic measures for fertility and with the new social concepts of marriage and family [9]." Surrounded by media controversy, France in June 2021 amended its legislation to allow AHR treatment for single women and lesbian couples.

In December 2021, the European Parliamentary Forum for Sexual

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and Reproductive Rights (EPF) along with Fertility Europe (ESHRE's partner patient organisation) launched the "European Atlas of Fertility Treatment Policies" [2]. This scores 43 European countries based on the results of a European IVF Monitoring (EIM) Consortium [5]. Ireland was ranked 40th, as one of only five countries in Europe which lack specific AHR legislation. The need for Irish AHR legislation was recognised by the Irish state in 2000 and a Commission on Assisted Human Reproduction (CAHR) was established, producing a report in 2005 [10]. Progress since has been slow. The legal status of the human embryo and surrogacy have been raised in the Irish High Court and Supreme Court [11–13]. In 2015, the Children and Family Relationships Act (CFRA) was introduced to modernize Irish law in terms of parentage, including families created with the help of donor assisted reproduction [14]. The AHR aspects of this law were not implemented until May 2020. A more comprehensive General Scheme of an Assisted Human Reproduction Bill was published by the Department of Health in 2017 [15]. This underwent pre-legislative scrutiny by a parliamentary Joint Committee on Health in 2018/2019 [16]. A revised version of this Bill was published by the Irish government on 10th March 2022 [17] and will soon be debated in the Irish Dáil and Seanad (Houses of Parliament), with a view to enacting legislation this year.

We believe that it is important to involve healthcare practitioners and service providers in discussions regarding AHR legislation. Such consultation has proven beneficial in Belgium [18,19] and might have averted problems in Italy and Germany. Ireland is now in a unique position to introduce an AHR law that reflects the many developments in ART and also the changes in social mores that have occurred in recent years. The aim of this study was to investigate the opinions of healthcare professionals towards the proposed national AHR legislation, as defined in the General Scheme of an AHR Bill 2017.

Materials and methods

Patient and public involvement and questionnaire design

A survey was designed to investigate attitudes and perceptions towards a broad range of issues contained within the draft AHR Bill of 2017, focusing on six key themes: (1) a national AHR regulatory authority, (2) AHR treatment type and availability, (3) age limits for treatment, (4) counselling prior to ART, (5) surrogacy and (6) posthumous use of gametes and embryos. The survey questionnaire is available on request. Particular reference was made to aspects of the Bill that had been questioned in submissions to government from the Institute of Obstetricians and Gynaecologists (IOG) and the Irish Fertility Society.

Study participants and recruitment

The study was approved by the Research Ethics Committee at the National Maternity Hospital, Ireland (EC19.2021). Three main groups of Health Care Practitioners (HCPs) were targeted: Obstetrician/Gynaecologists (Consultants and trainees), General Practitioners and trainees and Fertility clinic staff including doctors, nurses, scientists and administration staff. The questionnaire was distributed via secure email link to participants. Doctors working in obstetrics and gynaecology were recruited via the IOG and the Junior Obstetrics and Gynaecology Society. General practitioners were identified based on a clinic database of referrals received. A "snowballing" method was also used i.e. existing study subjects recruit future subjects from among their acquaintances [20]. Invitations were also sent to the directors of all Irish ART clinics with a request to distribute the questionnaire to their employees.

Statistical analysis

The questionnaire was based on a 5-point Likert Scale. For analysis, the responses "strongly agree/agree" and "strongly disagree/disagree" were combined. Data was further analysed based on age (over/under 50 years), gender and prior/current experience working in an AHR clinic. GraphPad Prism was used to explore descriptive statistics and frequencies. Categorical variables were analysed using χ^2 test or a Fisher's exact test where appropriate; a p-value of < 0.05 was considered significant.

Results

Demographics

Of the 245 respondents (Fig. 1), most were doctors, female and aged 31–59 years, with 42.2 % indicating current or previous experience working in AHR. Response rates among Consultant Obstetrician Gynaecologists and trainees were 32 % and 22 %, respectively. It was not possible to calculate a response rate for other groups due to the method of recruitment.

Attitudes to the implementation of AHR legislation in Ireland

Most respondents (93 %) support the establishment of a national regulatory authority and believe that board members should include medical, scientific, legal and ethical experts. Eighty-six percent believe that issues which may change with future developments and international practice (e.g. age limits for treatment, number of embryos to transfer etc.) should be specified by the regulatory authority, rather than defined in primary legislation.

AHR treatments that should be available in Ireland

Respondents believe that all currently available ART treatments should be available in Ireland (Table 1). There is some uncertainty (but not disapproval) regarding embryo donation and embryo research, particularly among female respondents. Support for more recently available laboratory techniques such as pre-implantation genetic testing (PGT) and sex selection in the case of sex-linked disorders is overwhelmingly positive. Results were not influenced by age, gender or experience of working in AHR developed AHR technologies.

Most respondents agree with AHR treatment for couples (both same and opposite sex relationships) and single women (Table 1). However, 20–30 % are unsure about treatment for single men and transgender men and women, with respondents over 50 years of age being more unsure. Half of respondents agree that a couple should be able to access AHR treatment if they are not in a relationship (i.e. not married, cohabiting or in a civil partnership) but wish to co-parent together, while 20–30 % are unsure regarding this.

Age limits in ART

Overall, 81 % of respondents feel that there should be an upper age limit for women to access ART while 65 % feel there should be an upper age limit for men (Table 1). Suggested upper age limits for women range from 40 to 55 years (mean 46.8) and for men from 40 to 70 years (mean 50.6). These results were not significantly influenced by age, gender or experience of working in AHR.

Counselling prior to ART treatment

There is strong overall support for ART counselling services (Table 2), particularly for those engaging in third party donation, surrogacy or posthumous conception and for patients whose doctors were concerned about their wellbeing; those with experience working in AHR feel more strongly about this. There was less support for mandatory counselling for every-one undergoing ART.

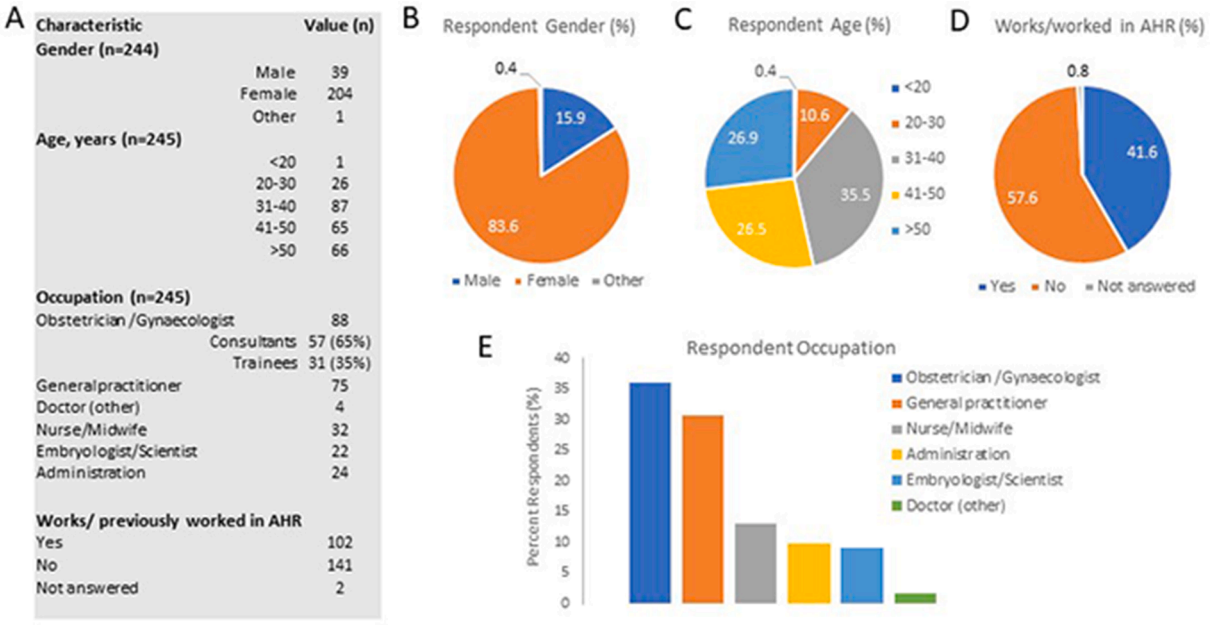

Fig. 1. Respondent demographics. (A) Characteristics and demographics of healthcare professionals who responded to the survey and breakdown by gender (B), age (C), experience working in the field of assisted human production (D) and occupation (E).

Gamete donation

Most respondents feel that gamete donation treatments should be available (Table 2) and that donation should be altruistic. Expenses should include compensation for time lost at work, particularly for egg donors, with less support for payment of a modest fee for donation.

Surrogacy

The draft Bill provides only for domestic surrogacy, not international surrogacy. As outlined in Table 2, 60 % of respondents disagree with this, particularly those who have worked in AHR. The Bill also stipulates that either the egg, sperm or both must come from one of the intending parents; over 50 % disagree with this. A large majority (84 %) favour a pre-birth order to assign parentage from birth, rather than the proposed birth order 6 weeks after birth.

Posthumous AHR

As shown in Table 3, 90 % of respondents agree that any posthumous use of sperm, eggs or embryos requires consent for same prior to death. The draft Bill stipulates that a surviving female partner, in an opposite sex or a same sex relationship, may use posthumously any stored gametes or embryos belonging to the deceased male partner/the couple, respectively. In contrast, a surviving male partner is not allowed to engage in posthumous conception. Close to 60 % of respondents disagree with this exclusion of men.

Discussion

This study is, to our knowledge, the first to ascertain the views of healthcare professionals regarding every aspect of AHR for which regulation and legislation is proposed in a draft national Bill. Our findings confirm a desire for legislation among healthcare staff who deal with individuals facing reproductive challenges and shows that there is no resistance in Irish clinics, all of which are private, to legislation and regulation.

Support among respondents for all AHR techniques, including newer technologies is in keeping with the growing trend towards liberalisation in Irish society and a move away from the Catholic and pro-natalist ideologies of the past [21]. A 2013 Irish telephone study of 1003 msembers of the general public also showed support for AHR techniques [22] but support was much higher in our current study. In the previous 2013 study, 80 % of respondents supported IVF, compared to 100 % in our study. Support for other treatments were respectively as follows: egg donation 64 % vs 91 %; sperm donation 65 % vs 91 %; embryo donation 51 % vs 75 %, surrogacy 52 % vs 87 %; PGD 45 % vs 96 % and PGS and sex selection 21 %vs 91 %. In the previous study 63 % felt that the Irish government should introduce legislation on AHR while virtually all respondents (93 %) in the current study supported this.

The liberal trend among our study respondents is also evident in the strong majority view that AHR treatments should be available without discrimination to all groups in society, including same sex couples and transgender individuals. This contrasts with many European settings where, as of 2018, 11 countries legally restricted access to heterosexual couples [5], and is in keeping with Ireland's status as the first country in the world to legalise same sex marriage by popular vote.

The current study investigated the views of health care professionals working in Ireland who encounter patients seeking and needing AHR treatment. While their views are very likely to reflect the attitudes of their patients, it would be helpful and interesting to also ascertain the current views of service users and of the general public. Such a follow-on study is being planned by our group.

Our study has highlighted several important situations where HCP views are at variance with proposals in the draft legislation. Following discussions held by the parliamentary Joint Committee on Health in 2018/2019, some of these issues have been amended in the new version of the Bill released in March 2022. Disappointingly, many have not. The draft legislation limits treatment to those in a stable relationship together i.e., married, co-habiting or in a civil partnership but 49 % of HCPs believe that treatment should be allowed for any two people who wish to co-parent.

A key finding is that most HCPs (86 %, n = 199) believe that issues which may change in line with future developments and international practice should not be defined in primary legislation but should instead be specified by the regulatory authority. Given the wide range of views in our study on suggested age limits, and the wide variations within European jurisdictions [5], it is likely that specifying this in legislation

Table 1
Access to AHR treatment and new technologies.

Survey Question	Total, n (%)			
	Agree	Unsure	Disagree	P-value
AHR Treatments				
IVF and ICSI	218 (100)	0 (0)	0 (0)	NS
Sperm freezing	217 (100)	0 (0)	0 (0)	NS
Egg freezing	213 (98.2)	2 (0.9)	2 (0.9)	NS
Sperm donation	197 (90.8)	15 (6.9)	5 (2.3)	NS
Egg donation	198 (90.8)	15 (6.9)	5 (2.3)	NS
Embryo donation	163 (75.1)	42 (19.4)	12 (5.5)	NS
Surrogacy	189 (87.1)	20 (9.2)	8 (3.7)	NS
Treatment to enable a child/family for:				
Opposite sex couples	216 (99.1)	1 (0.5)	1 (0.5)	NS
Same sex females[a]	208 (95.4)	6 (2.8)	4 (1.8)	*
Same sex males	195 (89.4)	14 (6.4)	9 (4.1)	NS
Single women	200 (91.7)	15 (6.9)	3 (1.4)	NS
Single men	156 (71.9)	46 (21.2)	15 (6.9)	NS
Transgender men[b]	138 (63.3)	59 (27.1)	21 (9.6)	**
Transgender women[b]	140 (64.5)	56 (25.8)	21 (9.7)	**
AHR treatment should be allowed for 2 people:				
Only if they are spouses, civil partners or cohabitants	87 (39.9)	40 (18.3)	91 (41.7)	NS
Who wish to co-parent but who are not spouses, civil partners or cohabitants	107 (49.3)	61 (28.1)	49 (22.6)	NS
New Techniques and Research				
Pre-implantation genetic diagnosis	209 (96.3)	6 (2.8)	2 (0.9)	NS
Pre-implantation genetic screening	198 (91.2)	15 (6.9)	4 (1.8)	NS
Sex selection of embryos in the case of serious sex-linked disorders	195 (89.9)	17 (7.8)	5 (2.3)	NS
Sex selection of embryos for "family balancing"	21 (9.7)	25 (11.5)	171 (78.8)	NS
The donation of supernumerary embryos for use in research[c]	148 (67.9)	49 (22.5)	21 (9.6)	*
New techniques such as mitochondrial donation and replacement	148 (67.9)	66 (30.3)	4 (1.8)	NS
Age limits				
There should be an upper age limit for:				
Women to receive AHR treatment	170 (80.6)	26 (12.3)	15 (7.1)	NS
Men to receive AHR treatment	136 (64.5)	50 (23.7)	25 (11.8)	NS
There should be a lower age limit for:				
Women to receive AHR treatment	134 (63.5)	24 (11.4)	53 (25.1)	NS
Men to receive AHR treatment[a]	132 (63.5)	28 (13.5)	48 (23.1)	*
Age limits should be:				
Determined by the regulatory authority	162 (76.8)	31 (14.7)	18 (8.5)	NS
Defined in legislation	68 (32.4)	38 (18.1)	104 (49.5)	NS

Note: x^2 test for comparisons between respondent groups (works in AHR v non-AHR; male v female; ≤ 50 years v > 50 years).
a: * $p < 0.05$; works in AHR v non-AHR.
b: ** $p < 0.01$; ≤ 50 years v > 50 years.
c: * $p < 0.05$; male v female.

would lead to conflict and differences of opinion in the future.

Counselling was an area where respondents were largely in favour of the proposed legislation. A substantial 42 % disagree with mandatory counselling for all couples undergoing ART. This would be in line with other specialities, e.g. oncology, where counselling is recommended but not mandated in primary legislation. Contrary to the proposed legislation of both 2017 and 2022, HCPs - particularly those who work in AHR - are in favour of compensation and payment of a modest fee to gamete donors, particularly egg donors. This is in keeping with policies in other countries such as the U.K.

Surrogacy is a very complex process and the subject of much international debate. As of 2018, surrogacy is allowed in only 15 of 43 European countries [5]. Contrary to the proposed legislation, most respondents (83.8 %) believe that any arrangement should involve a pre-birth order, which would come into effect at birth and make intended parents the legal parents from birth. This was the majority view of the Irish CAHR in 2005 [10] and is the practice in many U.S. states. Proposed Irish legislation follows the current U.K. practice that has been deemed outdated by the Law Commission of England and Wales and the Scottish Law Commission [23] and which is likely to change in the near future. Irish legislators are now in a unique position to learn from other countries in this regard. Respondents also favoured legislation to make clear provision in Irish law for the parentage of children born through international surrogacy arrangements. Many countries are currently grappling with this issue. The Hague Conference on International Private Law is currently examining parentage and surrogacy and in February 2019 called for uniform private international law (PIL) with regard to legal parentage [24].

Posthumous reproduction is another controversial aspect of AHR treatment. In line with ESHRE and ASRM guidelines, the majority of respondents agree that consent prior to death is important [25,26]. An interesting feature of the draft Irish legislation is that a surviving female partner, but not a surviving male, will be allowed to use any remaining gametes or embryos in the event of a partner's death. This seems discriminatory towards men. Posthumous conception was not addressed in the 2018 EIM survey of European countries [5].

A limitation of this study is that there is currently no public funding of ART in Ireland. All services are privately run. Therefore, respondents to the questionnaire provided views based on a private sector service. However, the study specifically addressed legislation and regulation and, in the covering letter regarding the study, respondents were asked to consider these issues "as if we had equitable access to fertility treatment for all.".

Conclusion

Legislation and regulation are pivotal to AHR, where complex medical, legal and social issues intersect and several parties must be protected – most notably children and offspring, but also intending parents, donors of gametes and embryos, surrogates and their families and service providers. No country has perfect legislation but the

Table 2
AHR Counselling and Third-party Reproduction (Donor gametes, donor embryos and surrogacy).

Survey Question	Total, n (%)			
	Agree	Unsure	Disagree	P-value
Counselling should be mandatory:				
For every person undergoing AHR treatment	101 (50)	15 (7.4)	86 (42.6)	NS
Where the treating doctor/GP/clinic is concerned about the patient's wellbeing	201 (99)	0 (0)	2 (1)	NS
For every person planning to use donor sperm/eggs/embryos	182 (89.7)	7 (3.4)	14 (6.9)	**
For every person involved in a surrogacy arrangement	193 (95.1)	6 (3)	4 (2)	NS
For every person involved in posthumous conception	185 (91.1)	7 (3.4)	11 (5.4)	*
Gamete Donors				
Sperm donors should donate altruistically i.e., receive no payment apart from reasonable expenses	120 (60.9)	36 (18.3)	41 (20.8)	NS
In addition to expenses, sperm donors should be compensated for time lost at work	128 (65)	27 (13.7)	42 (21.3)	NS
Sperm donors should be paid a modest fee (circa €100) in addition to listed expenses	60 (30.5)	54 (27.4)	83 (42.1)	*
Egg donors should donate altruistically i.e., receive no payment apart from reasonable expenses	99 (50.3)	34 (17.3)	64 (32.5)	NS
In addition to expenses, egg donors should be compensated for time lost at work	156 (80.4)	20 (10.3)	18 (9.3)	NS
Egg donors should be paid a modest fee (circa €1000) in addition to listed expenses	79 (40.1)	49 (24.9)	69 (35)	NS
Surrogacy				
The draft Bill allows only domestic surrogacy. It does not provide for international surrogacy.	35 (19.1)	39 (21.3)	109 (59.60)	*
The draft Bill stipulates that it is prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted.	17 (9.3)	43 (23.5)	123 (67.2)	*
The draft Bill stipulates that the surrogate may not provide the egg used to achieve pregnancy.	47 (25.7)	50 (27.3)	86 (47)	NS
The draft Bill stipulates that either the egg or the sperm or both must come from one of the intending parents.	26 (12.3)	42 (23.1)	114 (62.6)	**
The surrogate (and her husband, if she has one) is/are the legal parent(s) of the child until such time as a parental order has been granted to the intending parent(s) - this must be a minimum of 6 weeks after birth.	29 (15.7)	31 (16.8)	124 (67.4)	NS
A pre-birth order should be put in place whereby the intending parents are the legal parents from birth.	155 (83.8)	19 (10.3)	11 (5.9)	NS

Note: x^2 test for comparisons between respondent groups;
* $p < 0.05$ and ** $p < 0.01$, works in AHR v non-AHR.

Table 3
Posthumous AHR.

Survey Question	Total, n (%)			
	Agree	Unsure	Disagree	P-value
Any posthumous use of sperm, eggs or embryos should only be allowed if the deceased person had, prior to death, given consent for such posthumous use	171 (89.5)	10 (5.2)	10 (5.2)	NS
If a man in an opposite sex relationship who has previously had sperm frozen dies, his surviving female partner should be allowed to use his sperm for conception	121 (63.4)	46 (24.1)	24 (12.6)	NS
If a man in an opposite sex relationship who previously had embryos frozen dies, his surviving female partner should be allowed to use these embryos for conception	142 (73.6)	36 (18.7)	15 (7.8)	NS
If a woman in an opposite sex relationship who previously had eggs frozen dies, her surviving male partner should be allowed to use her eggs for conception	104 (53.9)	55 (28.5)	34 (17.6)	NS
If a woman in a same sex relationship who previously had eggs frozen dies, her surviving female partner should be allowed to use these eggs for conception	112 (58.3)	51 (26.6)	29 (15.1)	NS
If a woman in an opposite sex relationship who previously had embryos frozen dies, her surviving male partner should be allowed to use her embryos for conception	111 (58.1)	54 (28.3)	26 (13.6)	NS
If a woman in a same sex relationship who previously had embryos frozen dies, her surviving female partner should be allowed to use these embryos for conception	121 (63)	47 (24.5)	24 (12.5)	NS
Posthumous retrieval of sperm or eggs, should be allowed if the deceased person had, prior to death, given consent for this	83 (43)	54 (28)	56 (29)	***

Note: x^2 test for comparisons between respondent groups;
*** $p < 0.001$, works in AHR v non-AHR.

international experience to date, and the results of this survey, should help to ensure that Ireland creates an international best practice model fit for the 21st century. It is hoped that the results of this study will help inform the proposed national AHR legislation as it nears completion and, in turn, elevate Ireland's low position in the European Atlas of Fertility Policies [2].

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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