European monitoring of
Medically Assisted Reproduction (EuMAR)

PATIENT CONSULTATION REPORT

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Acronyms and abbreviations

CSC	ClinicSwitch code
EU	European Union
EuMAR	European monitoring of Medically Assisted Reproduction
ESHRE	European Society of Human Reproduction and Embryology
GDPR	General Data Protection Regulation
ICSI	Intracytoplasmic Sperm Injection
IRCC	Individual Reproductive Care Code
IUI	Intra-Uterine Insemination
IVF	In-Vitro Fertilisation
JPG	Commonly used method of lossy compression for digital images.
MAR	Medically Assisted Reproduction
MP4	digital multimedia container format commonly used to store video.
WP	Work Package

Executive Summary

This report provides an overview of the findings of a patient consultation carried out as part of the European monitoring of Medically Assisted Reproduction (EuMAR) project, a three-year EU-funded project managed by the European Society of Human Reproduction and Embryology (ESHRE) with the aim to establish a European cycle-by-cycle registry of medically assisted reproduction (MAR) treatments.

Patients were consulted through an online survey translated into several EU languages, as well as through a series of focus group sessions to learn about patients' awareness and attitudes towards MAR data collection and the EuMAR registry and to understand patients' preferences regarding the management of a European MAR registry. The patient consultation took place in two stages: first a survey was carried out, and then, respondents were given the option to sign up for focus group sessions to expand more on their responses.

From a total of 735 survey respondents, the majority was between 35 and 44 years old (n=453, 62.92%), female (n=689, 95.83%) and white (n=673, 93.47%). Most respondents (n=616, 88.38%) indicated that they would be in favour of sharing their data with a registry like EuMAR and that they would trust an international registry managed by a European professional association to handle their data securely (n=482, 80.2%). A majority indicated they would have more confidence in a fertility clinic that participates in an EU-wide MAR data collection (n=458, 75.83%), understood as applying to all the member states of the European Union. Most survey respondents did not know whether data on their MAR treatments is currently being collected in a national registry (n=549, 74.69%). The answers from the questionnaire and focus groups were used to extract relevant themes and make recommendations on how the EU and member states may better support infertility patients and improve overall access to and quality of infertility care.

Although the survey achieved a high sample size, some limitations can be noted to this study. Firstly, most responses came from countries speaking the languages into which the survey was translated. Secondly, it is possible that there were misunderstandings on the part of some participants with some of the questions.

Introduction

This report provides an overview of the findings of a patient consultation carried out as part of the European monitoring of Medically Assisted Reproduction (EuMAR) project, a three-year EU-funded project managed by the European Society of Human Reproduction and Embryology (ESHRE) with the aim to establish a European cycle-by-cycle registry of medically assisted reproduction (MAR) treatments.

The success of the EuMAR project and the long-term implementation of the EuMAR registry is dependent on several stakeholders. As the data needs to be provided by professionals at clinics and national registries, there is a strong focus on actively engaging these groups in the project. An extensive consultation of national institutions involved in MAR data collection was carried out in the first year of the project (Achótegui Sebastián et al., 2024) and a consultation of the professionals who participated in the EuMAR pilot study is planned to take place at the end of the study.

Another group whose support is crucial to the success of the EuMAR registry is patients. As a professional society that aims to bring benefits to patient care and collaborates closely with patients' rights advocates, it is important for ESHRE to understand patients' preferences, expectations and priorities with regards to data collection on their treatments and to take these into account in the development of the registry and the data management. Moreover, patients also have a direct role in the data collection. Indeed, as the system envisioned for collecting cumulative data across different clinics and countries, one of EuMAR's key aims, is entirely based on patients' collaboration, who need to request a "ClinicSwitch Code" (CSC) at the clinic where they have undergone the previous treatment and present it to the next clinic if they decide to continue their treatment elsewhere. Thus, knowledge of patients' support and attitudes towards the EuMAR project is important to gain a clear view of the feasibility of inter-institutional and cross-border data collection in the EuMAR registry.

Patients were consulted through an online survey as well as through a series of focus group sessions. The aims of the patient consultation were:

1. To learn about patients' awareness and attitudes towards MAR data collection in general and the EuMAR project/registry in particular.
2. To understand patients' preferences and expectations regarding how a European MAR registry should be set up and managed.

Methods

The patient consultation took place in two stages: first a survey was carried out, and then, respondents were given the option to sign up for focus group sessions to expand more on their responses.

Survey

Target population

The target population for the EuMAR patient survey included infertility patients that were seeking, undergoing or having had one of the following procedures in a European country: egg retrieval, IVF/ICSI, IUI, embryo transfer, or fertility preservation. European countries were defined as those that are members of the Council of Europe, as these will be the ones the EuMAR registry will be open to in the future, even though participation is currently limited to EU member states only, due to the financial restrictions of EU-funded projects.

A sample size calculation yielded that to calculate descriptive statistics for a population of several million infertility patients in Europe (based on an infertility prevalence of 16.5% (Cox et al., 2022) and an estimated European population of reproductive age (15-49 years old) of 192 million people (Eurostat, 2024) with a margin of error of 5% and a 95% confidence interval, 385 responses were needed.

Survey development

The survey questions were initially developed by EuMAR Work Package 3 (Integration into national policies and sustainability) and revised by the Project Steering Committee, as well as ESHRE's patient partner organisation Fertility Europe. The final survey consisted of 19 questions covering the following three areas: respondents' demographics, their awareness and attitudes towards MAR data collection, and their preferences and expectations regarding how data should be collected and managed. The full set of questions is available in Annex 1.

Translations

The survey was translated into all the national languages of countries where a local focal point committed to supporting the dissemination of the survey to the local patient community. The plans for the patient consultation were presented to the national patient associations that are members of Fertility Europe at a webinar. Following this webinar, the member organisations were asked whether they would be willing to support the dissemination of the survey among patients in their countries and whether it would be relevant to translate the survey questions into their national language. Based on the responses, the survey questions were translated into Dutch, French, German, Polish, Portuguese, and Slovenian.

The survey was further translated into Estonian, since Estonia is a EuMAR pilot country and the participating clinic was able to disseminate the survey to its patients. It was also translated into Spanish, following a commitment of a member of the ESHRE Young Talent Group to disseminate the survey among Spanish patients, after which the Spanish patient association became involved in its dissemination.

Dissemination

The survey was conducted on SurveyMonkey and kept open from 23 July 2024 until 31 December 2024. A dissemination package with captions for social media posts and graphics in JPG and MP4 formats was shared with the supporting patient associations. Furthermore, the

survey was promoted in a series of social media posts on X, LinkedIn, Facebook and Instagram from the official ESHRE accounts.

Data analysis

The proportion of responses per option was calculated for all questions. For the construction of 95% confidence intervals, standard errors (SE) were calculated based on the assumption of normal approximation to the binomial. For this, the formula $SE = \sqrt{\frac{p(1-p)}{n}}$ was applied, where p denotes the proportion of participants who selected a specific response option and n denotes the total number of participants who responded to the question.

Focus group sessions

At the end of the survey, patients were given the option to complete a form if they were interested in participating in a focus group session to discuss the topics of the survey in more detail. Based on the languages spoken by the respondents and the languages spoken by the EuMAR members facilitating the sessions, there were three sessions in English, one in French, one in Spanish and one in German. Each session lasted one hour and they took place during the third week of February 2025. They were held online via Microsoft Teams. Following consent from the participants, each focus group was recorded for transcription purposes.

All participants received the following materials prior to the session: a confidentiality agreement, a copy of the questions of the survey, the information leaflet for patients used for the pilot study, a PowerPoint presentation with an overview of the project, and the agenda.

Following the transcriptions, the analysis of the data collected through the focus groups combined inductive and deductive approaches to coding the content. Pre-determined codes, developed prior to reviewing the data, were based on the themes that guided the discussion, which included: Use of ClinicSwitch Code (CSC); Patient Reports; Benefits & Improvements; Privacy; Use of Informed Consent. These codes were supplemented with codes for additional content that emerged during the sessions. This resulted in seven different codes for analysis: 1) ClinicSwitch Code (CSC) Use; 2) Patient Reports; 3) Benefits; 4) Privacy; 5) Informed Consent; 6) Improvements & Ideas; 7) Concerns. Additional codes were created as subcategories for the different themes for analysis, such as benefits and risks of CSC, patient reports perceived as useful, or support for the registry.

Results

Survey and Focus Groups

Number of participants and demographic characteristics

The privacy declaration of the survey was accepted 933 times, but in 133 instances, only the questions were viewed without providing a single response. A further 65 respondents only provided data on their demographic characteristics. Thus, there were a total of 735 participants who responded to at least one question related to their awareness, attitudes, preferences and expectations on (MAR) data collection (78.78% of those who started the survey). Of the total number of times that the privacy statement was accepted, English was the most used version of the survey, with 529 responses, followed by responses using the translations into Spanish (223), Portuguese (53), French (33), Dutch (24), German (21), Slovenian (21), Estonian (17) and Polish (12).

Among those who responded to at least one question about their awareness, attitudes, preferences and expectations towards (MAR) data collection, 718 patients answered the question about their nationality and 708 about the country where they started their fertility treatment. Eight respondents (1.11%) indicated that they preferred not to provide information on their nationality and 15 respondents (2.12%) indicated that they preferred not to provide information on the country where they started treatment. In total, 44 different nationalities were represented among the survey participants and respondents had started their treatments in 27 different countries. The vast majority of respondents were nationals of (86.77%) and started their treatment in (89.41%) one of the ten countries that are displayed in figure 1. Most respondents held the nationality of the country where they started treatment. Only 57 patients indicated a different nationality than that of the country where they started their fertility treatment.

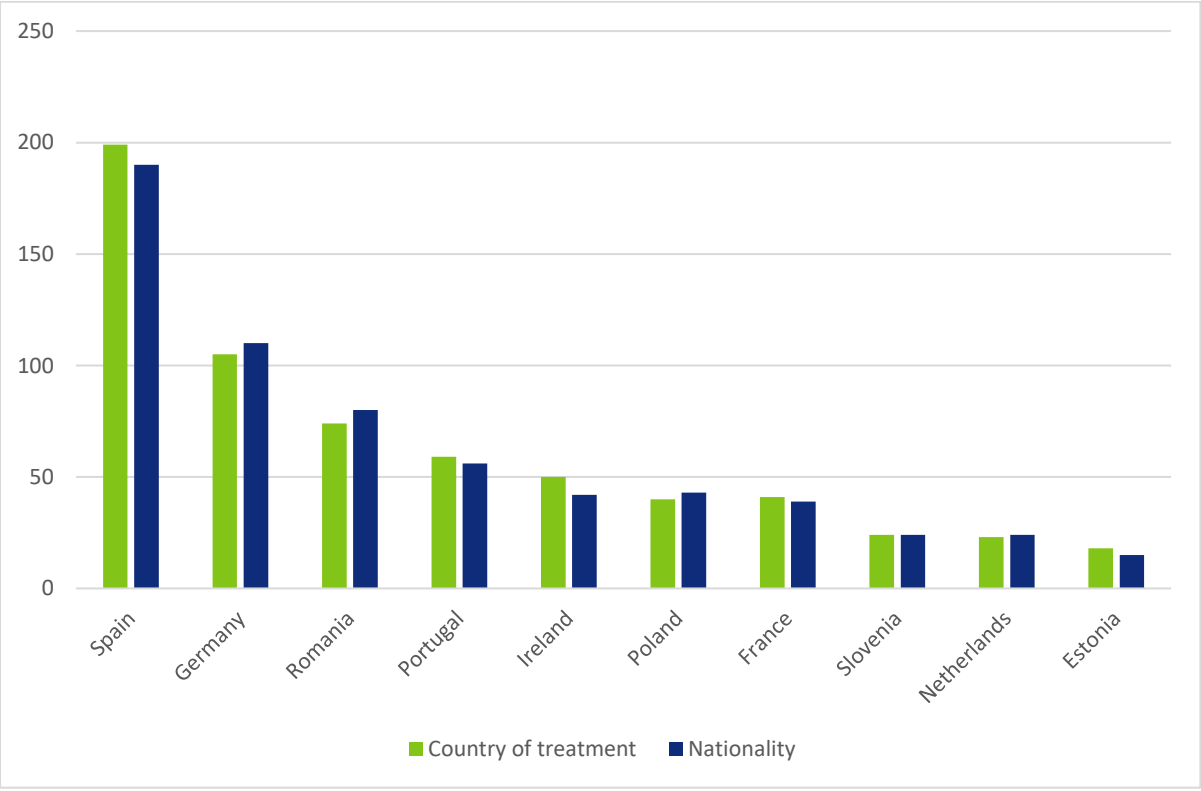

Figure 1: Number of respondents by country of treatment and nationality (10 most frequent countries)

Table 1 provides an overview of the demographic characteristics of those participants who responded to at least one question about their awareness, attitudes, preferences and expectations related to (MAR) data collection. The majority of respondents was between 35 and 44 years old, female and white.

Table 1: Respondents' demographic characteristics		
	N	**Percent**
Current age		
18-24	3	0.42%
25-34	225	31.25%
35-44	453	62.92%
45-54	34	4.72%
55-64	4	0.56%
65+	0	0.00%
Prefer not to say	1	0.14%
Total	720	
Sex		
Female	689	95.83%
Male	27	3.76%
Other	2	0.28%
Prefer not to say	1	0.14%
Total	719	
Ethnicity		
Asian	12	1.67%
Black	3	0.42%
White	673	93.47%
Mixed	10	1.39%
Other	17	2.36%
Prefer not to say	5	0.69%
Total	720	

For the focus groups, a total of 103 people expressed initial interest via the registration form and were contacted with instructions to register for specific sessions in January 2025. Thirty patients registered for one of the focus group sessions, resulting in six sessions with a total of 19 participants each. The focus group in German had the highest number of participants (n=7), while the other sessions had between two to three participants. All patients who participated in the focus groups were women and all but one were European.

Awareness of (MAR) data collection

Among the 721 patients who responded when asked whether they were aware of health data registries in general, 434 (60.19%, 95% CI [56.62%, 63.76%]) responded 'no' and only 287 (39.81%, [36.24%, 43.38%]) responded 'yes'.

Similarly, the majority of respondents did not know whether data on their MAR treatments is currently being collected in a national registry (n=549, 74.69%, [71.55%, 77.83%]). Among

those who indicated knowing, it frequently occurred that responses seemed implausible in light of the situation in the country where the patient indicated having started treatment. As an example, some stated that their data is collected in a national registry even though the country where they started treatment does not have a national registry, others stated that their data is not being collected in a national registry even though the country where they started treatment has a mandatory national registry that covers 100% of treatments. It could not be inferred whether these mismatches were due to a misconception of the patients or to another explanation, such as the patient having started treatment before the national registry was created or the patient having had treatment in several countries and their data being collected in the national registry of another country than the one where they had started treatment.

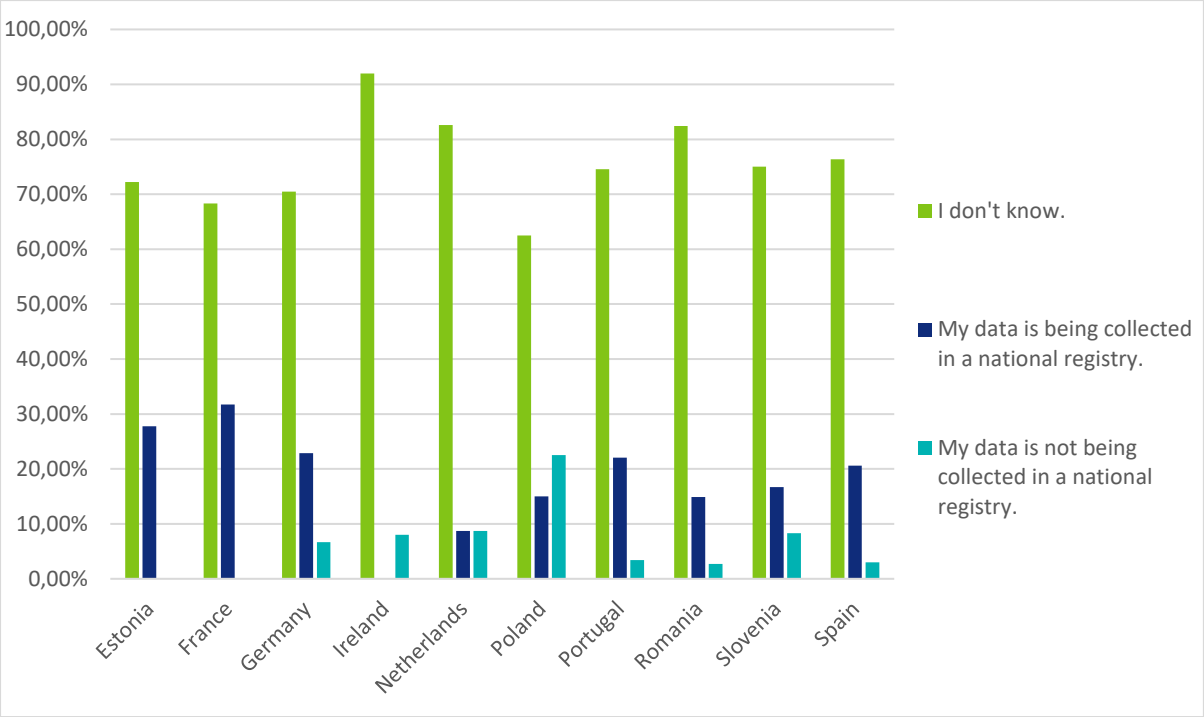

Figure 2: Responses to the question "Do you know if data on your infertility treatments is currently collected in a national MAR registry?" by country of start of treatment (10 most frequent countries)

Patients who indicated that their data is currently being collected in a national MAR registry (n=142) were asked how they were informed about this data collection, to which 128 patients responded and several selected more than one response. Most respondents indicated that they were informed by their clinic, either through a consent form (n=60, 46.88%), a conversation with their healthcare provider directly (n=32, 25.0%) or information materials such as posters or leaflets (n=22, 17.19%). Furthermore, 37 patients (28.91%) indicated learning about the national MAR data collection through other routes, most prominently through social media and national patient organisations. In the focus group sessions, some patients acknowledged the difficulties to be informed about data collection at the start of a treatment and provided some explanations for the low level of awareness: *"I actually can't remember consenting to the data collection in the [national] IVF registry. To be honest, I have no idea how to best inform patients about the data collection because you sign thousands of papers and I*

think this information would just be buried in it because at least for me personally, it would be of low relevance."

Attitudes towards a European MAR registry

Patients were asked whether, based on their current knowledge and perceptions, they would be in favour of their data being shared with an EU registry of Medically Assisted Reproduction in an anonymised format, to which 697 patients responded. Most respondents (n=616, 88.38%, [86.00%, 90.76%]) indicated that they would be in favour, 52 patients (7.46%, [5.51%, 9.41%]) responded that they do not know, and only 29 patients (4.16%, [2.68%, 5.64%]) stated that they would not support their data being shared with an EU-wide MAR registry in an anonymised format. When asked about the reasons why they are against sharing their data, the most frequent reasons were concerns regarding the data handling or losing control over one's own or one's child's data. Only four patients indicated that they do not see any societal benefit or relevance in contributing to such a registry.

Several patients in the focus groups mentioned the idea of sharing their data to try to improve the situation for the next generations of patients, as one of the participants stated: *"If I don't get what I most want from this journey, at least I'm working actively in sharing what I have, which is information and experience, in order to pass something forward"*.

The majority of patients (n=458, 75.83%, [72.42%, 79.24%]) indicated that they would have more confidence in a fertility clinic that participates in an EU-wide MAR data collection, while 35 patients (5.79%, [3.93%, 7.65%]) indicated that they would not have more confidence in such a clinic and 111 patients (18.38%, [15.29%, 21.47%]) responded that they do not know. When asked about this, patients explained their positive attitudes towards clinics participating in EuMAR as a sign of transparency in data sharing, but also of innovation and keeping up to date with the latest research. Clinic's participation in EuMAR was seen as positive, but it was not considered a deciding factor when choosing a clinic, and other elements, such as treatment costs or distance remained more important. One patient added that *"It's important to understand EuMAR, what it's doing. I don't know if the existence of this project is well known enough yet to be a game changer in the choice of a clinic"*.

Participants were provided with a list of potential benefits of an EU-wide MAR data collection and were asked to rate the importance of each of them. The responses are presented in figure 3. These questions were completed by 600-603 respondents, depending on the potential benefit. Each of the potential benefits was considered very important by the majority of patients, with advancing research into the treatment of infertility and improved estimates of the real chances of a live birth receiving the highest importance ratings.

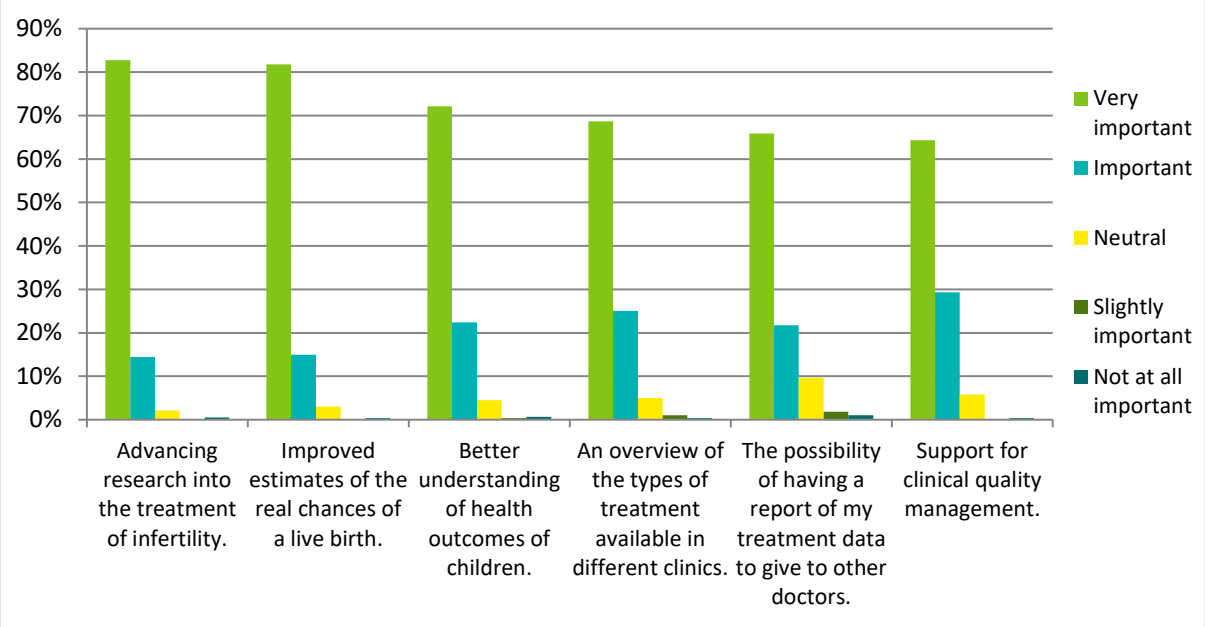

Figure 3: Participants' rating of the importance of different potential benefits of an EU-wide MAR registry

Participants were asked whether they would trust an international registry managed by a European professional association to handle their data securely, which was confirmed by the majority of respondents (n=482, 80.2%, [77.01%, 83.3%]). A further 109 respondents (18.14%, [15.06%, 21.22%]) responded that they do not know, and ten respondents (1.66%, [0.64%, 2.68%]) indicated a lack of trust.

When prompted on this topic during the focus group sessions, other benefits perceived by patients in support of the registry emerged. There was a general perception that the EuMAR registry could become a tool to help clinics improve the care they provide to patients, as expressed by one participant: *"If I was starting my journey in fertility treatment now and this program [EuMAR] was on for a few years, I would have had better data, better statistics, better care"*. Participants in the focus groups mentioned having more accurate predictions, continuity of information collection and success rates from the start of a treatment as important benefits of the EuMAR registry. An impact on EU and national policies (e.g., reimbursement, availability of care) was also expected as an outcome of the analyses obtained from EuMAR data.

Preferences regarding MAR data collection

Participants were asked how their data should be managed so that they feel it is fair to them, to which 562 patients responded. Seven options were available and participants were asked to select all that apply. In addition, respondents were given the option to select "Other" and provide an open text response. An overview of the participants' responses is shown in figure 4. Most patients indicated that it should not be possible to identify them based on their data in the registry, that they should be informed about the data that is collected, who has access to it, and what it is being used for, and that the data should not be used for immediate commercial purposes. Despite the importance that participants attributed to advancing research into the treatment of infertility, less than half of the patients indicated that the data

should be openly accessible for research and that the outcomes of research with registry data should be openly available to everyone.

Seven open text responses were received. These suggested that patients should be inquired for approval every time somebody wants to use their data, that the patients should receive all the outcomes of the use of their data (studies, articles), that the data collection should be compliant with the General Data Protection Regulation (GDPR), that no DNA data should be stored, that for non-anonymised data very high cyber-security standards need to be applied, that the data should not be used for commercial or insurance purposes, and that treatments should also be registered if they do not result in a live birth.

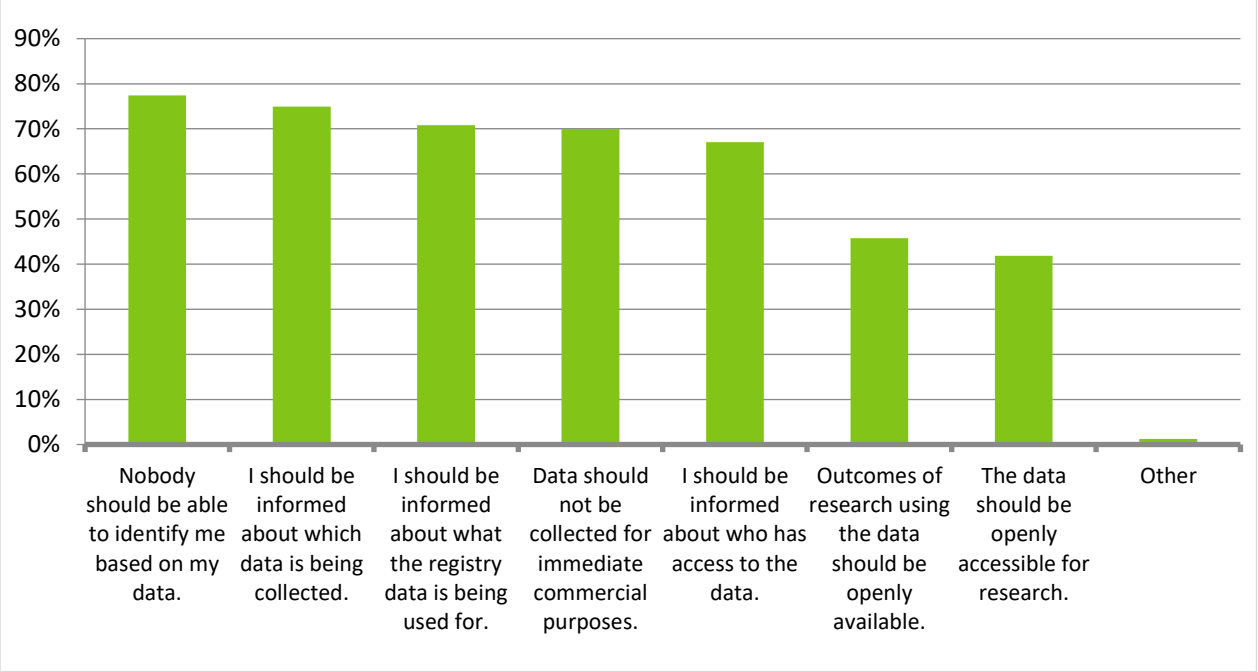

Figure 4: Responses to the question "How should your data be managed in an EU-wide registry so that you feel it is fair to you?"

When asked whether it is important to them to access the data in the registry, 561 patients responded, with almost half of them indicating that they would either like to be able to access a report with their own data (n=272, 48.48%, [44.34%, 52.62%]) or that they would like to be able to access overall statistics on the data in the registry (n=209, 37.25%, [33.25%, 41.25%]). A minority of patients responded that it is not important to them to access the data in the registry (n=47, 8.38%, [6.09%, 10.67%]) or that they do not know (n=33, 5.88%, [3.93%, 7.83%]).

Patient reports were more deeply explored in the focus groups. The majority of participants saw an added value in these reports and the most commonly cited positive elements raised can be summarised in three groups. Firstly, patients agreed that this is useful information for the next clinician to improve care. To support this argument, patients explained that it can be difficult, confusing and even painful to explain everything again when starting at a new clinic. Similarly, patients expressed that they do not always know what details are relevant to mention to the next clinic and that "*it would be nice to a have formal overview of things that are*

important for the [next] treatment". Secondly, it was also considered useful as a personal overview to remember what they as patients had gone through, especially for long MAR treatments that last for years; for some patients this is a way to "*reflect on the journey"*. Patients said that these reports could also be useful for making their personal decisions about what to do next and for reassurance about the information that was shared with EuMAR. Lastly, the idea of collectivity came up again when it was explained that the reports could be a way of putting into context what was happening to an individual and to seeing the bigger picture: *"… to think that it's useful for something, it allows you to have something material and say to yourself: what I'm going through, it might be useful later on for something good"*.

It is worth noting that in one focus group session, participants questioned the relevance of the patient reports, explaining that they already knew the treatment they had gone through themselves and that the reports will not contain all the details on previous treatments that patients perceived as important, e.g., diagnostic tests performed, exact medication and dosage, etc. Participants who underwent treatment in countries such as Portugal and France reported that they systematically received medical records after their treatments that they could take with them to new clinics, but that the EuMAR report could be a useful summary with explanations and medical terms simplified. In contrast, participants doing treatments in countries such as Spain, reported not always receiving documents from clinics with the information on their treatment, thus, reinforcing the importance of the EuMAR patient reports.

The question whether patients would like to have the option to control which type of data are shared with an EU-wide MAR registry received 568 responses. The majority of patients (n=377, 66.37%, [62.48%, 70.26%]) indicated that they would prefer to have this option, while 97 patients (17.08%, [13.99%, 20.17%]) stated that they would not prefer to have this option and 94 patients (16.55%, [13.49%, 19.61%]) indicated that they do not know. Those patients who expressed a preference to be able to control which data is shared were asked which data they would feel comfortable sharing (figure 5). The responses to this question revealed that there is a majority of patients who would feel comfortable sharing their data for each data category listed.

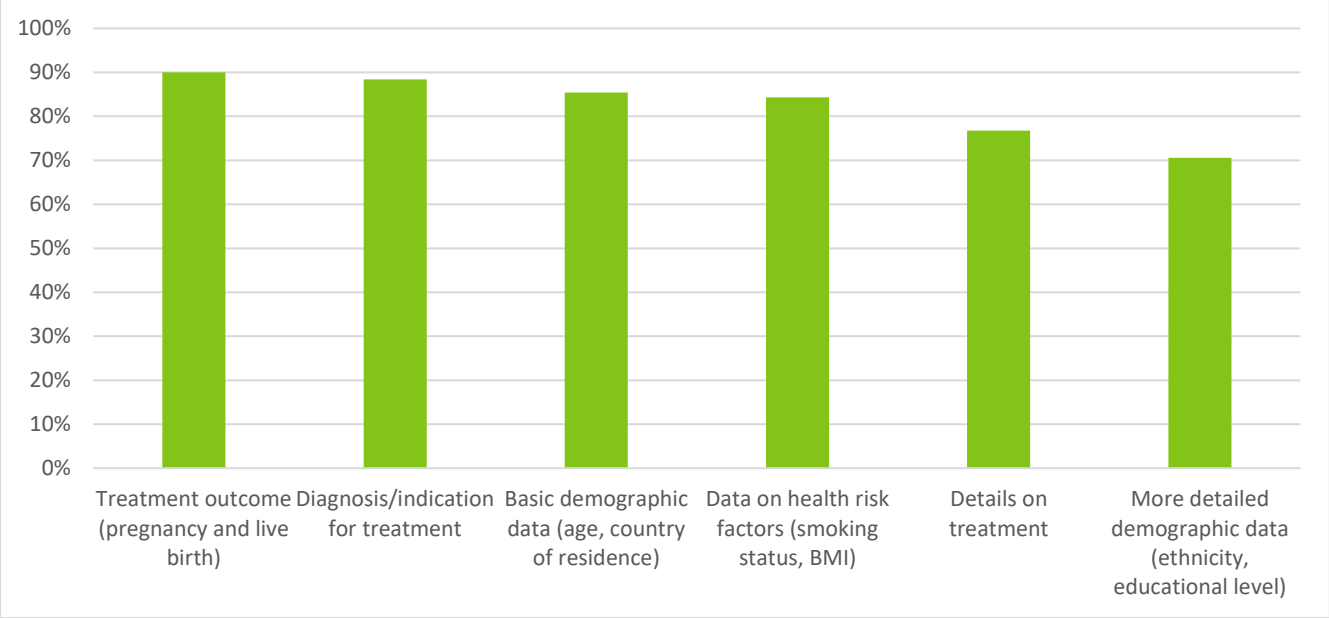

Figure 5: Responses to the question "Which data would you feel comfortable sharing?"

There were 551 responses to the question how patients would like to be informed about the existence of an EU-wide MAR registry. A significant number of respondents indicated that they would like to be informed personally by their healthcare provider (n=256, 46.46%, [42.30%, 50.62%]), followed by consent forms (n=155, 28.13%, [24.38%, 31.88%]), their clinic's website (n=76, 13.79%, [10.91%, 16.67%]) and information materials such as posters and leaflets at their clinic (n=53, 9.62%, [7.16%, 12.08%]). Only eleven patients (2.0%, [0.83%, 3.17%]) indicated that it is not so important to them to be informed about the existence of such a registry. When the topic was raised during the focus groups, consent was considered important by some patients, while others indicated that they see no problem with not asking for consent if it is not legally required. A participant proposed facilitating the process by requesting consent only once per country and another participant proposed introducing a possibility for patients to opt out.

When asked how they would prefer to be informed about updates or findings from a health registry where they are enrolled, 546 patients responded. Ca. two thirds of the respondents preferred to be informed via email after signing up for a newsletter (n=351, 64.29%, [60.27%, 68.31%]), while ca. one third (n=184, 33.7%, [29.74%, 37.66%]) preferred to check this information on the website of the registry. Eleven patients selected "Other" and provided an open response, mentioning social media and information by their healthcare providers as additional pathways how they would like to receive the information. One respondent also suggested that the subscription to an email newsletter with updates from the registry should be automatic for all patients whose data is being recorded.

Use of the ClinicSwitch code

The use of the ClinicSwitch codes (CSCs) was discussed during the focus groups only and it was not asked about in the survey. During the discussions, patients raised some of the risks they saw in the current CSC model. Participants questioned both, the step of patients having to return to a clinic where they had treatment to request the CSC, and the step of patients

presenting the CSC to the new clinic where they start treatment. On the first one, participants shared mainly two reasons why it can be challenging for patients to request the CSC: on the one hand, they may be embarrassed to do so, especially if there was a negative experience with the clinic. The request of the CSC was cited as *"another factor of stress"*. On the other hand, it was mentioned that patients may forget about it, particularly as the change from one clinic to another does not always happen directly, and months can pass in between. Patients may also not find it important enough to return to the clinic to request it. One patient said: *"I don't see what the point is for me as a patient to use it"* and *"In cases where the patient did not dare to tell the clinic that she did not trust them or that she thought they did not do everything they should have done, she will not be back to request a code for statistical reasons"*, meaning that the incentives to request it in such a way are not enough.

Presenting a CSC to a new clinic also raised some concerns during the conversations. It was noted that some patients may not want to share with a new fertility clinic that they had been to a previous clinic, which would prevent them from using the CSC. Two specific examples were given to support this assertion. One patient explained that patients who have had many cycles and are perceived to have difficult cases may want to withhold certain information for fear of being turned down by clinics if they reveal that they have been through many cycles. This is in belief that the clinic will not want to take on 'difficult patients' in order to maintain the success rates. Another patient explained that the reimbursement policy in her country had a cap of three cycles, regardless of whether they had been done in a private or public setting. Therefore, when she got her chance at the public hospital after being on the waiting list for months, she hid some information from previous cycles carried out in a private clinic to keep her chances with reimbursed cycles: *"I am currently on my sixth cycle, but for the public health system, I am on my third one. In this case, I don't know if the EuMAR QR code would have been useful for me, as I actually wanted to hide some information"*. To clarify, the CSC is a QR code that, when scanned, does not provide information about previous treatments. However, CSCs have been discussed alongside the provision of patient reports, where cycle information is given to patients to take with them to the next clinic, explaining the association of information sharing with CSCs.

Many participants suggested that CSCs should be given to patients at the start of treatment, and one patient supported this suggestion by saying that *"the risk of losing it is less than the risk of things going badly and the patient not daring to ask [for the CSC]"*. It was also suggested that professionals should keep asking about the CSC when treating new patients/couples to avoid it being the responsibility of the patient alone. Another suggestion was to allow the possibility that the staff at the new clinic contacts the old clinic for the CSC, so that the professionals manage the process between themselves without it being initiated by the patient.

Discussion

The results of this survey show several positive points for EuMAR, which reaffirm that the structure that the project is following is aligned with the interests of the different stakeholders, including those of patients.

Educating patients about the importance of data

A very important result is that infertility patients support data collection at the European level, with the majority of respondents indicating that they would be in favour of their data being shared with an EU-wide registry. This is a particularly positive finding for EuMAR, as the cooperation of patients in requesting and sharing the ClinicSwitch codes is the only way to ensure that cumulative data is collected for inter-institutional and cross-border treatments. This patient support for data collection could be expected to stem from a solid knowledge of data and patient registries. However, most patients reported that they were unaware of health data registries and whether their data is being collected in one. This highlights the need of educating patients about the power of data and informing them about the uses given to their own treatment data. Educating patients about infertility treatment data would not only be empowering but it would also promote further acceptance of data sharing. Overall, we recommend raising patients' awareness of the role of data in advancing research as a fundamental step to improve patients' willingness to share their data. This is essential in moving towards fairer and more complete data registries.

Getting informed about a European data collection

The results also show that patients want to be informed about the existence of a European registry, which further stresses the importance of notifying them about data sharing and the relevance for both, patients and MAR professionals, as key stakeholders in ensuring the correct submission of cycle data to EuMAR. In this regard, not only does EuMAR provide an opportunity for meaningful interaction between healthcare professionals and patients, but it also increases patient confidence in fertility clinics that participate in the project, as evidenced by the majority of respondents who indicated they would have more trust in a clinic submitting data to an EU-wide registry. It is expected that EuMAR will bring several benefits to participating clinics, such as increased patient trust, but also others that were mostly rated as important by respondents, such as advancing research for infertility treatment and improving the estimates of the real chance of having a live birth thanks to the calculation of cumulative outcomes.

Additionally, it can be observed that the most commonly used method to inform patients about data registries is through informed consent forms. It is interesting to note that the majority of patients had a preference to be informed about an EU-wide registry in conversation with their healthcare provider and not via consent forms, despite the latter being the most commonly used method to do so for national registries. This preference is in line with the current approach of EuMAR, where MAR professionals are encouraged to communicate with patients about the registry directly, supported by information materials, such as leaflets and posters. EuMAR-specific consent forms were not considered mandatory in the pilot study, given the anonymisation process that is applied to data before reaching the registry. However, consent forms remained an optional choice of MAR centres and two pilot countries used

specific consent forms under the guidance of their respective national data protection authorities. In EuMAR, it is not only good practice to promote patient understanding of the registry; we need to ensure that patients are well-informed enough so that they are willing to use the CSCs to collect cumulative data across centres and countries and avoid duplicating IRCCs for the same patient, what would lead to the collection of incorrect data.

Data privacy

Respondents assigned great importance to the advancement of research through data sharing, however, the notions of control over one's own data, anonymity and the preservation of one's identity prevail. For instance, among patients who selected that they would not agree to their data being shared with an EU-wide registry, most of them indicated that this was because they would prefer to control over who has access to their data, even when anonymised. Similarly, on the question of how data should be handled in order for it to seem fair, most patients said it was necessary to ensure that individuals were not identified through data sharing. Privacy has been a constant concern for EuMAR and several steps have been taken to ensure that EuMAR data is anonymised, such as the use of unique patient codes per clinic that are not stored in the EuMAR registry, the IRCCs, and the CSC system for cases where treatment takes place in more than one institution. The privacy of patients will continue being a priority for the registry and patient anonymity shall be guaranteed in all instances.

Another point on this topic is that the majority of patients indicated a preference to control which specific data are being shared with an EU-wide registry, which is currently not a possibility within EuMAR. At present, there is a list of parameters that participating clinics and national registries are expected to submit and that patients agree to when they sign consent forms, where applicable. The silver lining is that most patients said they would be comfortable sharing the data already collected in the EuMAR parameters. The need for EuMAR consent in the long term will be revised as a part of the pilot study validation, taking into consideration the findings of this patient consultation.

Regarding access to one's own data, the most frequently selected option was to receive reports with their own data in the registry, which is a feature being developed and believed to be of benefit not only for patients, but also for MAR professionals that can revise easy-to-read, standardised documents from patients who had treatment at a different centre before. The content of these patient reports will need to be adapted so that it serves the purposes of informing both patients and professionals. It also became evident that associating the patient reports with the CSC QR codes can be an incentive to the use of the codes, but it can also lead to the false idea that scanning the QR code would show the patients data, with any implications that that can have on the utilization of the codes by patients. A revision of the process will be needed to ensure maximum utilization, applying to, for instance, when to recommend that the CSCs are given to patients.

The possibility of having a patient portal where patients could access their own data in the EuMAR registry has been a challenging task, as the anonymisation process is applied to data before it reaches the registry and therefore does not allow for the identification of patients that could access their data. The solution to allow patients to see their own data in the registry

was to create patient reports that fertility clinic staff can share directly with patients, giving them access to their own data in EuMAR.

The potential of data to inform policymaking

The survey results also highlight the importance of data collection on cross-border reproductive care. Despite the growing numbers of individuals seeking fertility treatment abroad, the literature has shown us that very little is known about this topic, due to the lack of available data and the few empirical research studies on the subject (Inhorn & Gürtin, 2011). The responses to the survey on nationality and country of start of treatment shed some light on this issue. In Spain, a country with notorious high volumes of reproductive travel *(Sociedad Española de Fertilidad*, 2022), more respondents chose Spain as the country of start of treatment than that of origin, suggesting that individuals of different nationalities travel there to seek treatment. Despite this reality, there is currently no system to collect complete data on these treatments. This research gap leads us to recommend that the collection of data on cross-border care becomes a priority in the EU health policy agenda, which would strengthen EuMAR's proposed solution to fill in this gap by using the ClinicSwitch codes to collect cross-border reproductive care data. Conversely, we can identify countries such as Germany, where the results show that more patients selected Germany as their nationality than as the country of start of treatment, which could be explained by the restrictions on certain types of treatment (e.g., oocyte donation) that lead some patients to seek treatment abroad. This finding prompts the recommendation to improve access to fertility treatment for all and to remove barriers that push patients to travel abroad to receive the most appropriate treatment for their condition.

Patients expect EuMAR to improve access to information and accurate statistics from clinics. This will support patient confidence in clinics participating in EuMAR and ensure that EuMAR data informs policies and decision-makers. It will be important to keep a balance between ensuring transparency in data sharing and respecting confidentiality of clinics' own data, which will remain private to each participating clinic and only aggregated statistics will be made publicly available.

Finally, it should be noted that the majority of responses came from white (93%) and female (95%) patients. A more diverse representation would be needed to explore possible differences by subgroup categories and we, therefore, support the European Commission's recommendation to move towards collecting data disaggregated by racial or ethnic origin (European Commission, 2020) and to collect data disaggregated by sex and gender so that future research can address differences between different groups and enable policymakers to design and evaluate interventions.

Limitations of the study

Although the survey achieved a high sample size, some limitations can be noted to this study. Firstly, the survey was translated into only a few languages due to the involvement of some national patient organisations, which resulted in most responses coming from countries where these languages are spoken. The availability of a more multilingual survey would likely facilitate responses from patients in more countries to increase the number of nationalities represented.

Secondly, it is possible that there were misunderstandings on the part of some participants with some of the questions, such as with those on awareness of MAR data collection, where some answers were implausible with the situation in countries.

Conclusion

This patient consultation presented very promising results for the EuMAR registry. It has provided a clear idea on the interests and worries of patients regarding data collection of their fertility treatments and it has proven that EuMAR is heading in the right direction to accommodate the needs of patients while establishing the registry.

The successful implementation of the EuMAR registry does not only depend on stakeholder support, but also on the policies that are in place at national and EU levels. Therefore, one of the deliverables of the EuMAR project is to develop a set of policy recommendations. The results of this patient consultation will feed into the policy recommendations to advocate for the united interests of MAR patients and professionals.

All in all, EuMAR will continue working on raising awareness and informing patients about the uses of data for research, while caring for privacy concerns in the data collection process.

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