

Chapter
10

Use of ART Surveillance by People Experiencing Infertility

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Introduction

Pursuing assisted reproductive technology (ART) is a major life decision. In many countries it is a very costly medical treatment, for which there is limited or no reimbursement through government-provided national health insurance. Therefore, it is vital that individuals and couples considering and undergoing ART make use of comprehensive information regarding treatment options and outcomes. National ART surveillance data are one such option in those countries where these data are publicly available.

Expectations of ART Treatment

The multifaceted ART intervention raises many challenges not only for practitioners but also for patients. Do patients receive sufficient information prior to embarking on treatment, to understand the chances, risks and potential complications of treatment to enable them to make an informed decision to undergo ART? Clinics have a duty to provide comprehensive information about all aspects of treatment, not only orally prior to treatment, but also written, web based or through audiovisual means. A basic understanding of ART should cover what the treatment involves, medications and interventions, under- and overresponse to stimulation, adverse reactions to medication used, complications of egg collection, low embryo availability and blastulation rates, low success rates, particularly in women older than 35 years of age, the likelihood and risk of multiple pregnancies and, last but not least, child and pregnancy risks.

More than 25 years' experience from patient support organizations suggests that many patients pursue ART without a full understanding of the risks and potential complications [1]. Therefore, it is imperative that providers ensure adequate patient education to enable them to make an informed decision about undergoing ART. This helps to manage their expectations about commencing and continuing with treatment. However, in

addition to the information presented to patients by providers, it is important that publicly available ART surveillance data be available in a format that is unbiased, understandable and meaningful. Most developed countries publish ART registry reports, but the format of these varies considerably and they are usually written for a scientific audience. In the digital age, patients increasingly expect to have access to information on health service outcomes. More research is needed to guide the patient-friendly presentation of ART data collected by national ART registries, including on treatment success rates for different patient groups, risk of complications and different ART treatment modalities.

The chance of an ART cycle being successful varies by prognostic factors including the age of patients, reasons for treatment and, for those who have already commenced treatment, how many failed attempts they have undertaken. These will inform a patient's decision making; however, their final choice will most likely be related to confidence in the treatment and quality of care provided by a particular clinic. They want to know which clinic will give them the best chance of taking home a healthy baby while respecting their particular circumstances and needs. **Choosing a clinic based solely on reported success rates either based on ART national registry data or published clinic data on their websites can create unrealistic expectations about the possibility of having a baby at a particular clinic.**

How Can Patients Inform Themselves about National and International Trends in ART Success Rates?

ART statistical data are complex to present and understand even by clinicians and scientists working in the field. A recent review of clinical trials evaluating ART treatment has identified more than 800 reported outcome measures [2]. The reason for the complexity relates to the many numerators and denominators

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that can be chosen to represent ART success. In addition, ART treatment involves multilevel exposures (e.g. multiple treatments within one woman), multiple stages within an ART cycle (initiated, follicular aspiration, embryo transfer) and multiple end points (implantation, pregnancy, live birth/s). (See more information about variations of ART success rates in Chapter 5, Reporting ART Success Rates.) Therefore, where national ART surveillance data are published, it should be in patient-friendly language and include comprehensive information about how to interpret the statistics. In particular, it should be emphasized that the results from national ART registries are population-based averages of all patients who have undergone treatment and may not be applicable to an individual patient's circumstances and chance of success. Such guidance is important because it can help to inform expectations prior to deciding whether to embark on treatment.

Furthermore, available data on which to base a patient's decision to commence or continue with treatment are often lacking and can be biased, as few countries have a compulsory, cycle-by-cycle national reporting system that encompasses all ART therapies performed. Consequently, the burden lies with patients to identify and understand data pertinent to the ART clinic they are considering and any other services or national and international results for comparison purposes.

Using ART Surveillance to Understand Success Rates

How Do ART Surveillance Data Help Patients to Enrich Their Understanding and Ability to Choose?

Standardized data about ART treatment outcomes are difficult for patients to find, despite most developed countries publishing ART registry reports. Due to the competitive nature of these interventions and the continuous enlargement of the 'for profit' ART services globally, there is limited drive for clinics to present uniform, realistic and accurate results of treatments. Having to rely on published clinic-based results, such as those on clinic websites, can be misleading because of the varied way that clinics choose to present their results and the possible omission of some patient groups to artificially improve the published success rates [3].

The only information the vast majority of patients seek is that provided directly by the clinics in their region or country. Information about world regions where surveillance data are available can be found in Section 4 of this book. In order for patients to be aware of national and international registry data that provide overall results in a standardized way, clinics and patient organizations should be encouraged to make this information known, and to encourage ART surveillance reports to be made publicly available with accompanying lay summaries for patients.

At the heart of a patient's question about a clinic's success rates is the need to know whether they can be assured of the best chance of taking home a healthy baby. Some of the more popular means of measuring success rates are live birth rate or positive clinical pregnancy (positive fetal heart showing on ultrasound) per treatment cycles commenced, per egg collection or per embryo transfer. Considerable debate exists on what is the most reliable measure [4] [5]. A discussion on measuring success rates using ART registry data is presented in Chapter 5, Reporting ART Success Rates.

What Counselling Is Available?

Infertility is a major life crisis, and for some the treatment can be somewhat of an emotional roller coaster. Even people who have particularly challenging lives may be surprised by the impact that infertility and its treatment can have on well-being. Under these circumstances, good friends and a supportive family can be important.

Emotional responses to infertility are complex and at times are so strong they can seem overwhelming. Having a professional counsellor available at the clinic can help patients understand that these feelings are normal.

The outcome of ART treatment is not only the possibility of getting pregnant. Emotional support during treatment by an infertility counsellor, friendly opening hours, continuous contact, spontaneous support such as a phone call when the treatment has not worked – all help patients navigate the challenges of ART treatment.

For patients or potential patients reading ART surveillance reports, the stark numbers and percentages presented in multiple tables do not provide any indication of the complex emotions associated with falling on either side of the very binary outcome

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associated with ART treatment – that is, achieving pregnancy or not.

Measures That Can Be Used to Determine Success Rates

It would be particularly helpful for patients if ART surveillance reports provided more lay vocabulary regarding ART treatment. The following measures explain in patient-friendly language what each of these terms means and give some indication of their respective limitations:

Live birth – this relates to the number of live births per treatment cycle, multiple births being classed as a single live birth. This measure is closest to the intention of the infertile couple; however, collection of data is often slow – at least until all the live births have occurred and been followed up by the clinic and recorded. Live birth figures reflect a number of factors, including the following: age of the female, the number of eggs recovered, fertilization rates, the quality of embryos and embryo transfer technique, not to mention the quality of the laboratory.

Clinical pregnancy – This relates to an ultrasound test, usually at about 7 weeks into the pregnancy when a fetal heart is seen. This is a more rigorous test than that of biochemical pregnancy (the first blood test that shows a positive pregnancy test) and has the advantage that it provides more recent data from the perspective of patients receiving contemporaneous information directly from the clinic rather than from the annual report. However, these data do not show how many of these clinical pregnancies result in a live birth.

Pregnancies / live births per treatment cycles commenced – This relates to the number of pregnancies / live births per cycles where hormonal stimulation of the ovaries has been initiated irrespective of whether any of the cycles were cancelled prior to egg pickup.

Pregnancies / live births per egg collection – This relates to the number of pregnancies / live births per cycles where the woman has proceeded as far as egg collection and would include also all those patients for whom eggs were retrieved but did not result in embryos for transfer.

Pregnancies / live births per embryo transfer – This relates to the number of pregnancies / live births per cycles where the woman has proceeded as far as embryo transfer and would not include those couples for whom the

cycle was cancelled, who did not make it to egg pickup, who were overstimulated (ovarian hyperstimulation syndrome (OHSS)) or who did not produce embryos. These data would also include frozen embryo transfers.

Pregnancies / live births per embryo – This refers to the rate of pregnancies / live births per embryo transferred. There is now greater emphasis on transferring a single embryo and reducing the risk of multiple births.

Cumulative pregnancy rates – Some clinics may have data on their cumulative pregnancy rate, which is either pregnancy or live birth per all transfers from one fresh egg collection and includes data from both fresh and frozen cycles.

It is important to realize that as we move down this list, the apparent success rate increases. Armed with this information, it becomes important to ask clinics about the specific per cent figure they are reporting.

An excellent tool is the International Committee Monitoring Assisted Reproductive Technologies (ICMART) glossary of terms [6]. See Appendix B, International Glossary on Infertility and Fertility Care.

Questions That May Be Useful for Patients to Ask

- *What is the success rate for my particular age group?*
- The age of the woman is a known predictor of the chance of achieving a pregnancy. Patients will find it useful to know what the likely outcome is for their age bracket.
- What is the success rate for my/our particular case of infertility?
- Certain etiologies such as endometriosis can reduce the likelihood of pregnancy after ART.
- *What is the risk of a multiple birth?* Note: success rates could be higher for clinics that transfer a higher number of embryos, but the multiple pregnancy rate is likely to be higher also. Some clinics may have specific policies on how many embryos should be transferred, so ask them about their policy. In some countries, reimbursement may be linked with the number of embryos transferred, while in other countries, compliance with medical guidelines is required.

Clinical practice guidelines may restrict the number of embryos transferred to no more than one or two, unless in exceptional circumstances. There is a recommendation in some countries that no more than one embryo be transferred on the

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first or second treatment cycle when the egg has been obtained from a woman under 35 [7] [8].

- How many cycles are conducted per year by the clinic?

For smaller clinics, the results can become skewed because of the lack of something called statistical power. This means that their results may look ‘good’ one year, and then the following year they may look ‘bad’ but the results cannot be compared. A clinic may have 200 cycles one year and 200 the next; in the first year there were 55 live births and in the second there were 60. The percentages would be 27.5% and 30%, respectively. The percentage difference may look quite different, but in reality, we are only talking about the difference of 5 live births out of 200. It is important that patients understand such discrepancies.

- What is the success rate achieved for a so-called gold standard prognosis group?

This ‘good prognosis’ group may be composed of women under 35 years of age who have undergone 3 or fewer cycles. Pregnancy rates vary significantly depending on the type of treatment, the age of the patient and cause of infertility. The success rates achieved by a clinic for the ‘good prognosis’ group primarily reflect the quality of the clinic rather than the variety of patients.

A recent advance in the reporting of ART surveillance information is the inclusion of web-based patient prediction calculators, where patients enter individual characteristics about themselves and the treatment they are considering. Two examples are provided the Society for Assisted Reproductive Technology (SART) based on United States (US) data and using the Human Fertilisation and Embryology Authority (HFEA) data from the United Kingdom (UK) [9] [10] [11]12. These prediction tools are based on pooled data from reporting clinics and provide a much more user-friendly way for patients to access information about their chances of ART success, but it is important that these tools be used in conjunction with advice from a patient’s clinician.

Opportunities for ART Clinics in Using ART Surveillance Data

Result Presentation

There is an opportunity for clinics and ART registries to drive a new way of reporting their results, one that

not only gives live birth rates but also presents the efficient running of the service, protocol personalization, efficiency of stimulation, laboratory quality and utilization of reproductive material, or the ability of the clinic to offer the largest number of good quality embryos from the oocytes and sperm made available to their laboratory.

Presenting results for all patients receiving treatment is informative, particularly at upper age limits, yet the performance of a clinic is best measured by comparing success rates in a standard cohort, for example, ‘good prognosis’. Clinics should offer information on their rate of complications during treatment, how efficient they are in creating an embryo from 100 eggs collected, what the likelihood is of a blastocyst forming from 100 fertilized eggs, the percentage of patients who reach an egg collection and an embryo transfer, the percentage of elective single embryo transfers and freeze rates and clinical pregnancy and delivery rates.

One area of interest for patients is represented by the non-in vitro fertilization (IVF) therapies such as ovulation induction with or without intrauterine insemination (IUI), results of which are extremely rarely collected and reported at the national level. In consequence, questions concerning treatment success, treatment safety and cost-effectiveness as well as when one should transit from non-IVF to IVF therapy remain unanswered on large-scale data. From a patient perspective, consideration should be given to collecting such data at national and international levels to aid decision making.

Service Presentation

Reporting of results presents only part of the patient experience during treatment. The idea that patients must pay attention only to the success rates should be challenged. Clinics should describe how they offer a comprehensive treatment to include clinical and laboratory expertise, availability of counselling and out-of-hours contact, friendly hours services and support after the treatment, particularly if it has not worked. Furthermore, clinics have an opportunity to assess the quality of their services through patient satisfaction questionnaires that could be published on an annual basis to reflect the ‘non-medical’ spectrum of care.

Finally, presenting ‘results’ creates the opportunity to misinform and mislead vulnerable patients. In contrast, presenting the services provided can

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help patients to understand how the clinic will support them as they undergo treatment, with realistic expectations about reaching their desired destination. It is important for patients to be confident that the clinic will endeavour to meet their specific needs in a business that offers no guarantees of delivering their dream of a child and in the majority of cases does not.

While correct reporting of results should be a legal obligation for all ART services, correct presentation of services must be a minimal ethical obligation!

Creating Confidence in ART Surveillance Data

When Reporting Success Rates, Should Clinics Be Identified or Anonymous?

An integral function of accrediting bodies and licensing authorities is to collect results for a specific group of patients who have a similar likelihood of having a live birth or pregnancy, in order to compare success rates at different units. Alternately, or in addition to, results should be risk-adjusted to account for differences in the case-mix of patients attending clinics. The use of these data to measure performance for accreditation purposes is a useful means of identifying ways to improve practice while maintaining confidentiality. A major strength of the data in surveillance reports where clinics are not identified is their anonymity. There is no incentive to manipulate data, so stakeholders can be confident of their reliability [13].

Information that may be provided in national surveillance data identifying clinics can be used to compare the results. But how meaningful is this comparison and do patients truly understand what it represents? It can weaken the quality of the information available for patients because they do not present an accurate picture of an individual's chance of success. This prevents them from making an informed decision about where they choose to undergo treatment.

What is important is not that one clinic's results are better than others, but how their services compare when plotted against all the other clinics in the country. Are the results in the top percentiles or not after risk-adjusting for the prognostics characteristics of patients? When clinics present their results, they should develop a graphic interface that facilitates a transparent and uncomplicated understanding for patients.

National ART surveillance data should be presented in such a way that league tables cannot be created of best- and worst-performing clinics. League tables can be highly misleading. They create incentives for clinics to focus on pregnancy rates at the expense of providing a holistic approach to fertility treatment for patients suffering from infertility. For example, success rates can be optimized by limiting treatment to good prognosis patients and reporting their results while refusing care to harder to treat patients.

Should Clinics Use ART Surveillance to Advertise Their Success Rates?

Advertising on a clinic's website or in other media claiming to have significantly better success rates compared with other clinics or the average of *all* other clinics can be misleading and are arguably deceptive. Unequivocal claims can create unrealistic expectations of live birth rates in vulnerable people needing ART treatment. This may lead them to make financial decisions to choose the clinic that *claims* to give them a better chance of realizing their dream of having a baby. It may also, in some countries, be in breach of the law. However, if patients do not have access to or do not know how to interpret standardized clinic success rates provided by national registries, resorting to website advertisement is the source from which they can make decisions about starting or continuing with treatment.

The Role of Patients' Organizations

The International Alliance of Patients' Organizations (IAPO) has identified key principles of patient-centred health care, including respect for their unique needs, preferences and values, access and support, in addition to choice, empowerment and information [14].

Patients' organizations must be empowered to play meaningful leadership roles in supporting patients to exercise their right to make informed health care choices.

Patient involvement in health policy is supported by the World Health Organization (WHO), which states that patients' organizations should engage in constructive dialogue with health professionals and be represented on appropriate scientific and professional committees. It is the opinion of the authors that ART registries need to involve patients and patients' organizations when making decisions about selecting

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success rates measures with the hope of providing information that is meaningful to them or use visual presentation of treatment results.

Factual, objective and comprehensive information is essential to enable patients to make informed decisions about health care treatment [15].

International organizations that have recognized and endorsed these principles include the following:

- United Nations Economic and Social Council
- WHO
- International College of Person-Centered Medicine
- World Health Professions Alliance
- International Hospital Federation

These principles, particularly with a focus on information provision, should apply to ART surveillance data, ensuring that the complex ART statistics and success rates are presented in a patient-friendly and meaningful way.

Conclusion

Health services exist because of patients. ART patients are more informed than ever. They read broadly and often challenge practitioners with new data and new therapies, some of which are of value, while others are without any proven benefit. The role of the practitioner and clinics is to assess patients for their suitability for ART, discuss the implications for them and the child to be and ensure that all relevant information has been offered prior to their informed decision to proceed with treatment.

Including a patient representative on licensing bodies in the regulation of ART will ensure transparency and can build public confidence in the accuracy of ART surveillance data. In Australia, this has proved effective and is evidence of the continuing cooperation between all stakeholders: health professionals, government and, most significantly, patients.

Dealing with patients as partners and not passive recipients has been recommended by WHO, which states that there is a need for the profession to have a constructive dialogue with consumer groups in which both sides can listen to each other and talk to each other [16].

In working towards a model that meets the needs of all stakeholders, consumers seek a spirit of cooperation, which will ensure transparency and quality in the delivery of infertility services [17]. This is

appropriate, as it is patients who will live with the consequences of policy and treatment decisions.

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