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OPINION

Is your IVF programme good?

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Few standards exist today to assess the quality of an IVF centre. Although much focus is placed upon pregnancy rates, emphasis on this outcome alone is inadequate. The purpose of this report is to examine those factors that should be considered in assessing the overall quality of an IVF centre. Current methods to assess quality are reviewed. Many governing bodies throughout the world currently focus solely on pregnancy rates, which can be misguided if factors such as multiple pregnancies, ovarian hyperstimulation, patient satisfaction, and the proper evaluation of laboratory and clinical protocols are not taken into account. Measurements of quality and methods to improve it are critical in all business models, including IVF. We propose an international standard such as the ISO 9001 for IVF centres to properly evaluate and improve the delivery of their care.

Introduction

The quality of products and services is of paramount importance to consumers. When comparing one make of automobile with another, one can resort to several consumer reports that compare multiple parameters amongst the different manufacturers and a reasonable conclusion can be made before even test driving the car. But what about an infertility centre? How does the public know that a given centre is better than another or, at the very least, meets certain acceptable standards? How do insurers and governmental agencies know that a fertility centre is of good quality?

Unfortunately, few standards exist to compare fertility centres with IVF programmes. National reporting of clinic-specific pregnancy rates has lead to consumers' use of these numbers to assess quality (Lass and Brinsden, 2001). But is this reasonable? High pregnancy rates per cycle come at a 'price'. The price takes the form of excluding less than ideal candidates, accepting high order multiple pregnancies, excessive number of cases of ovarian hyperstimulation, and often recommending IVF to patients who would otherwise conceive with simpler approaches.

The use of pregnancy rates as the sole or most important criteria for the measure of quality in an IVF centre is misguided. A plea is made for the better definition of quality in our field, using more standardized approaches.

What standards are currently being used for quality of IVF?

Many countries have set up national registries to report outcome data. The establishment of these agencies has resulted from public and political pressures for IVF centres to report their outcomes. Inferred is the intent to have some measure of quality in the form of pregnancy rates. The USA has the Society of Reproductive Technology (SART), while FIVNET in France, the Human Fertilisation and Embryology Authority (HFEA) in the UK and DIR in Germany perform similar roles. Furthermore, several countries have governing bodies that evaluate and certify IVF laboratories. For example, SART inspects laboratories of IVF centres and Clinical Laboratory Improvement Amendment (CLIA)—a national laboratory licensing body—certifies IVF laboratories in the USA.

Another type of quality standard is represented by guidelines for good practice, for example those issued by the European Society of Human Reproduction and Embryology (Gianaroli *et al*., 2000). Such guidelines are very valuable, but are inevitably subjective and reflect the local practices of the country or region in which they were produced. In order to allow valid comparison of programmes, a more international approach is required.

What is the 'right' pregnancy rate for IVF?

National registries report, amongst other data, pregnancy rates. Despite clear statements of some agencies to the contrary, clinic-specific data are used (misused?) to compare programmes. So, does the clinic with the highest pregnancy rate 'win'? If not, what is the right pregnancy rate for an IVF programme?

A low pregnancy rate (for example, 15% per cycle) may

indicate a poor laboratory, but may equally reflect a high percentage of patients with poor prognosis, such as poor responders. If most of the patients were prior failures at other centres and had elevated day 3 FSH levels, then a 15% pregnancy rate may be regarded as excellent. Similarly, a 70% pregnancy rate per cycle should immediately raise concern that only good prognosis patients are being treated. Patients with less than average expectations would be excluded. But this is poor practice. Should a patient with less than average prognosis (say 15% per cycle) be denied IVF? Centres with pregnancy rates of 70% must exclude patients with poor prognosis if they want to maintain their high success. But does this reflect good quality care for the public?

Although national registries were initially developed to measure quality amongst centres, the reverse may actually have occurred. The focus on pregnancy rates only has placed pressure on IVF centres to have the highest pregnancy rate, sometimes at any cost. A review of the USA national registry indicates that those centres with pregnancy rates over 50% had unacceptably high multiple gestation rates (Society for Assisted Reproductive Technology and American Society for Reproductive Medicine, 2000). High neonatal morbidity and mortality is the price paid when pregnancy rates are the first priority for quality assessment.

How should we define quality in an IVF centre?

In order to define quality measures, we need to define our product. If our product is a baby at any cost, then the baby rate would be the sole or most important measure of outcome. What is our product? Our product is a service—to help infertile couples manage their disorder. Sometimes we are successful and sometimes we fail. But quality in the context of an IVF programme means the quality of service that we provide to the couples who approach us for help. We will now look briefly at some quality measures, starting with perhaps the most fundamental: patient satisfaction.

Patient satisfaction

A satisfied customer/patient is one who understands their condition and its treatment, and feels that the best advice was given and the treatment, if indicated, was attempted with the best possible medical supervision and service. Patients who are treated successfully and deliver a healthy baby may still be dissatisfied with the treatment they received.

A number of studies of patient satisfaction with IVF services have been carried out and provide important lessons for service providers. For example, while the majority of patients are generally happy with their treatment, patients studied in the USA (Hallman *et al*., 1993), UK (Souter *et al*., 1998) and Denmark (Schmidt, 1998) expressed a wish for more information, particularly written information. Longer-term follow-up (Hammarberg *et al*., 2001) can provide valuable and considered insights into how patients view the experience of IVF. Clinics may be able to use the results of such studies to minimize stress and improve the overall well-being of their patients.

If we take patient satisfaction seriously, a robust system for handling complaints and learning from our mistakes is essential. More broadly, is patient satisfaction something that we should measure routinely and make available to the public? If so, a number of questions will need to be answered. How should we measure satisfaction with treatment? What standards are available? Clearly, patient satisfaction is less easy to measure and compare across centres than pregnancy rates, but this does not mean that it should be neglected.

Procedures

A fundamental aspect of quality control is to establish and document the procedures to be followed. This needs to be done at various levels ranging from the creation of an overall ‘quality manual’ (Huisman, 1994) setting out quality control policies and standards, to the standardization of everyday procedures and protocols.

Laboratory methods

The quality of the service that we provide to our patients is critically dependent on the quality of the methods and equipment used in the IVF laboratory. Equipment needs to be the best available and well maintained. Cleanliness, both of the equipment and staff personal, is clearly essential. Safety procedures are of the highest importance in any laboratory. IVF laboratories must also guard against any risk of cross-contamination between samples. To achieve all this, a high level of attention to detail is required. In one laboratory (Wikland and Sjöblom, 2000), quality procedures require, for example, that ‘a record of the batch number of all culture media, disposables and laboratory ware used for a particular patient are kept in the protocol for each treatment’ and ‘incubators are checked every day with regard to temperature, humidity and CO_2.’ The measurement of best practice in the laboratory is another potential criterion for measuring the quality of an IVF centre.

An optimum embryo culture environment is important for the success of an IVF programme involving embryo transfer. Gametes and early embryos are sensitive to small changes in temperature, pH and the physical properties of the culture medium. Attention paid to improving these aspects is likely to be directly reflected in the centre’s IVF success rate.

Clinical aspects

The main clinical quality objective is to ensure that every couple receives the best possible treatment according to their medical needs. This requires that appropriately qualified and competent staff perform all procedures and that the methods used are reproducible. The provision of high quality counselling and information for patients is another important aspect of clinical quality in the IVF centre.

Staff training and development

An IVF centre is only as good as the staff it employs. A good centre will endeavour to attract the highest calibre of staff at all levels and will encourage them to develop their skills through training and, if appropriate, through research and attendance at conferences. Skills and training should be documented and training needs determined by regular appraisals.

Audit

It is not sufficient to just have quality control programmes in place; they must also be audited to check how they are working in practice. A high quality IVF centre will subject its procedures to regular audit, both internal and external.

International standards are desperately needed

The tools and principles used to measure quality within an IVF centre are similar to many other industries. The international standard for quality measurement is the ISO 9001. Although a few IVF centres (in Europe) have applied the ISO 9001 standards (Wikland and Sjöblom, 2000), the practice is rare. But there are distinct benefits: an internationally agreed upon standard has the advantage of eliminating the need for national bodies to set country-specific regulations for quality (Lass and Brinsden, 2001); standards of quality help centres understand their processes, which leads to improvement of their product (Gianaroli *et al*., 2000); comparing standards can allow for better co-operation between centres from around the world in research and other areas (Society for Assisted Reproductive Technology and American Society for Reproductive Medicine, 2000); focusing on total quality measures de-emphasizes pregnancy rates as the outcome measurement (Halman *et al*., 1993).

Conclusions

We propose that serious consideration be given to introducing ISO standards to units providing infertility services worldwide. This international standard will better define the outcomes that are important to our patients and will create a mechanism to improve the care that we provide. The adaptation of an international standard to infertility treatment has the major advantage of being able to unify national guidelines and develop a consensus on what are important quality measurements in our field.

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