Experience with ISO quality control in assisted reproductive technology

Michael M. Alper, M.D.

Boston IVF, Waltham, Massachusetts

Assisted reproductive technology (ART) programs are complex organizations requiring the integration of multiple disciplines. ISO 9001:2008 is a quality management system that is readily adaptable to an ART program. The value that ISO brings to the entire organization includes control of documents, clear delineation of responsibilities of staff members, documentation of the numerous processes and procedures, improvement in tracking and reducing errors, and overall better control of systems. A quality ART program sets quality objectives and monitors their progress. ISO provides a sense of transparency within the organization and clearer understanding of how service is provided to patients. Most importantly, ISO provides the framework to allow for continual improvement. (Fertil Steril® 2013;100:1503–8. ©2013 by American Society for Reproductive Medicine.)

Discuss: You can discuss this article with its authors and with other ASRM members at http://fertstertforum.com/alperm-iso-quality-control-art-ivf/

Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

* Download a free QR code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

The practice of IVF is not a simple process. Unlike a typical doctor's office, an IVF program involves the integration of numerous individuals from various disciplines, such as embryology, ultrasonography, medicine, and nursing. How all these individuals work together in a safe and productive atmosphere is the challenge that faces all IVF centers.

Complex organizations require a system to ensure that the service or product is being delivered in the best way. A quality management system (QMS) is a process within an organization to ensure that the service is provided consistently and with as little variation as possible. ISO refers to a particular QMS developed by the International Organization of Standardization; more on this later.

My particular experience as medical director of an IVF program is not unique. After completing my obstetrics and gynecology and fellowship training, I cofounded an academically affiliated (Harvard Medical School), private IVF center (Boston IVF) in 1986. Our center was relatively small, with one main office, 4 physicians, and a small laboratory and operating room. Despite the start-up challenges, life was relatively simple. We had 1 location, everyone knew each other well, we were all paper-based, and the organization was highly physician-focused. Over time our volume increased, we hired new physicians and scientists, and we expanded to several locations; life was getting more complicated, and our ability to provide consistent service was more difficult. Individuals would not follow protocols—so called "protocol drift" occurred more frequently. Systems were being stretched.

The exciting part of IVF is the technology and reproductive biology. Our specialty attracts individuals who seek new technology and hunger to learn about reproductive biology. However, as medical director I was charged with making sure all the science and medicine fit together to ensure that patients were treated with high-quality, consistent care. As we grew, we became more susceptible to systems breaking down, communication issues, and protocol drift. I found virtually no references to turn to, to help organize our company better. A colleague of mine from Europe suggested a QMS (ISO 9000) to help our company perform optimally. I learned more about it, discussed it extensively with my staff, and we embarked on instituting the QMS in 2005. The purpose of this article is to review ISO and the benefits that can be achieved with its application to IVF.

QUALITY AND PREGNANCY RATES

We all have a sense of what we mean when we say that a product or service is "high quality"; but what do we really mean when we say, for example, that a luxury hotel is a top-quality hotel. We mean that the service is consistently excellent, the rooms are elegant, and the food is superb; in fact, what we are saying is that our high expectations are being met. An important point to

Received August 8, 2013; revised August 22, 2013; accepted August 30, 2013; published online October 7, 2013.
M.M.A. has nothing to disclose.
Reprint requests: Michael M. Alper, M.D., Boston IVF, 130 Second Avenue, Waltham, Massachusetts 02451 (E-mail: malper@bostonivf.com).

Fertility and Sterility® Vol. 100, No. 6, December 2013 0015-0282/$36.00

http://dx.doi.org/10.1016/j.fertnstert.2013.08.055

realize is that quality is not an amorphous subject; quality must be measurable. If it cannot be measured, then it cannot be quality. For a company to say that it meets a high standard, it must be proven with data. The data could be patient satisfaction, low error rates, or any other measure that is deemed to be important to quality. In IVF the most commonly used measure of "quality" is pregnancy rate. For patients to choose an IVF program on the basis of reported pregnancy rates is unfortunate because it can be a misleading measure of "quality" (1). A key determinant of success rates is local economic forces. For example, mandated insurance coverage encourages more cycles per patient (and pregnancy rates decrease with increasing number of attempts [2]), as well as patients willing to undergo IVF when expected pregnancy rates are lower than average because there is no financial barrier.

To illustrate the misuse of clinic-specific pregnancy rates, consider the following: a patient reviews the publically available IVF statistics online and notes that one program (called "Perfect IVF") reports a live birth rate of 65% for younger women, whereas another program closer to home reports a 42% live birth rate in the same population. The patient's intuition is that it would definitely be worth the longer drive to go to the program with a higher pregnancy rate. Right? Unfortunately for the patient, this could be an unwise decision. The program with the higher pregnancy rate could actually be treating patients inappropriately. Improper practice patterns that could lead to higher pregnancy rates at the expense of good patient care include no clomiphene or intrauterine insemination treatments before IVF; patients encouraged to do IVF prematurely; no IVF offered if testing of ovarian reserve is in any way abnormal; high cycle cancellation rates; replacing high numbers of embryos; starting IVF as ovarian stimulation for IUI and converting to IVF only if a good response follows; and avoiding treatment of poor responders or patients with lower than average expectations.

Other factors are also important for patients in choosing an IVF program (3), as expressed in these patient questions: Can I communicate with my doctor and nurse? Do they use the latest technologies? Do many errors occur at the IVF center? The purpose of a QMS is to identify what quality really means for an IVF center and how to monitor it and improve.

ADVANTAGES OF A QMS IN IVF

There are many advantages to implementing a QMS such as ISO into an IVF practice. The most compelling reason is that it helps refocus the entire staff on the primary customer—the patient. Everyone in the organization understands that the patient is our main customer and that if a company is to be successful then the needs of the customer must be understood, fulfilled, and ultimately exceeded. This applies as much to the nurses and physicians as it does to the receptionist and billing department.

Another valuable feature is that developing the system allows one to take inventory of how processes are actually occurring within the organization. For example, part of the QMS exercise is to understand workflow. When understanding how the patient interfaces with the staff, one quickly learns what is working and, at the same time, what are the weaknesses. It ultimately results in improved efficiency. A QMS also allows the organization to become more organized. For example, document control is an essential part of a QMS. It is critical for a nurse to know that the proper consent or other form is being used. With a QMS such as ISO, all documents are electronically categorized and stored for easy access. There are a lot of procedures that occur outside the laboratory (the laboratory is typically the most organized aspect of the IVF center). For example, the medication protocol for a frozen embryo transfer should not just be in the physician's mind. It must be clearly written and stored where any nurse or other physician can access it. If the protocol changes then the revisions must be clearly tracked.

An important goal of any business is to have systems in place to ensure that the product or service is provided in a reproducible way. The receptionist in one office should greet patients in a similar way to those in other offices. Laboratory procedures should not vary much depending on the technician. Consistency is critical, and a QMS system puts in writing how many of the processes, instructions, and procedures should be done and serves as a reference for all.

There are many other generic benefits from ISO. ISO clearly describes the responsibilities for all members of the team, enhances communication, improves efficiency, and controls and reduces errors. It is also important to point out that implementing a QMS is equally important for both private and public IVF units because the issues are similar for both. Furthermore, it should be pointed out that, although ISO is the most widely used QMS, other certifications are available (such as the American College of Obstetrics and Gynecology Scope Program).

WHAT IS ISO?

ISO is derived from the Greek word "isos," meaning standard or equal. The official ISO organization is the International Organization of Standardization, which was established in 1947 and has offices in virtually every country worldwide. The purpose of the organization is to develop worldwide standards across many industries and products in many disciplines, including, among many, engineering, banking, information technology, agriculture, medical devices, and manufacturing. Currently ISO has developed more than 14,000 standards (which includes 1,200 standards in the area of healthcare).

Although many standards have been published by ISO, the most widely known standard is ISO 9000. The most recent version is ISO 9001:2008. The value of this standard is that it is generic and can be applied to any company that produces a product or service. The ISO 9001 standard has been used in healthcare for some time, and several hospitals in the United States have adopted it. European IVF programs were early adopters of ISO, often related to government regulations requiring a QMS. Many IVF centers worldwide are now ISO-certified, but very few exist in North America.

THE PROCESS OF ISO CERTIFICATION?

ISO certification of an IVF program is a process, and I have outlined our experience in Table 1. I believe the first step is

TABLE 1

Steps toward ISO certification.

1. Learn about the ISO standard
2. Engage management team to learn about ISO
3. Hire an ISO consultant with healthcare experience
4. Document a QMS
5. Implement a QMS
6. Be surveyed by an accredited Registrar
7. Be issued a certificate of conformity
8. Be listed in the register of certified companies

Alper. ISO quality control in ART. Fertil Steril 2013.

for someone in the company (myself in our case) to research and develop a passion for the benefits of ISO. I had a colleague from Germany who had completed the process at his IVF center present his experience to our physicians and scientists. Management quickly became engaged in an exciting process. ISO must never be imposed on a company: it is something that the staff should welcome because it empowers them to contribute to how the service is being provided in the company. The staff is intimately involved in creating the workflow and procedures, and their engagement is paramount to success. Another key element to success is to work with an experienced ISO consultant who has some knowledge of implementing ISO in the healthcare industry. The consultants will work closely with the staff to fulfill the requirements of ISO. The cost for the consultant varies considerably according to the size of the company, number of locations, and the current structure and processes in place. Our consultant spent a lot of time performing a detailed gap analysis to provide an estimate for the project.

After the implementation of the ISO system, a registrar conducts a review of the system to be sure it complies. If so, the company is issued a certificate of conformity. Afterward, annual inspections occur to maintain ISO certification.

A manual for the generic ISO 9001:2008 requirements is available online (www.iso.org). Publications to apply these requirements specifically to an IVF are not many (4). The ISO consultant will help "translate" the generic ISO 9001:2008 requirements to your organization. I have outlined some of the ISO requirements in Table 2 and will describe how they are used to implement them in IVF. This is neither a systematic nor comprehensive review of the specific ISO requirements (ISO chapters 1–8) but is meant to highlight the essential features that are required.

In simple terms, ISO asks the company to "Say what you do, and do what you say."

TABLE 2

Interpretation of ISO 9001 requirements for IVF.

1. Control of documents and records
2. Managing customer requirement
3. Document your quality and objectives
4. Control of Nonconformity; Corrective and preventive action
5. Resource Management
6. Monitoring and measurement

Alper. ISO quality control in ART. Fertil Steril 2013.

DOCUMENT CONTROL

Before instituting ISO, I requested that every document within the organization that has our Boston IVF name on it be sent to me. The findings were shocking. We had more than 3,000 documents that were "out of control," such as outdated consents, flow sheets that had been revised years before, and forms that no one knew existed. Our documents were a mess. ISO provides the organization with a method to manage all documents. The idea is to set up a system that determines how any document gets approved to be an official document, how documents are managed and reviewed, who is assigned to manage that document, how one keeps tracks of revisions, and where the document will be located for easy access. An example of a controlled document is found in Figure 1. Every document used by the company needs to have an ID number, an initial date, and a revision date if any.

An important part of any QMS is to develop a master document that has all the documentation of *QMS: The Quality Manual* (Fig. 2). This document is the source for all the systems that have been put in place for implementing the QMS.

MANAGING CUSTOMER REQUIREMENTS

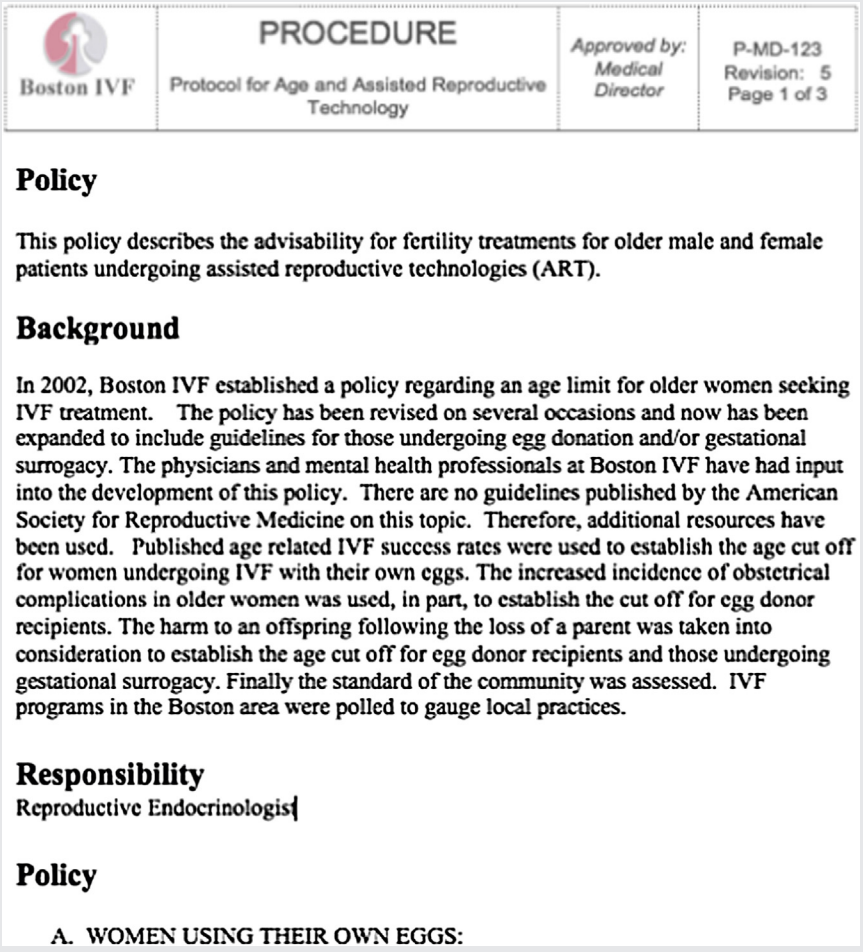
A key benefit of ISO is that it helps define who exactly our customers are. Obviously the main customer is our patient, but others include referring doctors, suppliers, and even our employees (internal customers) all of whom must be managed correctly. For an IVF center to be successful it must clearly understand the needs of its patients. No company will survive with customers who are not happy with the service they receive. Often our patients choose our IVF center for reasons other than what we imagine. For example, easy parking may be more important to them than the last couple of excellent research papers that you published. Boston IVF spent a lot of resources understanding where within our organization our patients were satisfied and where improvement was needed. On a yearly bases, we have a lengthy, detailed survey of all departments and aspects of the company, and superimposed on this we perform quarterly shorter surveys. The data are tracked to institute changes to continually improve our patient satisfaction.

QUALITY POLICY AND QUALITY OBJECTIVES

ISO requires a quality policy that transcends the organization and provides a simple description of the core of the company. We chose the term "C.A.R.E.," representing Compassionate, Advanced, Responsive, Experienced—attributes that we feel represent our core values and principles. Everyone in the organization should know this simple policy.

Another key element of ISO is that every department must have quality objectives. An example that we decided for the clinicians is doctor-specific pregnancy rates related to ET. Every physician performing ETs has their pregnancy rate monitored as a rolling average. Physicians know their rank relative to the others, and statistics are reviewed quarterly. The physician with the consistently highest success rate is, at times, asked to present their technique down to the smallest of details so that others can learn and possibly modify their

FIGURE 1



Boston IVF

PROCEDURE

Protocol for Age and Assisted Reproductive Technology

Approved by: Medical Director

P-MD-123
Revision: 5
Page 1 of 3

Policy

This policy describes the advisability for fertility treatments for older male and female patients undergoing assisted reproductive technologies (ART).

Background

In 2002, Boston IVF established a policy regarding an age limit for older women seeking IVF treatment. The policy has been revised on several occasions and now has been expanded to include guidelines for those undergoing egg donation and/or gestational surrogacy. The physicians and mental health professionals at Boston IVF have had input into the development of this policy. There are no guidelines published by the American Society for Reproductive Medicine on this topic. Therefore, additional resources have been used. Published age related IVF success rates were used to establish the age cut off for women undergoing IVF with their own eggs. The increased incidence of obstetrical complications in older women was used, in part, to establish the cut off for egg donor recipients. The harm to an offspring following the loss of a parent was taken into consideration to establish the age cut off for egg donor recipients and those undergoing gestational surrogacy. Finally the standard of the community was assessed. IVF programs in the Boston area were polled to gauge local practices.

Responsibility

Reproductive Endocrinologist

Policy

A. WOMEN USING THEIR OWN EGGS:

An example of an ISO-documented procedure.

Alper. ISO quality control in ART. Fertil Steril 2013.

approach. As a result of transparency and monitoring, the variation in pregnancy rates among our doctors performing ETs is currently very tight.

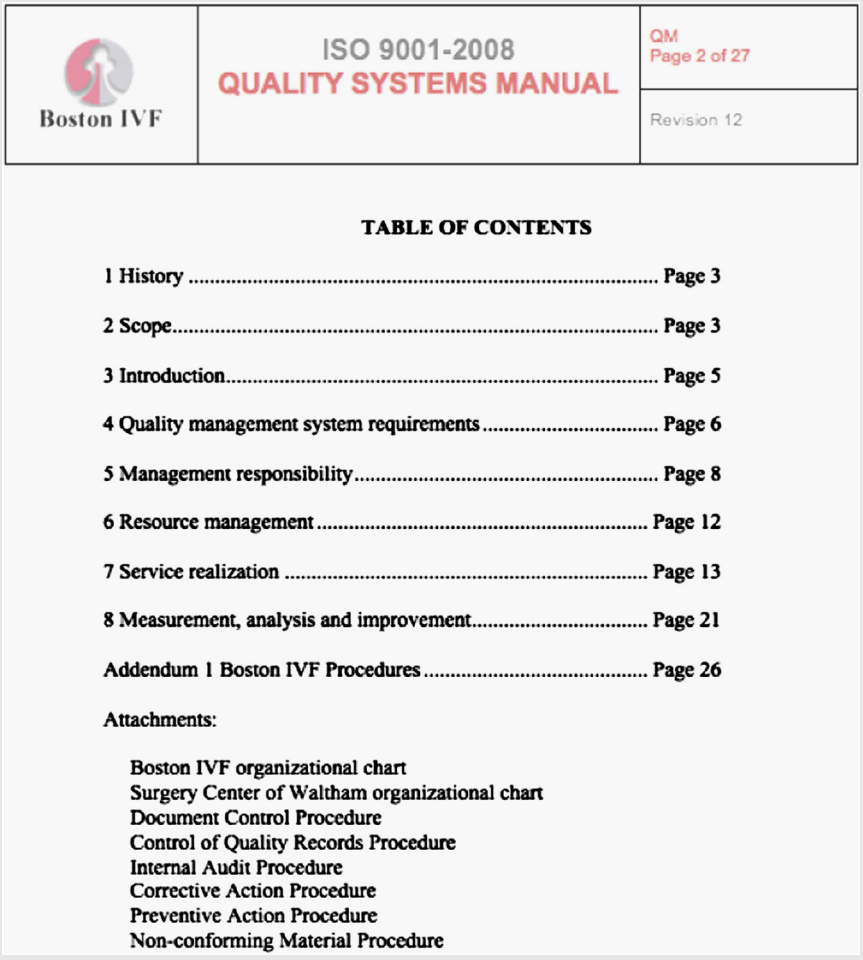
CONTROL OF NONCONFORMITY

We aim to provide services to patients in a particular way. Sometimes we err, or problems develop that prevent us from providing our service properly. ISO calls such an occurrence a "nonconformity." Errors in medicine are common and account for an enormous amount of morbidity and mortality. Similarly, errors in all aspects of IVF (clinically, administratively, and in the laboratory) occur, and it is important to track them. We have developed a nonconformance database in which staff is encouraged to enter all errors and problems so we can develop some metrics of problems. We found that the rates of significant errors in our IVF program were low (for example, only 0.006% per laboratory procedure) compared with other areas of laboratory medicine (D. Sakkas and B. Barrett, personal communication).

To err is human. As a service industry, IVF is prone to errors. In our experience, severe errors are rare in IVF, but errors resulting in a suboptimal outcome do occur with some regularity; examples include inadvertently not checking off instructions to perform intracytoplasmic sperm injection when it was indicated, missing an elevated P level on the day of hCG administration, and attempting blastocyst culture when cleavage-stage transfer was requested. A process must be in place to deal with errors. When a nonconformance occurs, the cause should be determined and steps taken to reduce the likelihood of recurrence, as well as a plan to monitor that these steps are actually working. This "corrective plan" must be initiated for all nonconformances. This not only closes the loop so everyone knows that the problem was solved but also serves as a database for the future.

Another important aspect of ISO is a "preventative action" plan. Employees, being on the front lines, often know what needs to be done to improve operations. Because they often have answers, it is important to have a system in

FIGURE 2



Boston IVF

ISO 9001-2008
QUALITY SYSTEMS MANUAL

QM
Page 2 of 27

Revision 12

TABLE OF CONTENTS

Attachments:

Boston IVF organizational chart
Surgery Center of Waltham organizational chart
Document Control Procedure
Control of Quality Records Procedure
Internal Audit Procedure
Corrective Action Procedure
Preventive Action Procedure
Non-conforming Material Procedure

Every ISO-certified company must have a quality manual describing how it manages and conforms to the ISO 9001:2008 system.

Alper. ISO quality control in ART. Fertil Steril 2013.

place so that new ideas can be used to prevent a potential non-conformance in the future. At Boston IVF we have a database where any employee can enter a preventative action to reduce potential issues or problems in the future.

RESOURCE MANAGEMENT AND MANAGEMENT RESPONSIBILITY

Part of the ISO process allows a company to reflect upon how it allocates its human resources. Every employee within the company must have a job description and a description of competences needed to perform their duties, and employees need to understand their individual roles and its importance within the organization.

Initial training for the job as well as recurrent training (if any) needs to be clearly outlined. A clear understanding of the reporting structure and organizational chart of the company also must be clear. The working environment and infrastructure needs for employees throughout the company are paramount.

A QMS is fluid and requires surveillance and attention. The company must designate a quality manager to oversee the QMS and act as a resource for staff. The manager can be from any discipline. Our first quality manager was our laboratory director, and now our system is managed by an experienced nurse.

MONITORING AND MEASUREMENT

A particularly important part of ISO is monitoring that the system is working. As mentioned, annual inspection by an external auditor is required to maintain ISO certification. Equally important is the requirement of internal auditors. Internal auditors are company employees who receive instruction on how to audit departments within the company. For example, a person who works in billing will visit the laboratory and review their procedures to be sure they are conforming to their documentation. The auditor does not need to be familiar with the science but needs to be able to ask the rights questions to confirm conformity. Simply put, ISO

is not simply a mechanism to document how you do things. It is equally important to demonstrate that you are actually doing what you have documented. Audits are an important method to verify this.

SUMMARY

Our IVF center has benefited greatly from implementing a company-wide ISO QMS. As any company grows, it is critical that the basic operation of the company is clearly documented. A quality management system sets the tone for the company and helps to focus on the customer(s) results, which ultimately results in improving the delivery of our service. ISO removes confusion about how tasks are supposed to be done because documents and workflow, as well as roles and responsibilities, are clearly delineated. Most importantly, ISO provides tools to monitor what we do, which ultimately leads to improvement in all our efforts to achieve the goals of the company. ISO also encourages data-driven decisions as opposed to emotional ones. For any program to be of high quality it must have (internal) metrics to prove it; but quality cannot be determined by a single number—and this includes pregnancy rates.

REFERENCES

1. Alper MM. In vitro fertilization outcomes: why doesn't anyone get it? Fertil Steril 2004;81:514–6.
2. Malizia BA, Dodge LE, Penzias AS, Hacker MR. The cumulative probability of live born multiples after in vitro fertilization: a cohort study of more than 10,000 women. Fertil Steril 2013;99:393–9.
3. Alper MM, Brinsden PR, Fischer R, Wikland M. Is your IVF programme good? Hum Reprod 2002;17:8–10.
4. Carson BE, Alper MM, Keck C. Quality management systems for assisted reproductive technology. London: Taylor and Frances; 2004.