

# Establishing a quality management system in a fertility center: experience with ISO 9001

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In Fertility Centers, quality should be measured by how well the organization complies with pre-defined requirements, and by how quality policies are implemented and quality objectives achieved. Having a quality management system (QMS) is a mandatory requirement for IVF centers established in most countries with regulatory guidelines, including Brazil. Nevertheless, none of the regulatory directives specify what a QMS must have in detail or how it should be implemented and/or maintained. ISO 9001 is the most important and widespread international requirement for quality management. ISO 9001 standards are generic and applicable to all organizations in any economic sector, including IVF centers. In this review, we discuss how we implemented QMS according to ISO 9001 and what we achieved 5 years later. In brief, with ISO we defined our structure, policies, procedures, processes and resources needed to implement quality management. In addition, we determined the quality orientation of our center and the quality objectives and indicators used to guarantee that a high-quality service is provided. Once measuring progress became part of our daily routine, quantifying and evaluating the organization's success and how much improvement has been achieved was an inevitable result of our well-established QMS. Several lessons were learned throughout our quality journey, but foremost among them was the creation of an internal environment with unity of purpose and direction; this has in fact been the key to achieving the organization's goals.

**KEYWORDS:** Quality Management System, ISO 9001, Fertility Center.

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## ■ WHAT IS QUALITY?

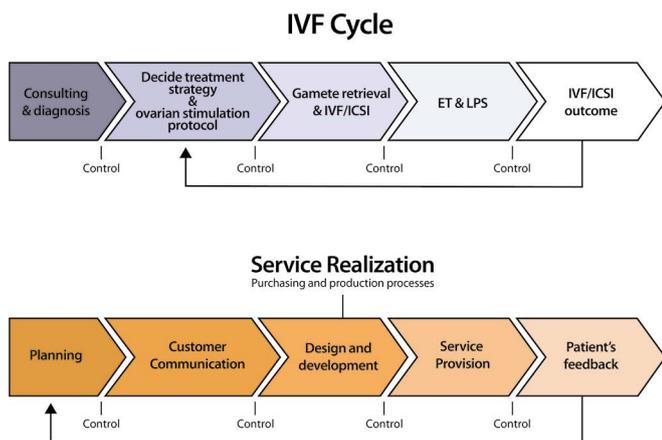
Quality can be roughly defined as a “characteristic”, “nature” or “essential character”. It is therefore something that distinguishes an object, but that may be variable in terms of customer perception because it is almost invariably based on individual expectations. Despite being a relative concept, quality cannot be established in a vacuum. It has to be measurable in terms of standards and indicators. If it cannot be measured, then it cannot be quality.

For a fertility center to say that it meets high quality standards, it must prove it. In IVF the most commonly used measure of “quality” is pregnancy rate. However, measuring the quality of an IVF program on the basis of reported pregnancy rates is unfortunate because it can

be misleading. Pregnancy rates of 30% are not necessarily worse than 50%. It depends on several factors, including (a) how long the center is established (older centers tend to receive the more difficult cases); (b) the number of IVF cycles and babies born; (c) the credentials of specialists dealing with difficult cases and complications; (d) patient selection bias (e.g. exclusion of poor prognosis cases); (e) availability of an individualized approach that includes all treatment options other than IVF only; (f) availability of all treatment options for severe male and female infertility cases rather than relying extensively on gamete donation; (g) the number of replaced embryos and multiple birth rate; (h) how often embryo freezing is used to increase the cumulative pregnancy rates per treated couple; (i) error rates and number of patient complaints, to name only the most important. Altogether, all of the aforesaid means that improper practice patterns can lead to higher pregnancy rates at the expense of good patient care.

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Given that the “process” is one of the most objective and measurable aspect of quality, it necessarily follows that quality control can be applied to a fertility center because the activities we perform within our centers are essentially process-based, as illustrated in Figure 1. A “process” is any activity or set of activities that uses resources to transform raw materials, supplies and labor (inputs) into products or services (outputs).<sup>1</sup>



**Figure 1** - Flowchart of mapping procedure applied to the in vitro fertilization (IVF) treatment cycle (ICSI: intracytoplasmic sperm injection; ET: embryo transfer; LPS: luteal phase support).

In fertility centers, quality should be measured by how well the output of our processes complies with a set of pre-defined requirements, and by how quality policies are implemented and quality objectives achieved. In essence, all these concepts form the pillars that define what a quality management system (QMS) stands for.

### ■ WHAT ARE THE MOST IMPORTANT QUALITY INDICATORS IN INFERTILITY CARE?

Quality indicators are measurable elements in health care for which there is evidence or consensus that they assess quality of care. A valid indicator should be reproducible and consistent. The measurement and the monitoring of indicators makes it possible to document the quality of care; it enables comparisons (benchmarking) over time and between places (e.g. fertility centers); it allows judgments and the setting of priorities (e.g. choosing a fertility center or organizing fertility care); it supports accountability, regulation, and accreditation; it also supports quality improvement, and supports patient choice of providers.<sup>2</sup> However, because quality is multidimensional, indicators are only part of the various measurements.

The vast majority of quality indicators in infertility care address effectiveness and safety.<sup>3</sup> However, indicator sets should fully represent health-care quality, and

therefore, cover the six dimensions of quality care, including effectiveness, safety, efficiency, timeliness, equity and patient centeredness.<sup>4</sup> Studies on the development and selection indicators for fertility care that involve physicians, other healthcare professionals (embryologists, and nurses, for instance), and patients who receive this care are scarce. Of note, two recent studies of this kind have shed light on to the relative importance of these quality indicators to the field of Assisted Reproductive Technology (ART). Dancet et al<sup>5</sup> were the first to show that all quality dimensions of infertility care could be assessed with quality indicators. These authors conducted a three-round iterative Delphi survey involving two European countries including patients and health care professionals (gynecologists, embryologists, counselors, nurses/midwives). Participants ranked the six aforesaid quality dimensions and agreed on the measurable indicators that represented each quality dimensions. It was concluded by consensus, with a high coefficient of concordance among participants, that safety, effectiveness and patient centeredness were the most important quality dimensions, and twenty-four indicators (four per dimension) were selected to represent quality in infertility care. Dancet et al.<sup>5</sup> proposed that those three most important dimensions and the quality indicator set, as shown in Table 1, could be used by ART centers to objectively assess quality. Interestingly, the group of gynecologists, embryologists and nurses rated safety and efficiency as top priority dimensions, while patients gave more weight to patient-centeredness. Subsequently, Cai et al.<sup>6</sup> confirmed, in a multi-center survey study involving 389 patients and 83 care providers from China, that while patients valued the patient-centeredness aspects the most, fertility care providers considered effectiveness (pregnancy rates) as the most important quality dimension in infertility care.

Both studies highlight the importance of the patients’ perspective in assessing the quality of fertility centers. Fertility care providers should not underestimate such aspects, because they ultimately influence not only the patients’ choices when searching for a fertility center, but also their adherence to the provided treatment. In a recent systematic review assessing the reasons why patients discontinue fertility treatment, which compiled twenty-two studies and more than twenty thousand patients from eight countries, the authors concluded that the top reasons for discontinuation were: (i) psychological/physical burden; (ii) treatment rejection; (iii) organizational problems, and (iv) poor quality of care delivered by the fertility center. What patients meant was that the treatment was associated with too much stress (in psychological terms) and was too aggressive/painful (physically); there was also fear of an abnormal child as well as short and long-term complications (rejection); the therapeutic program was difficult to integrate with their work (organizational); and

**Table 1** - Quality dimensions and quality indicator set in infertility care as per consensus between health care professionals and patients. Safety, effectiveness and patient-centeredness considered the most important dimensions in an iterative Delphi survey. Adapted from Dancet et al., Hum Reprod. 2013; 28(6):1584-97, with permission from Oxford University Press

Quality dimension	Quality indicator	Type of indicator*
Safety	Number of fresh ART cycles with severe complications (OHSS, bleeding, infection, complaints of serious pain) resulting from the fertility treatment, which require hospitalization relative to the total number of ART cycles during a certain time period	Outcome indicator
	The number of fresh ART cycles with complications (OHSS, hemorrhage, infection) as a result of MAR relative to the total number of fresh ART cycles during a certain time period	Outcome indicator
	The number of MAR cycles in which gametes or embryos get lost as a result of an accident, human error or mistake relative to the total number of MAR cycles during a certain time period	Process indicator
	The number of reported mistakes or incidents caused by all care providers relative to the number of treatment cycles during a certain time period	Process indicator
Effectiveness	The number of treated patients who go home with a live born baby relative to the total number of treated patients during a certain time period	Outcome indicator
	The number of patients who after a maximum of three fresh ART cycles (oocyte aspiration actually performed) had a live birth (the expulsion or extraction of minimally one fetus showing evidence of life) relative to the total number of patients starting an ART cycle during a certain time period	Outcome indicator
	The number of live births (the complete expulsion or extraction of a product of fertilization that shows evidence of life) after a fresh ART cycle with embryo transfer relative to the total number of fresh ART cycles with embryo transfer during a certain time period	Outcome indicator
	The number of pregnancies in women younger than 36 years old as a result of a fresh ART cycle relative to the total amount of fresh ART cycles in women younger than 36 years old during a certain time period	Outcome indicator
Patient-centeredness	The number of patients of a fertility clinic to whom psychosocial counselling was offered relative to the total number of patients of that fertility clinic during a certain time period	Process indicator
	The regular organization of a multidisciplinary meeting of the fertility clinic in which the psychosocial context of the patient can be discussed if necessary during a certain time period	Structural indicator
	The provision of the offer to patients of psychosocial counselling at a certain moment in time	Structural indicator
	The number of patients who opinionated that their personal experiences and wishes were actually heard relative to the total number of interrogated patients during a certain time period	Process indicator
Efficiency	The number of patients undergoing a very thorough diagnostic phase and reaching a diagnosis prior to starting MAR relative to the total number of patients starting MAR during a certain time period	Process indicator
	The existence of a website of the fertility clinic containing all the basic information, contracts and information about studies and FAQs at a certain moment in time	Structural indicator
	The provision of the use of an electronic patient record containing all relevant clinical information and allowing the extraction of letters and reports at a certain moment in time	Structural indicator
	The total number of FTE care providers relative to the total number of treated patients per type of care provider during a certain time period	Structural indicator
Timeliness	The average duration of the waiting time per new patient between the asking and the getting of the first appointment during a certain time period	Process indicator
	The average duration of the waiting time during MAR per patient between having the need for and attending an urgent consultation in case of unexpected negative results (e.g. fertilization failure) during a certain time period	Process indicator
	The average duration of the waiting time per patient between the first appointment and the start of the first treatment cycle during a certain time period	Process indicator
	The average duration of the waiting time in the waiting room per patient between the agreed time to start a consultation and actual starting time of the consultation during a certain time period	Process indicator
Equity	The number of patients who opinionated that she/he is being respected by her/his physician relative to the total number of interrogated patients during a certain time period	Process indicator
	The provision of clearly described in- and exclusion criteria for MAR in the fertility clinic (among others taking into account the national legislation) at a certain moment in time	Structural indicator
	The provision of a clearly explained vision of the fertility clinic concerning ethical limitations (e.g. no surrogacy) of which at no time nor for no reason (e.g. power, money) can be deviated at a certain moment in time	Structural indicator
	The provision of protocols that are in accordance with international guidelines/ recommendations of care concerning equity and taking account of the universal needs at a certain moment in time	Structural indicator

ART: assisted reproductive technology; OHSS: ovarian hyperstimulation syndrome; MAR: medically assisted reproduction; FTE: full-time equivalent; FAQ: frequently-asked questions; \*Outcome indicators describe the effects of care; process indicators denote what is actually done in giving and receiving care (i.e. assess what the provider does for the patients); structural indicators denote the attributes of the settings in which care is provided (i.e., material resources such as facilities, equipment and financing, human resources including the number and qualification of personnel, and organization structure, which includes methods of peer review, payment, etc.) (Mainz, 2003a).<sup>2</sup>

the fertility center was unable to provide sufficient and well-formulated explanations about the infertility treatment, in addition to poor management of the psychological aspect.<sup>7</sup> Discontinuation is a key determinant for the effectiveness of IVF treatment because it attenuates optimum clinical benefits.

### ■ HOW FERTILITY CENTERS CAN ADDRESS THE QUALITY DIMENSIONS OF INFERTILITY CARE?

To properly address all quality dimensions of infertility care, and to objectively measure quality with evidence-based/consensus indicators, fertility centers need to rethink the way they offer their services, and this is where a Quality Management System (QMS) can help. A QMS, such as ISO 9001, is easily adaptable to fertility centers, and is a valuable tool to set quality objectives, organize the workflow, define processes and procedures, define responsibilities, reduce errors, guarantee safety and monitor performance, among others.

One of the most compelling reasons to implement QMS is to make the entire staff focus on the primary customer, namely the patient. A patient-centered approach is a key element of QMS, and therefore this critical quality dimension of infertility care will be fully contemplated. If a center is to be successful or even to survive within the confines of the competition, then the needs of the customers must be understood, fulfilled, and ultimately exceeded; this applies as much to the nurses, physicians and embryologists as it does to receptionists and the billing/administrative personnel. For example, establishing and analyzing internal values can help the staff understand their part in the whole system so that they can reflect and determine what they have to do to accomplish goals as a group, as illustrated in Figure 2.

Another critical aspect is that developing the system allows us to define the center’s structure, policies, procedures, processes and resources needed to deliver the services with high quality standards. For example, part of the QMS exercise is to understand how processes are actually being performed within the organization and the responsibility of each individual in the realization of each service. It ultimately results in opportunities to improve critical quality dimensions, including effectiveness and safety. A SWOT analysis (S = Strengths; W = Weaknesses; O = Opportunities; T = Threats) can be very helpful, and can determine where to start (Figure 3).

Using flowcharts to visualize entire processes can also help staff to see all personnel involved and all procedures performed to complete a whole process. This visualization can also help those in charge of the organization to see what is already standardized and what is not, showing where there is space for improvements (Figure 4).

In summary, a QMS comprises a series of coordinated activities to direct and control an organization to continuously

#### Example of Moral Value

##### RESPECT PEOPLE

WHO	HOW
Secretary / Receptionist	<ul style="list-style-type: none"> <li>• Being cordial</li> <li>• Understanding patients' needs</li> <li>• Not letting patients wait</li> <li>• Being helpful</li> <li>• Informing patients of delays or any other problems</li> <li>• Trying to schedule appointments at the best time for patients</li> </ul>
Nurse	<ul style="list-style-type: none"> <li>• Being cordial</li> <li>• Treating patients according to their individual needs</li> <li>• Being helpful</li> <li>• Explaining procedures so as to calm patients</li> <li>• Understanding patients' worries and nervousness</li> <li>• Following correct technical procedures at all times</li> </ul>
Laboratory Technician	<ul style="list-style-type: none"> <li>• Being cordial</li> <li>• Doing everything possible to help patients accomplish their parenthood dream, for example, exhaustively search semen samples, working extra hours when necessary to finish procedures, etc</li> <li>• Giving clear explanations</li> <li>• Being honest and transparent</li> <li>• Following the described laboratory procedures</li> <li>• Communicating problems and deviations immediately</li> </ul>
Physician	<ul style="list-style-type: none"> <li>• Being cordial</li> <li>• Making an exhausting investigation</li> <li>• Explaining diagnosis and treatment clearly</li> <li>• Giving patients a choice based on well-explained treatment options and outcomes</li> <li>• Following correct technical procedures at all times</li> <li>• Admitting limitations</li> </ul>

Figure 2 - Practical example of interval values.

#### SWOT Analysis Summary

<b>Internal Factors</b> <ul style="list-style-type: none"> <li>• Appropriate infrastructure</li> <li>• Investment in equipment</li> <li>• Consistent results</li> <li>• Multidisciplinary team</li> <li>• Organization</li> <li>• Personalized care</li> </ul>	<ul style="list-style-type: none"> <li>• Bureaucracy</li> <li>• Constant delays</li> <li>• Internal competition</li> <li>• Lack of internal communication</li> <li>• Bad telephone system</li> </ul>
<b>External Factors</b> <ul style="list-style-type: none"> <li>• Demand for oocyte cryopreservation</li> <li>• Improve site on the internet offering patient-friendly tools</li> <li>• Marketing opportunities</li> </ul>	<ul style="list-style-type: none"> <li>• Costs of medication</li> <li>• Emphasis on a single type of treatment</li> <li>• Seasonality</li> <li>• A new clinic was open</li> <li>• Legal law suits</li> </ul>

Figure 3 - Practical example of a SWOT analysis summary.

improve the effectiveness and efficiency of its performance. A QMS enables the organization to achieve the goals and objectives set out in its policy and strategic plan. It provides consistency and satisfaction in terms of methods, materials and equipment, etc., and interacts with all activities of the organization, starting with the identification of customer requirements and ending with their satisfaction, at every transaction interface (Figure 5).

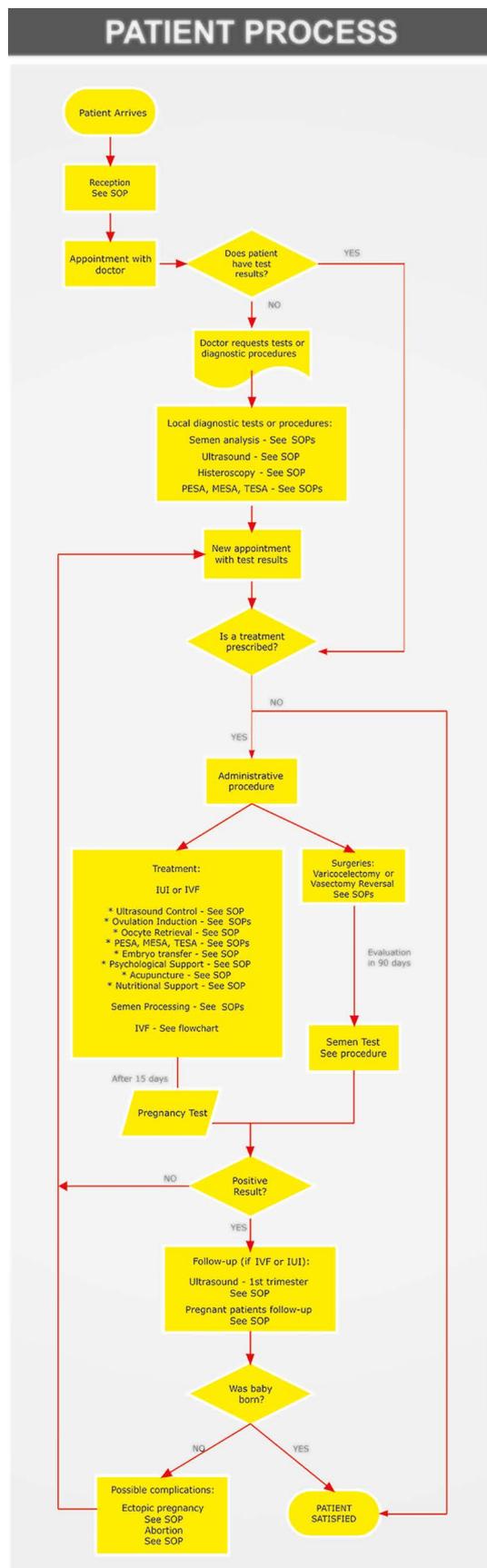


Figure 4 - Practical example of a flowchart depicting the patient process in the fertility center.

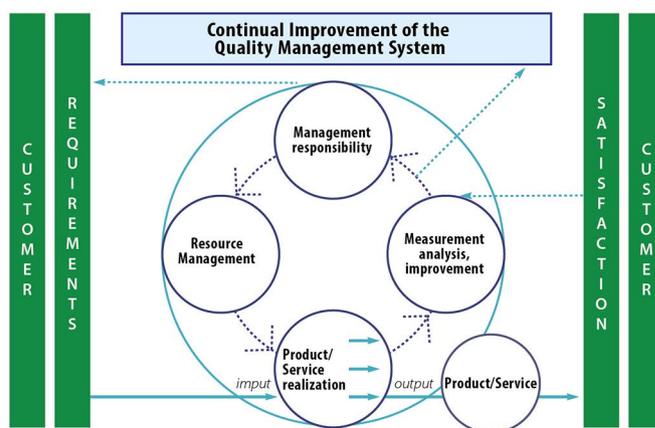


Figure 5 - Conceptual model of QMS as per ISO 9001.

### HOW TO IMPLEMENT A QUALITY MANAGEMENT SYSTEM IN AN ART CENTER?

There is more than one QMS model available to healthcare, but ISO 9001 is considered the most important and widespread international requirement for quality management. Setting a QMS according to the ISO 9001 standards is compelling as it is generic and applicable to all organizations in any economic sector, including fertility centers. At present, many fertility centers worldwide have already implemented QMS as per ISO 9001 specifications. Although not mandatory some of them are now ISO-certified, often as a consequence of government regulations, which require quality management systems.<sup>8-13</sup> But how can we translate generic QMS as per ISO 9001 requirements to our fertility centers? Our experience with ISO quality control dates back to 2006 when we started implementing QMS. The implementation was done in-house without hiring any external consultancy. Our manager studied ISO 9001, trained and acquired skills on the subject, then passed on this knowledge to the team, making changes and gradual adjustments, and thereby slowly introducing concepts and processes. We followed a simple program with some main objectives, as depicted in Figure 6; we believe this may guide others interested in implementing ISO quality control.<sup>13</sup> Other relevant information appertaining to this discussion is reported elsewhere.<sup>14,15</sup>

#### Creating a mission statement

The mission statement defines who the fertility center's clients are, what the center does and the services it provides, and how the center achieves what it professes to do, i.e., the methods used, philosophy, objectives, etc. Basically, the mission determines needs and expectations of customers and others (legislation, professional societies, etc.). As an example, our center's mission is as follows: *"To help couples with conception difficulties become parents, especially when the difficulty is partially or totally related to men, through counseling, diagnosis and treatment, and to offer our associates facilities of excellence, including proper infra-structure and technologic resources for them to perform assisted reproductive techniques"*.



Figure 6 - Flowchart depicting a model for QMS implementation as used in Androfert.

### Defining the quality management focus

One of the main pillars of a QMS as per ISO 9001 is the quality management focus. It will determine the quality orientation of the organization, and what quality objectives and indicators will be used to guarantee that a high-quality service is provided. Hence, it is of utmost importance to define not only the quality policies and quality objectives, but also the indicators to measure them, thus ensuring that the pre-determined goals are being achieved and excelled.

A quality policy should include brief, simple and direct statements that define top management’s commitment to quality, i.e., the general quality orientation and basic intentions. At Androfert, our quality policy includes: (i) a guarantee that our clients are satisfied; (ii) a guarantee of the professional development of our staff; and (iii) a continuous improvement of the quality of our service. Everyone in the organization must be aware of this simple policy.

Quality objectives are measurable elements that represent the goals of each quality policy. Also, quality indicators define how quality objectives are monitored, i.e., the tools used to check if the objectives, and therefore the policies that are being achieved, as shown in Figure 7. For example, one of our quality objectives concerning the In Vitro Fertilization laboratory states that we must improve laboratory performance. Consequently, each embryologist is assessed for individual-specific fertilization rates, in terms of embryo development and pregnancy related to embryo transfer. Every embryologist has his/her rates monitored. Another example is that we monitor pregnancy rates per physician performing embryo transfers. Also, we have defined a list of quality indicators for the IVF laboratory with acceptable limits. Statistics of the aforesaid examples are reviewed periodically. Staff with consistently low rates are asked to refresh; staff with high rates may possibly serve as models.

### Determining processes and procedures, and controlling documents and records

A process is any activity or set of activities that uses resources to transform raw material, supplies and labor into products or services; a procedure represents a sequence of steps to execute a task. Both are key elements of QMS. It is therefore important not only to identify all

QUALITY POLICY AND QUALITY OBJECTIVES					
POLICY	OBJECTIVE	Indicator	Periodicity	Responsibility	Goal
Guarantee clients' Satisfaction	Satisfy clients	Satisfaction questionnaire	Every three months	Manager Assistant	80% of satisfaction
	Satisfy clients	Satisfaction surveys	Every two months	Nurse	Recover 50% of patients
Improve service quality continuously	Improve laboratory performance	Laboratory report	Every two months	IVF Embryologists	See IVF quality program
	Invest in structure and equipment	Investments' plan	Annually	General Manager	See annual report
	Improve QMS	Internal audit report	Annually	Quality Manager	Decrease number of non-conformities
	Improve QMS	Non-Conformities and Preventive Actions	Annually	Quality Manager	Decrease non-conformities and increase preventive actions
Guarantee staff professional development	Improve general performance	Management report	Every month	Quality Manager	Improve results
	Offer periodic training	Training Program and Investment Plan	Annually	Quality Manager	See plans

Figure 7 - Practical example of quality policies and quality objectives at Androfert.

processes and procedures involved in the realization of the services provided, but also to standardize all procedures necessary to offer the services, by writing standard operating procedures (SOPs) and training the team on how to follow them. Standard operating procedures represent the sequence of steps that have been standardized to execute a task, and are used every time a given task is performed to ensure that it is executed in the same way every time and by every staff member. In other words, SOPs comprise detailed instructions to achieve uniformity on the performance of a specific procedure. Despite being usually written in a hierarchical manner, SOPs can also be expressed as flowcharts and drawings.

The main reasons why fertility centers need SOPs as integral elements of the quality control system are: (i) IVF involves repetitive high-complex critically important tasks; (ii) variation must be controlled; (iii) more than one person often perform the same task; (iv) safety risks are present; and (v) quality control must be ensured. SOPs are dynamic and should be constantly reviewed/updated, based on new knowledge and variation/errors detected after implementation. As a reference, the key elements of a laboratory SOP are listed in Table 2. An SOP-based practice can help reduce variation/errors and therefore enhance safety and efficiency. In order to achieve this, SOPs

should be intelligently designed, which means they are proved to be workable in a given practical condition before implementation. From a clinical perspective SOPs should contain (if applicable) post-analytical information that is useful for clinical interpretation and decision-making. Specifically, the three basic questions one should ask before designing/updating clinical SOPs are: (i) does the SOP address a specific clinical question, i.e., what does the doctor want to know? (ii) does the SOP post-analytical information help determining what to do? (iii) does the SOP provide a solution for panic/alert values?

**Table 2** - Elements of a laboratory standard operating procedure (SOP)

<b>I. General information:</b>
Name of test or procedure
Principles (goals and general information)
<b>II. Pre-analytic information:</b>
Patient instruction for test/procedure preparation
Specimen collection instructions
Specimen labeling, transport, referral
Specimen acceptability (including rejection criteria)
<b>III. Analytic information:</b>
Equipment, materials and reagents
Conditions required (e.g. laminar flow cabinet)
Instrument calibration and verification
Quality control (negative/positive control if required)
Step-by-step procedure description
Assay/procedure performance limitations
Troubleshooting
<b>IV. Post-analytic information:</b>
Calculations (if required)
Normal ranges (reference intervals or expected results)
Policy for handling alert or panic values
Report (post-analytical information)
References

In addition to SOPs, all existing documents and forms pertaining to the fertility center should be reviewed and approved. A system should be established to manage all documents, including how often they are reviewed and by whom, who is responsible for tracking and assigning the revisions, who is assigned to approve the revisions, and where documents are located for easy access. Having a single computer server to keep all documents and having someone responsible for keeping only the last reviewed version in use is essential. For example, it is critical for a nurse to know that the proper consent form (or any other form for that matter) is being used. It is also critical for embryologists to follow actual protocols and to know what forms need to be used and completed. It is important to have an easy way

for identifying, finding and tracking these protocols and documents; and again, it is of utmost importance to keep only last versions available. At Androfert, we do not work with printed instructions; in other words, everything is in the computer server, and we use a simple header in all documents with the number of the review and also the date for easier tracking. This is illustrated in Figure 8.



**Figure 8** - Practical example of the preventive maintenance program at Androfert. The header depicts the review number and date for easy identification.

There are many procedures that occur outside the IVF laboratory. As examples, (i) the protocol for ovarian stimulation in patients who are at risk of ovarian hyperstimulation syndrome or (ii) how to handle cases of azoospermia in which sperm retrieval fails should not just be in the physician’s mind; they must be clearly written and stored where any staff involved in patient care can have access. If the protocol changes then the revisions must be clearly tracked.

### Resource management and management responsibility

An important feature of QMS is to reflect how the fertility center allocates its human resources and infrastructure. Every employee within the organization must have a job description as well as a description of competences needed to perform their duties, and all employees must understand their individual role and importance within the company.

The working environment and infrastructure needed for employees to perform daily tasks are paramount. The same applies to personnel training. It is not possible to demand certain procedures and conducts if appropriate training, instruments and equipment are not available. For instance, we have discussed the importance of exclusively following the last reviewed version of a procedure, but first one must make sure everybody has easy access to computers in order to avoid using old versions, and also to having an established system where only the latest version is available, so that no one can access an old one.

As staff professional development is one of our center's quality policies (Table 2), initial and recurrent training are clearly outlined. The training program covers both new training as well as a review of concepts and procedures to guarantee internalization. Training includes ethical issues and moral values, as well as compliance with biosafety regulations. Staff performance and proficiency are periodically evaluated and feedback systematically given.

Another important aspect of staff development is enrolling in an external quality control and proficiency program. Having a regular evaluation and inter-technician comparison allows centers to identify variations, training needs, and ultimately validate their processes, without any internal bias, because evaluation is external and independent. At our clinic, we have chosen FertAid ([www.fertaid.com](http://www.fertaid.com)), a computer-based quality assurance and competency program that provides proficiency assessment and continuing education. This system met our needs because it is computer-based, allows embryologist to work on the exercises at their own pace, and uses benchmarks to compare individuals with peers around the world with the same time and experience as our embryologists.

A QMS must be fluid and requires surveillance and attention. It is important to point out that implementing a QMS is not the only thing to consider. Running such a system is another critical issue, and this is not an easy task. In our program, a fully dedicated quality manager is part of our team. Our quality manager establishes a unity of purpose and direction of the internal environment, and creates an environment where people are fully involved in achieving the organization's objectives. Leadership is an integral aspect of a QMS system.

### Control of nonconformity

Errors in all aspects of IVF (clinically, administratively, and in the laboratory) may occur, but it is important to track and treat them appropriately. Error registering should be incorporated into the organization culture and be accepted as a normative behavior. Our staff is asked to enter all errors and problems in a dedicated database so we can critically analyze the source of error and develop corrective actions.

In our experience, severe errors are rare in IVF, but errors resulting in suboptimal outcomes do occur. Examples include inadvertently not checking the warm plate temperature prior to performing intracytoplasmic sperm injection, having constant delays in procedures, not reporting problems or complaints immediately, etc. The root causes include lack of attention, insufficient education and/or training, and complexity of activity. A process must be in place to deal with errors. When a nonconformity occurs, which is defined by every deviation from what is established in the SOPs, 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 nonconformities. This not only closes the loop, so everyone knows that the problem was solved, but also serves as a database for the future. In essence, registering nonconformities help identify inconsistencies, weakness and improvement opportunities.

Another important aspect of a QMS is the implementation of "preventive action" and "improvement action" plans. 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 place that allows new ideas to be implemented in order to prevent potential non-conformities in the future. At Androfert, we have a database where any employee can enter/suggest preventive actions to reduce potential issues or problems in the future.

### Monitoring

A particularly important part of quality control is monitoring to ensure that the system is working. Annual inspection by an external auditor is required to maintain a certification such as the ISO. Equally important is the requirement of internal auditors. Internal auditors are company employees who receive instruction on how to audit sectors within the company. The auditor does not need to be familiar with the science but needs to be able to ask the right questions to verify conformity to established procedures.

An auditing process starts with planning the areas to be audited and allocating auditors in a timely manner. Employees should not be taken by surprise, so auditing dates should be published. The auditor has to study the procedures he/she will be seeing in advance, and on the actual auditing day, to observe the performance of the

procedures to verify compliance. The main objective of an auditing process is to verify compliance, not find nonconformities as many may think. As already mentioned, an integral aspect of quality management is to demonstrate that one is actually doing what has been defined as “official”. Audits are an important method to verify this.

### Managing customer requirements

A key benefit of ISO is that it helps define who our customers are and determine their needs and expectations, ultimately converting such needs to service requirements. Obviously the main customer is our patient, but others include referring doctors or the associates who use the center’s facilities, suppliers, employees (internal customers), regulatory authorities and even people in our community, all of whom must be managed correctly. For an IVF center to be successful it must clearly understand the needs of its customers. No company will survive with customers who are not happy with the service they receive. At Androfert we have spent a lot of resources understanding where within our organization our patients were satisfied and where improvement was needed. On a quarterly basis, we have a detailed survey of all sectors and aspects of the company based on patient satisfaction questionnaires. The results are used to institute changes to continually improve our patient satisfaction.

As for our internal customers, we run annual employee satisfaction surveys as a tool for workforce management, and then use the results to run both individual and group dynamics, training, or to make actual changes in work teams. Sometimes we even change the way we interact with specific employees, who may need more orientation, feedback, etc. Creating an internal environment with unity of purpose and direction is the key to achieving the organization’s goals.

### ■ RISK MANAGEMENT

Even though the ISO 9001:2008 does not contemplate risk management as a specific requirement, it does require a couple of measures that are ultimately related to risk management. One of these measures is the identification and traceability of samples, which starts with the correct identification of the patients when they arrive for a semen collection, oocyte pickup or embryo transfer, for example. It is important to implement a system of identification that is used throughout the center, and capable of preventing any possibility of mix-ups. There are some computer-based systems available in the market, but we have developed our own system that integrates our patients medical records with sample identification and traceability using the numeric sequence or bar code created by the system for each individual. However, even though this identification is personal and unique, it does not eliminate double-checking

and double witnessing during critic procedures, such as an embryo transfer. Traceability is totally guaranteed, once the system shows the exact identification and location of each sample.

Another aspect of risk management already present in the ISO 9001:2008 regards staff requirements. For instance, guaranteeing the appropriate number of embryologists to perform IVF, such as advised by ASRM and ESHRE based on the number of cycles, and guaranteeing staff is competent and trained to perform their activities is part of resource management, and is important to guarantee the quality of our services and also patients’ satisfaction. However, one must not forget that unexpected events may happen and an embryologist may get sick or have an accident, so equally important is having more than one embryologist available as a backup to perform each procedure, specially if we consider small clinics that have fewer cycles. When ASRM for instance advises a minimum of two embryologists for small clinics, it is important to consider a back up system, especially if these two embryologists have different working hours.

### ■ WHAT WERE THE BENEFITS OF QMS FOR OUR FERTILITY CENTER AND HOW TO MEASURE THEM?

IVF is in itself a complex process, which involves many people from various disciplines, such as medicine, embryology, ultrasonography, nursing and administration. How all these people interact and work together in a safe, productive and integrated way, both for them and for their clients, is the main challenge of an ART center.

Such a complex organization requires a system to ensure that the service offered is being delivered in the best way possible and is consistently standardized. Quality management is the process within the organization that will ensure that the service provided is performed in a standardized way, without variations, and that results are analyzed and improvements are regularly implemented, to guarantee a service of excellence with consistent and stable results.

With a QMS system, our Fertility Center was able to:

- Know who our customers are and what they want.
- Define the processes to meet their expectations.
- Define goals and objectives so that procedures and processes help achieve them.
- Measure performance and clients’ satisfaction to detect changes and new demands.
- Have all personnel involved in continuous improvement.
- Make changes, adjustments, and improvements based on facts rather than assumptions.
- And, last but not least, satisfy our patients.

Registration of quality actions (non-conformities, preventive actions, improvement actions and complaints), satisfaction surveys and questionnaires, and data collection of key performance indicators are key elements in measurement. Once monitoring is part of the daily routine of an IVF center, analyzing results using quality tools and methods is of utmost importance for evaluating the organization's success and how much improvement has been done. At our center, Pareto diagrams, diagrams of cause and effect, control charts, histograms and flowcharts are used as quality tools, and SWOT analysis, plan-do-act-check (PDCA) and balanced scorecards as quality methods (Figure 3). A more detailed explanation on quality tools and methods in QMS can be found elsewhere.<sup>1</sup>

## ■ CONCLUSIONS

Fertility centers can benefit greatly from implementing quality control as per quality management standards, regardless of its size and whether they are public or private. A Quality Management System makes it clear how tasks are supposed to be done because all documents, procedures and the workflow, as well as roles and responsibilities, are clearly defined. Quality management also addresses internal needs, such as the efficient use of resources (materials, human, technology and information), which is directly related to profitability. Such systems also guarantee the involvement of all staff in the process. As a result, improved communication and motivation to excel as a team is ensured. Importantly, a QMS provides tools to monitor what to do, leading inevitably to the continuous improvement of the service as a whole. It then encourages changes, adjustments and improvements based on facts and not on assumptions, because all data are formally recorded and analyzed. For any program to be of high quality it must have robust metrics involving the various dimensions of care, including effectiveness, safety, patient-centeredness, efficiency, timeliness and equity, and should not rely on a single parameter such as pregnancy rates.

The revised ISO 9001:2015 includes the concept of risk management from the beginning, during planning and the process-based approach. This new thinking guarantees proactivity in the strategic planning, because it is now necessary to identify opportunities, and to reduce or eliminate undesired effects and results, promoting continuous improvement. Identifying and understanding the risks and finding ways to mitigate these risks promotes changes and improvements.

## ■ AUTHOR PARTICIPATION

Bento FC planned the project, participated in writing the manuscript, revised and approved the final text. Esteves SC participated in the planning of the project and in writing the manuscript; both co-authors approved the final text.

## ■ CONFLICT OF INTEREST

Authors declare no conflict of interest concerning this project

## SISTEMA DE GESTÃO DE QUALIDADE NA CLÍNICA DE REPRODUÇÃO HUMANA: EXPERIÊNCIA COM A NORMA ISO 9001

Na clínica de reprodução humana, a qualidade deve ser medida pela maneira como a organização cumpre os requisitos pré-definidos, e pela forma como as políticas de qualidade são implementadas e os objetivos de qualidade alcançados. Ter um sistema de gestão da qualidade (SGQ) é um requisito obrigatório para centros de fertilização in vitro estabelecidos na maioria dos países com diretrizes regulatórias, incluindo o Brasil. No entanto, nenhuma das diretivas regulamentares especifica o que um SGQ deve ter em detalhe ou como ele deve ser implementado e/ou mantido. A norma ISO 9001 é a exigência internacional mais importante e adotada mundialmente para a gestão da qualidade. Os conceitos da norma ISO 9001 são genéricos e aplicáveis a todas as organizações em qualquer setor econômico, incluindo as clínicas de fertilização in vitro (ou bancos de células e tecidos germinativos tipo 2, como denominados no Brasil pela Agência Nacional de Vigilância Sanitária). Neste artigo, discutimos como implementamos um SGQ de acordo com a norma ISO 9001 e o que conseguimos 5 anos mais tarde. Em suma, com a norma ISO definimos nossa estrutura, políticas, procedimentos, processos e recursos necessários para implementar a gestão da qualidade. Além disso, determinamos a orientação da qualidade do nosso centro além dos objetivos de qualidade e indicadores utilizados para garantir que um serviço de alta qualidade seja fornecido para nossos clientes. A partir do momento que a mensuração do progresso tornou-se parte da nossa rotina diária, quantificar e avaliar o sucesso da organização e os resultados atingidos passou a ser uma consequência inevitável de um SGQ bem estabelecido. Várias lições foram aprendidas ao longo de nossa jornada de qualidade, mas o mais importante foi a criação de um ambiente interno com unidade de propósito e direção, que se tornou peça chave para alcançar os objetivos da organização.

**PALAVRAS-CHAVE:** Sistema de Gestão da Qualidade, ISO 9001, Clínica de Reprodução Humana.

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