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*Review paper*

# CREATING A SUSTAINABLE QUALITY MANAGEMENT SYSTEM IN ASSISTED REPRODUCTIVE TECHNOLOGIES

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***Abstract***

*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. 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.*

*Thus, the purpose of this study is to establish a framework by which to approach the issue of quality management system in ART, delineate the various components of quality that exist in health care, and explore how these elements affect one another.*

*The process management philosophy in ART begins its focus on the customer/patient and their requirements; everything to do with quality starts and ends with the customer/patient. What the customer/patient wants, needs and expects becomes the input to the quality management system. This input then feeds into the service planning process and finally into requirements for service delivery. Management responsibility (leadership), resource management (people, facilities and equipment), product realization (process) and measurement analysis and improvement (improvement for the customer/patient satisfaction) describe what practices must do to deliver quality services. To the customers, competitors and the outside world, a clinic/practice's business strategy is communicated through its marketing message, strategic partnerships and development of mutually beneficial supplier relationships.*

*In order to assure high quality and continual improvement, it is recommended that all ART centers striving for excellence should consider a Quality Management system.*

***Keywords:*** *assisted reproductive technologies, quality management system; ISO standards*

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## Introduction

On July 25, 2014, Louise Brown, the first test tube baby born in Oldham General Hospital Great Britain, turned 36. Her in vitro - conceived sister is already 32 years old. From that time until now, several million children all over the world have been conceived by IVF.

The assisted reproductive technologies (ART) are one of the fastest ever developed in human medicine, and they represent a sort of avant garde aspect of reproductive medicine. In a broader sense, they represent all the possible methods which can be used on the reproductive system for achieving conception and birth of an individual capable to live (Brinsden, 1999)[2].

In Macedonia, there is a high level of infertility. There are a lot of couples whose only option of conceiving is the ART/IVF procedure. Macedonia has been struggling with low birthrate for years. The ageing of the population is becoming more and more apparent. Furthermore, the low standard of living is taking its toll on the overall health and wellbeing of the people. The difficult socio-economic situation contributes to a low birthrate, and it leads to an increased incidence of diseases that affect both the male and female reproductive systems. All of this leads to a high percentage of infertility in the population. There are an increasing number of couples who are offered assisted reproductive techniques, IVF above all, as a choice for treating infertility. This is why organizing a quality management system in the assisted reproductive technology domain is of high priority and interest. Namely, a quality management system, which provides quality of service, professional attitude, and a positive outcome of the procedure, is of primary interest for the client/patient. A management system that is well organized through a standardized work process and brings appropriate financial reimbursement is a priority for the institution and staff involved in this process. All in all, a quality management system for assisted reproductive techniques and positive outcomes from the treatments are of paramount interest for the state and The Health Insurance Fund of Macedonia.

The primary concern of any healthcare system is, and will continue to be, medical performance. However, if we regard healthcare systems as 'corporations' dealing with patients, referring doctors, and employees, in addition to medical performance, then other qualities will have to be taken into consideration. More and more hospitals as well as independent medical practices will have to document the quality of their services to their patients and cost-bearers. This will mean that strict procedures for documentation of results will be needed and, furthermore, medical institutions will have to answer the question of whether or not they provide their services in a cost effective way. Many rules are set by law. However, beyond these rules, many medical institutions currently develop their own internal standards which are often only informally documented and, most of the time, are fragmentary. Although it is not always obvious, these standards can affect and direct the internal workings of the organization and the interaction of various areas within the company. They may also affect the interaction of the company

2 Brinsden, Peter R (1999) A Textbook of In Vitro Fertilization and Assisted Reproduction. The Bourn Hall guide to clinical and laboratory practice. London and New York: The Parthenon Publishing Group.

with external partners. With internal systems such as these, enormous differences can exist from one system to another with respect to the importance and validity of various sections and procedures. The Joint Commission on Accreditation of Health Care Organizations calls these elements of quality management 'functions.' One can show that these 'functions' differ from one institution to another, regardless of whether or not they are applied in clinics or private practices, group or single provider practices, or government medical institutions. Essential elements are identifiable and applicable to every institution that aims at fulfilling the wishes and demands of its customers. It is not only patients who are considered 'customers,' but all communication partners, including the referring physicians, the company's suppliers, and the company's own employees. The individual elements of a quality management system are developed to different degrees, always according to the tasks and the orientation of the particular institution. They exist in varied, yet always definable relationships to one another. All of these elements and their interconnection as a whole enable a clinic or private practice to reach the expected and agreed results with the customer on a timely basis, and with an appropriate use of resources. The sum of directive elements and elements that transcend or relate to the process is called the 'quality management system' of a clinic or a private practice.

In this study, the most important factors to creating a sustainable quality management system in reproductive medicine are described. The ISO 9001:2000 standard is based on eight quality management principles. These principles become the 'factors of success' for any IVF practice. These principles are customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making and mutually beneficial supplier relationships.

In the case of a quality management system, typical driving forces behind a quality management system are patient/customer needs and expectations, satisfaction and continual improvement within the practice. The implementation of a quality management system using the Involvement of People process management approach espoused by the ISO 9001:2000 standard is reflective of the need for quality management in assisted reproductive technology today. In the 1980s, ISO created regulations for quality management systems with the standard series 9001 through 9004 developed for the production of goods and services[3]. These manuals described the basic elements of the quality management system in a relatively abstract manner. Medical institutions were required to adapt these standards to suit them and this required some interpretation and modification. The introduction of ISO 9000 states: The demands of organizations differ from each other; during the creation of quality management systems and putting them into practice, the special goals of the organization, its products and procedures and specific methods of operation must be taken into consideration unconditionally. This means that, for medical applications, the standards state which elements should be considered in the Quality Management system, but the manner in which these elements should be realized in the specific medical organization have to be defined individually.

3 ISO 9001:2000 (1987) Quality management systems – Requirements. Geneva: International Standardization Organization.

The application of a certified quality management system for hospitals can be performed on the basis of ISO 9001 or ISO 9004.[4],[5]As mentioned earlier, in vitro fertilization (IVF) units occupy a special place within clinical medicine. It is a highly specialized field involving the interaction of staff in various areas, including the laboratory, ultrasound, and administration, and the optimal collaboration between physicians and nurses. A treatment can only be successful when a structured interaction exists between the clinical and laboratory departments. ISO 9001:20003 is very much concentrated on a process approach and directed to the outcome of the process; i.e. that the products or services meet the previously determined requirements.

ISO 9001:2000 suits the ART environment well because of the focus it places on the patient/customer and the emphasis it places on the IVF practice's management systems, processes, protocols and instructions. This is especially true in that an ISO 9001:2000 quality management system provides the framework and methodology for monitoring and measuring conformity to requirements, enhancing patient/customer satisfaction and continually improving the quality of service delivery. Implementing and maintaining a sustainable quality management system becomes the way that the practice operates, always keeping its focus on the patient/customer.

## Focus on the patient/customer

The ART/IVF practice should strive not just to meet, but also to exceed patient/customer expectations. The ability to actively and continuously identify patient/customer needs and expectations is a critical and inherent factor in the process of improving the quality management system in ART today. Identification, monitoring and delivering on client's expectations are some of the key conditions to ensure success and development of a free-market entity. After all, a satisfied patient/customer is the best advertisement for a company, whose gains are not only translated into economic terms, but also into company's reputation for being able to adequately identify and meet its patient/customer expectations by promptly and effectively responding to changing market needs (Phelps, 2008; Shevell, 2009) .[6],[7]

There is a great debate about how the infertility practice can focus on the patient/customer when it is unclear who the customer really is. Some practice administrators identify the physician as the primary customer due to the fact that the physician 'brings patients to the practice'. Clinical staff identifies the patient as the primary customer as that is the population that they serve. Social workers and clergy focus on the patient and their family members' physical, emotional and spiritual needs. Billing personnel

4 ISO/IEC 17025:1999 (1999) General requirements for the competence of testing and calibration laboratories. Geneva: International Standardization Organizatio.

5 ISO/IECGuide 25:1990 (1990) General requirements for the competence of testing and calibration laboratories. Geneva: International Standardization Organization.

6 Shevell, Michael I (2009) What do we call 'them'?: The 'patient' versus 'client' dichotomy, Developmental Medicine & Child Neurology, Vol 10 Page 770.

7 Phelps, Ceri et al (2008) "I Wouldn't Classify Myself as a Patient": The Importance of a "Well-being" Environment for Individuals Receiving Counseling about Familial Cancer Risk, Journal of Genetic Counseling, Vol 17 Issue 4

focus on payers and insurance companies as their primary customers. Risk managers and quality managers focus on collecting, collating and reporting practical improvement, clinical outcomes and other data related to accreditation and regulatory bodies, and to the practice's administration and Board of directors. The list goes on and on and so does the debate over, 'who is the customer'.

The fundamental mechanisms behind the free market, such as competition, start applying also to the public health sector. ART providers are gradually realizing that patients are actual clients of health care institutions, with physicians, nurses, supporting personnel, registration officers and other patient contact staff responding to those clients' demand for medical and auxiliary services (e.g. exam registration, provision of information). In view of that, all patient-related processes have to be placed in the focus of interest for IVF institutions using an ISO 9001:2008 compliant quality management system.

It is vitally important to ensure that customers are identified so that the IVF practice can 'enhance patient/customer satisfaction (Carr–Hull, 1992)[8]. The identification of customers is the key factor to a successful quality management when implementing a sustainable quality system in any practice. Administration must come together with staff to identify clearly and unambiguously the customer base, whether that be internal or external. If the identified customer base is too narrow then the practice will not serve all of its customers and other interested parties to the fullest of its ability.

Given the specific nature of the ART sector, it is much more difficult to identify patient requirements than to measure the same parameters for manufacturing companies, where client satisfaction levels and requirements are monitored based on characteristics of a final product in accordance with established standards (Gordon, 1998)**.**[9] Whereas perception of a medical service is very much affected by patients' subjective impressions, their psycho-social status in the course of treatment, and their general health condition while at hospital.

It is true that most patients do not have sufficient medical knowledge to assess whether the service they receive is of the best quality possible, delivered by qualified personnel using the most advanced equipment. Yet medically ignorant as they are, patients are able to judge from their own experience if the hospital staff is competent, friendly, responsive to their needs and problems and respectful of their rights, if the staff works in harmony or contrary: in chaos adding to patients' emotional tension (Stańczyk, 2011; Kowalik, 2010) **.**[10,11] For those reasons, the process of identifying patient›s requirements and satisfaction has to be carefully devised and, considering

8 Carr-Hill, R.A. (1992) The measurement of patient satisfaction, Journal of Public Health Medicine, Vol 14 Page 236.

9 Gordon, I (1998) Relationship Marketing: new strategies techniques and technologies to win the customers you want and keep them forever. London: John Wiley & Sons Inc

10 Stańczyk, M (2011). Music therapy in supportive cancer care. Rep Pract Oncol Radiother. Vol 16 Issue 5

11 Kowalik, A et al (2010) Basic tests in mammography as a tool in quality improvement. Rep Pract Oncol Radiother. Vol 15 Issue 5

the subjective nature of each patient›s perception, involve a joint effort of an interdisciplinary team composed of physician (head of department, head of clinic or a unit where patient's expectations are identified); ward nurse; quality officer; psychologist and health care institution management (as a decision-making body for requirements that can be met). An effective management system integrates both a system approach and process approach to operating the IVF practice. Because all personnel within the practice are critical and essential in carrying out the practice's mission, goals, objectives and vision, then all customers must be identified to ensure effective quality management.

## Quality policy

One of the first steps for the implementation of a Quality Management system in medical institutions is to define the quality policy. Quality policies are a group of principles according to which the medical institution works. The most important aspects of the quality policy should be posted in suitable and accessible areas of the institution for employees, patients, and visitors, to strengthen the employees' knowledge of common goals, improve their identification with their own fields of competence, and communicate these principles to others. It is important to state that the quality policies should be reviewed periodically and modified accordingly to make sure that the principles are still valid and that management and employees still agree with them ( Darr, 1999).[12]

## Management's responsibility

Management's responsibility can be defined differently in various medical institutions, according to ISO standards. The hierarchy of the institution has to be defined and outlined clearly. While, in most cases, hospitals are administered by an appointed director, the structure might be more difficult in private centers with multiple partners in equal positions. In such cases, an agreement that describes the division of responsibilities for particular fields among the partners must be in place and in these cases several possibilities are available. Therefore, it must be absolutely clear to everyone within the organization who has the competence and authority to make decisions. It is also important for all partners outside of the company to be aware of who the decision-makers are for various tasks. The organizational diagram can be placed in a suitable and accessible location, helping employees to understand everyone's roles and responsibilities. It is also important in communication with patients, interested parties, or cooperating departments and, therefore, the organizational diagram should be updated frequently.

12 Darr, K (1999). Risk management and quality improvement: together at last – Part. Hosp Top. Vol 77 Page: 29–35.

## Leadership

Administrators and managers within IVF centers and practices must understand and participate in high-involvement leadership. Leaders within the IVF center establish unity of purpose, cast a vision, provide direction, and create an internal environment within the practice so that employees can work to their fullest potential. Leadership within the practice creates an environment in which all staff and employees can become fully involved in achieving the practice's mission goals and objectives. Leadership is a dynamic or changing process in the sense that while influence is always present, the persons exercising that influence may change. The leader leads the practice in small steps with the knowledge and vision. ISO 9001:2000 requires the practice to determine the sequence and interactions of its processes in order to facilitate change and bring about improvement. Leaders must encourage and empower direct reports and other interested parties to bring forth 'best process practice' ideas. Leadership must enforce the 'one best way' of working when necessary. The high-involvement leader needs to be vocal in their support of the ISO 9001: 2000 initiative and not only talk about the process but become actively involved and visible throughout the project. Encouragement is needed in order to keep the project on-track and to ensure that people understand the importance of implementing a sustainable quality management system (Carson, 2014).[13]

## Employee/people involvement

Employee/people involvement is creating an environment in which people have an impact in decisions and actions that affect their jobs. How to involve employees in decision-making and continuous improvement activities is the strategic aspect of involvement and can include such methods as suggestion systems, work teams, continuous improvement meetings, Kaizen (the relentless pursuit for doing things a better way) events, corrective and preventive action processes, and periodic discussions with supervisors. Intrinsic to most employee involvement processes is training in team effectiveness, communication and problem solving; the development of reward and recognition systems; and, frequently, the sharing of gains made through employee involvement efforts. Improvement of personnel within the practice achieves maximum benefit when everyone is fully involved, using their abilities to the practice's advantage can create a positive effect and impact upon their jobs. When personnel realize the positive benefit that ISO 9001:Z000 Quality Management systems have for them personally, people will become more intimately involved in identifying methods for improving the processes they own (Fudge, 1999).[14]

High-quality treatment can only be realized with qualified staff. Therefore the recruitment, training, and motivation of highly qualified people are one of the most important tasks for the management team of an organization. The staff requirement plan must be set up so that it is possible to react sufficiently to unexpected situations.

13 Carson, Bruce E et al ( 2004) Quality Management Systems for Assisted Reproductive Tecnology - ISO 9001:2000. London and New York: Taylor & Francis Group.

14 Fudge, Robert S and al (1999) Motivating Employees to Act Ethically: An Expectancy Theory Approach. Journal of Business Ethics. Vol 18 Issue 3.

Furthermore, it must consider staff absenteeism caused by holidays, illness, and further education.

If ART practices expect their employees to do their work at the highest-quality level possible, they should give them proper training and education (internal or external: conventions, conferences, workshops, etc.). The advantage of internal events of further education is that they can be offered on a regular basis and are usually 'low-budget-projects,' whereas external events need more organizational and financial input. In ART centers, besides training activities for the doctors, adequate educational events for embryologists, nurses and technicians, etc., should be considered. However, a well-trained team can significantly reduce the workload for the doctor and, furthermore, tremendously increase the patient's trust in the institution while also improving the referring doctor's/ patient's satisfaction.

## Management of processes

Management of processes is all the procedures that are necessary for the completion of tasks. For medical facilities, the most important processes are those of diagnostic and therapeutic procedures. Practice and clinical processes are typically evaluated from the customer's viewpoint. Ensuring a smoothly running practice/clinical process is critical in maximizing the added value provided to its customers. When starting to establish a Quality Management system, it is necessary to define and describe precisely all relevant processes and to structure them according to Quality Management guidelines. A process model is designed to help all the people involved understand the whole picture and their part in it. A basic model can consist of things such as specific activities, process steps, organizational functions, information and material. Targets should be clear and measurable ensuring a strong commitment from management and practice/clinical personnel. The model can also contain notes about potential problems in the business process, ideas for improvement and other comments.

Typical ART/IVF processes include creating the methods, practices, protocols or services for patients/customers, scheduling and providing services to patients/customers and providing assistance to patients/customers after they have purchased the product or service. They also include planning of new methods, practices, protocols or services for patients/customers or refining the existing methods, practices, protocols or services.

Clinical/practice leadership must develop a process approach when managing the IVF practice's systems. Processes need to be defined and documented in order to understand more clearly the process flow of work. Once process flow is understood, improvements can be made when variation in process is identified and change is found necessary. Understanding and documenting the process flow of work also provides new employees with the opportunity to learn their jobs more quickly thereby limiting the number of errors made.

## Quality documentation

Quality documentation is an important part of business process management. Flow-charting 'work practice and work-flow is an excellent way of identifying the sequence and interaction of processes within the practice/clinic. Documenting all the processes within the practice/clinic aids in communication throughout the organization. The greatest challenge in the practice/clinic is to keep the documentation up-to-date and accessible to those involved. According to ISO 9001:2000 4.2.3 the clinic should establish and maintain procedures to control all documents that form part of its quality documentation. This includes both internally generated documentation such as standard operating procedures and protocol sheets, and externally generated documentation such as law texts, standards, and instruction manuals for equipment.

One of the most important documents in a QM system is the quality manual. A good-quality manual should be precise and brief; it should be an easily navigable handbook for the whole quality system. An easy way to start building a system is to make up a table of contents for the quality manual and to decide which processes should be described in the manual and which should rather be described in the underlying documentation (handbooks/job instructions or standard operating procedures).

Audits are essential in ensuring that a quality system is working. Audits can be internal, initiated by the organization itself, or external, initiated by a governing body, certification, or accreditation body. In order to determine how well the system is functioning and if it is effectively implemented and maintained, the management usually chooses internal auditors, and they should be familiar with both the standards and the activities performed in the clinic. The manual should include a document describing the approach and the areas of responsibility for the internal auditors and have well-documented procedures for how internal auditors are trained. To achieve a certification according to ISO 9001:2000, the clinic needs to be audited externally by a certification body. Together with the audits, the management review is important for improvement of the system and for the long-term correction of errors and incidents that might occur. When applying a quality system it is important not to hide these incidents and complaints received from patients, clients, and/or other parties, but to use them as resources to improve the system. The routines of how these are filed and how corrective actions are taken should be documented in a clinic's quality manual.

## Continual improvement

Continual improvement is a permanent objective of any practice/clinic. The continual improvement philosophy espoused by ISO 9001:2000 creates an important impact on customer satisfaction, satisfaction of other interested parties, profitability and longevity of the organization. As stated under customer focus, the IVF practice must know who the customer is, thereby turning their needs and expectations into requirements, establishing processes for soliciting customer feedback developing indicators, measuring and monitoring processes and service delivery and using the information to plan and execute effective corrective and preventive action in a timely manner.

Clinics and practices large and small are expected continually to improve their processes and practices. Leadership's commitment and active participation is essential to the success of continual improvement processes. Any activity that is repeated can be improved. A suggestion or improvement is not a statement of failure in the past, but of improvement for the future (Gardner, 2009). [15]

Developing a fact-based approach to decision-making is both a cultural and clinical/practice-wide process issue. As with any organizational priority, top management needs to drive the transition. The IVF center must base decisions on the logical or intuitive analysis of data and information. While the goal must obviously be zero errors, data creates real perspective instead of an emotional response. By developing organizational processes for identifying and considering key clinical, business and other outcome data, these practices/clinics are able to make higher-quality decisions. In the long term, this contributes to measurable business and clinical success.

Typically, there are three categories of organizations that lack a fact-based approach to clinical outcomes, business analysis and decision-making. There are uninformed clinics/practices who do not know that they should be collecting and integrating external and internal data into planning and decision-making. These organizations do not understand that good marketing is based on fact and that effective business and marketing strategy is mandatory to be successful. The frugal clinics/practices are those that would like to be fact-based but lack the motivation to invest in proper decision-based processes. The biased clinics/practices skew business and marketing facts, and introduce bias into their strategic and tactical plans (Carrere, 2003).[16]

To the customers, competitors and the outside world, a clinic/practice's business strategy is communicated through its marketing message and strategic partnerships. All decisions within the clinic/practice must be based on realistic and meaningful facts (Warnes, 2007).[17]

## Supplier relationships

ART/IVF practice should develop mutually beneficial supplier relationships**.** These require that purchasing relationships between the clinic/practice and its suppliers be structured in such a way as to benefit and enhance the ability of the organization and its suppliers/physicians/subcontractors to create value for its patients/customers.

15 Gardner, David K (2009) A Textbook of In Vitro Fertilization and Assisted Reproduction. Laboratory and Clinical perspectives. London: Informal Healthcare UK

16 Carrere, Carlos (2003) How to assess quality of an IVF centre? Human Reproduction. Vol 18, Issue 4

17 Warnes, GM et al (2007). Quality management systems in ART: are they really needed? An Australian clinic's experience. Best Pract Res Clin Obstet Gynaecol. Vol 21 Issue 1 Page: 41–55.

## Conclusions

No internationally accepted standards exist for quality in the IVF laboratory and the IVF center as a whole. In order to assure high quality and continual improvement, it is recommended that all IVF centers striving for excellence should consider a Quality Management system. A Quality Management system allows the organization to gain control of its documents and procedures and to monitor the clinical and nonclinical outcomes. Furthermore, the issues of staff recruitment and staff development can be addressed systematically and thereby, again, the overall outcome will be improved. The ISO standards offer the medical facility access to an internationally endorsed and proven Quality Management system.

ISO 9001:2000 organizes these eight principles into five clauses. When an IVF practice is audited for compliance, implementation of all ISO 9001:2000 quality management system requirements must be evaluated. These five quality management system standards are:

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| Clause 4 | Quality management system requirements; |
| Clause 5 | Management responsibility (leadership); |
| Clause 6 | Resource management (people, facilities, equipment); |
| Clause 7 | Service realization (process identification and process management); |
| Clause 8 | Measurement analysis and improvement (improvement for patient/customer satisfaction). |

These five clauses describe what clinics/practices must accomplish and implement in order to provide quality services to patients/customers. The practice is then required to evaluate pertinent information on customer/patient satisfaction and/or dissatisfaction. Measurements and evaluations become feedback on the practice's ability to meet customer/patient requirements. The clinic/practice is required to measure and monitor both service delivery processes and the service delivery itself. Satisfaction measures are used as feedback to evaluate and confirm whether customer/patient requirements have been met. ART practitioners in particular have the unique opportunity to set the standard in medicine for quality management principles.

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