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QUALITY MANAGEMENT SYSTEM IN CLINICAL LABORATORIES ACCORDING TO THE ISO 15189:2007 STANDARD - EVALUATION OF THE BENEFITS OF IMPLEMENTATION IN AN ASSISTED REPRODUCTION LABORATORY

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Abstract: *Biomedical science is a sensitive discipline and presents unique challenges due to its social character, continuous development and competitiveness. The issue of quality management systems and accreditation is gaining increasing interest in this sector. All over Europe, Health Services Units have started to introduce quality management systems and harmonization of criteria for accreditation is of increasing importance. Moreover, clinical laboratories, like the Assisted Reproduction laboratories and biochemical laboratories are required to apply a Quality Management System in order to ensure their correct, scientific and effective operation. Ultimately, it is a moral obligation for every health care organisation to supply the best possible care for the patient.*

The specific features and the diversity of clinical laboratories led to the introduction (2003) and, recently to the revision (2007) of the international standard ISO 15189, which is the first international standard developed specifically to address the requirements for accreditation of this type of laboratory.

The basic principles for the quality assurance in the clinical laboratories are:

- *Complete and unambiguous standardized operating procedures.*
- *Complete and unambiguous directives of operation.*
- *Obligatory detailed written documentation, i.e., how each action is done, who will do it, where will this action take place and when.*
- *Suitable scheduling of calibration/control/preventive maintenance of laboratory equipment and recording of each activity.*
- *Distribution of responsibilities among the staff and continuous education and briefing according to current scientific data.*
- *Complete and informed record file keeping.*
- *Continuous improvement which is monitored with the adoption of quantified indicators.*
- *Internal and external audit of all activities.*
- *Troubleshooting.*

All these principles should be supported by the Management in order that the necessary adaptations should be made in the provision of human resources, equipment, supplies and working environment and the resolution of organisational problems.

This article deals with the planning and the implementation of a Quality Management System, in accordance with ISO 15189 (2007), in the Assisted Reproduction Laboratory in one of the biggest Maternity Clinics in Greece. The benefits resulted; both for medical laboratory service and patients are also presented and discussed.

Keywords: *Quality Management System, ISO 15189, clinical laboratories, Assisted Reproduction laboratory.*

1. INTRODUCTION

The term quality means the extent to which a requirement is met. Quality can be defined by a number of criteria, which may include both objective evidence of quality and subjective preferences or desires. Quality can refer to a product or service offered.The services sector recognizes that customers are entitled to high quality and there is a growing use of quality improvement practices in the service sector. This expectation includes the provision of health services.

The area of health is a particularly sensitive area and has special characteristics and needs, given the social character of health services, the ever changing and high competitive environment in which those services are provided.

The remarkable progress in medicine over the past 30 years resulted in the development of health services and increasing demands for continuous improvement. Given the fact, that it is a moral obligation to provide the best possible care to the patient, the implementation of Quality Management System (QMS) in the field of health services automatically becomes a necessity [1].

The introduction and certification of a QMS in a Health Services Unit, such as a clinical laboratories, brings multiple benefits for both society and the service provide itself. However, requirements for Quality Management in Health must be approached very differently than in industry or in other types of enterprises for the following reasons:

Health services are characterized by physical and mental involvement of the patient in the healthcare process.

The public has little or no knowledge about the healthcare profession and the nature of services being provided.

Usually the recipient of healthcare services differs from the organisation who pays for such services.

The provision of health services is characterized by extremely complex and multifaceted collaboration of specialities.

Health services are subject to constant change due to the continuous evolving technology.

The so-called “Assisted Reproduction” is a particularly sensitive sector of health. To start with, the methods and techniques used are relatively new and constantly evolving. It should be noted that those methods and techniques require very subtle and careful handling by highly skilled and experienced scientists, under strictly controlled conditions.

Assisted Reproduction Laboratories are the epicentre of the Assisted Reproduction Unit. In these, lab methods and techniques are being applied which are associated with the treatment of infertility. It is a necessity to apply a Quality Management System, as it is crucial that those techniques must be safe and reliable with the objective being the care of the patient.

Greece has adopted two laws relating to the Assisted Reproduction [Law 3089 (2002) and Law 3305 (2005)]; see Ref. [2]. The conditions of those two laws describe safe practices of methods being applied in Medically Assisted Reproduction. Apart from the two laws an Act of Parliament has recently been established regarding the terms and conditions for the establishment and operation of Medically Assisted Reproduction units and Sperm Banking. This Act is based on the rules of good practices and existing national and European rules, as described in international codes of conduct [3, 4].

In Europe the Institution that represents professionals in medicine and reproductive biology is the European Society of Human Reproduction and Embryology (ESHRE). Since the year 2000 ESHRE has been prepared, under the auspices of the Special Interest Group, good practice guidelines in IVF (in vitro fertilization) laboratories [5]. In 2008 after the Directive 2004/23/EC of the European Parliament for the use of human tissues and cells, ESHRE has reviewed the guidelines, not only in response to the need of embryologists for support and guidance to their duties but also to complement the requirements set by this Directive; see Ref. [4].

On the basis of the above mentioned framework, it becomes clear how crucial it is to apply a quality management system in clinical laboratories, and especially in an IVF laboratory. At this point a question arises: Certification or accreditation of a clinical laboratory? Since the primary objective of a clinical laboratory is to have effective technical competence with formal recognition and reliability of the methods and techniques applied, accreditation is the answer [6-9].

Until recently, clinical laboratories were accredited according to Standard ISO 17025 [10]. In time, it became clear that the special needs and character of clinical laboratories led to the adoption of the standard ISO 15189:2003 see Ref. [11] and its recent revision in 2007 [3]. This article discusses the implementation of a QMS in clinical laboratories, according to ISO 15189:2007 and assesses the benefits arising from this application in an IVF laboratory.

2. ACCREDITATION OF CLINICAL LABORATORIES

2.1 Principles of Accreditation

A key factor for the correct functioning of a special workplace and a clinical laboratory is the ability to produce the most reliable results possible. This means that the objective is to maximize accuracy and minimize

error. This objective in an IVF laboratory, translates into applying the techniques with a high degree of repeatability and accuracy, resulting in embryos of good quality, high rates of pregnancy and of course without mistakes.

The results from the laboratory, of such importance, require a good laboratory procedure and effective communication with clinicians and patients. It is important to note that the implementation of quality systems requires adherence to and documentation of the implementation of relevant rules and procedures as specified in the standard accreditation by everyone involved, self-inspection and continuous improvement of the system, while providing adequate staffing of trained personnel and using specialised equipment in a suitable and safe environment [12, 13].

All these requirements imply specific, laborious and systematic preparation of the workplace, almost always (typically) using an external consultant for quality, before applying for accreditation and the final assessment by an external, independent National Accreditation Body (in Greece this body is ESYD s.a.).

2.2 Stages of preparing for accreditation - Levels of evidence

To develop and implement a quality system for accreditation of a laboratory requires first the enthusiasm and conscious intention of the director or the quality assurance manager of the laboratory. Certainly require willing cooperation of all employees, ensuring the necessary financial resources, but also requires the consensus of a supervising, administrative body. There is a need for corrective actions, establishment of mechanisms for documentation, registration, inspections, reports and improvements, new equipment, but more importantly accumulation of expertise.

In addition, to start a process of implementing a Quality System, the laboratory or the organization in which the laboratory belongs should be a statutory legal entity, must have a defined organizational structure, have designed responsibilities and relationships between staff members, have technical management, to nominate a staff member responsible for quality, to ensure the impartiality and integrity of the operation and finally to ensure the protection of confidential information and compliance to ethical standards [13].

The steps to be followed in order to achieve the predetermined goal of Accreditation include intervention in the organizational structure of the laboratory, the responsibilities of individuals and the procedures and instruments used.

Fundamentally using the "circle of quality" model, where initially there will be a general assessment of operation and identify problems, followed by the search for criteria upon which standards will be set and formulation of the necessary guidelines and working protocols. The final step is the overall system evaluation and implementation of corrective actions, depending on the requirements of the standards of Accreditation.

In particular, steps to be followed include:

Initial general registration of all activities of the laboratory (chart of operation) and specific detailed description of the accreditation activities. It should be noted that accreditation does not refer to all activities of the laboratory, but in certain (discrete) activities, which are determined in the laboratory application.

Defining the team leader who is responsible for coordinating all internal operations of the workplace related to the introduction and operation of the quality management system. It is also a link to the laboratory director of quality and has the authority of the Hospital Administration or other Administrator bodies.

Review of activities of the laboratory in comparison with the standard requirements and a decision on the scope of activities accreditation and determine the desired goals.

Detailed development design phases of the Quality System. The Quality System of the laboratory must be documented, notified and understood by the staff of the laboratory and should include:

The quality manual

The quality policy

The internal and external quality control

Suitable calibration program/control as well as adequate program of preventive maintenance of the laboratory equipment.

5. Formation of a network of the laboratory to receive, assimilate and disseminate to other staff members know-how from the consultant.
6. Planned and directed implementation on behalf of the staff, each phase of system development and system documentation; see also Ref. [14].
7. Administrative assistance for the necessary adjustments in the management of human resources, equipment, supplies, work environment, solving organizational problems, etc.
8. Development of quality procedures: The quality procedures define the functional aspects of the Quality System and designate by appropriate obligatory documentation, special instruction or procedure. How will all work be carried out, who will do what, where each task will be made, when it will happen.
9. Development of work instructions: They describe with the greatest detail how to perform each activity. They also refer to job descriptions, specifications and requirements to meet by the materials/products.
10. Verification - validation: The requirements of validation or verification and quality control methods for clinical trials are a key criterion for accreditation as specified in the standard and guideline for the Accreditation of clinical

laboratories to ISO 15189 [3, 15]. The laboratory also should have quality control procedures for ensuring the validity of the tests carried out.

11. Infrastructure: At this stage of preparation all the infrastructure material will be gathered, which includes the relevant legislation, standards and specifications of equipment and consumables forming a technical standpoint upon on which the lab operates.
12. Creation of Records: It involves the creation of records as defined by the standard to prove/document procedure and product/services, compliance with the Quality Management System being applied.
13. Preparation of the Quality Manual of the Laboratory: This is the official document of Accreditation, in which all the operating procedures of the laboratory are recorded versus the requirements of the standard.

To summarize, a standard planning, based on those outlined above for the preparation of implementing a quality system for accreditation, depending on the specifics of each workshop includes the following steps:

1. Detection of the current situation and shortcomings.
2. Development/modification of compulsory documentation.
3. System application - internal audits.
4. Accreditation.

The ISO 15189:2007 standard consists of two main sections, one of the requirements for the administration (§ 4) and the other for the technical requirements (§ 5). For the application and the documentation of the Quality System the following subjects should be analysed in detail in comparison with the requirements of the standard:

Organization and management.
Infrastructure and Equipment.
Policy and Procedures.
Evolution of Personnel and Training.
Evaluation.

3. IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM IN ASSISTED REPRODUCTION LABORATORY OF MATERNITY CENTER “MITERA”, ACCORDING TO ISO 15189:2007.

ISO 15189 was intended to provide a model for implementing Quality Management System in clinical laboratories. Assisted Reproduction Laboratories are a group of clinical laboratories, in which oocyte fertilization, culture of gametes and embryos, semen analysis, testicular tissue biopsies, and pre-implantation genetic diagnosis are practiced. The implementation of ISO 15189 in an IVF laboratory needs in some aspects, special adjustment, especially in pre-analytical and analytical procedures. For example, there are no reference values as in the case of biochemical laboratories. Also, in Assisted Reproduction the procedures are not automated, and there for, there are no analysers to be calibrated. However, a proper calibration of other equipment such as microscopes and especially incubators where, developing embryos and gametes are stored is needed [15].

The documents of the Quality System are built on three levels, according to the general trend that has prevailed and observed in all management systems.

Level 1: documents of the so-called "strategic level" which is the quality manual.

Level 2: Procedural documentation and guidance which are the QMS procedures (procedures, instructions on forms).

Level 3: Files generated by the implementation of the QMS [14, 16-18].

4. CONCLUSIONS

The benefits arised from the implementation of the QMS are both internal and external. Internal benefits come from better internal functioning of the Unit as a result of the introduction of clear and documented procedures and instructions. This includes:

- Identify the organizational framework
- Determining the framework for handling everyday business
- The active involvement of staff members
- The systematic training
- Better organization and management of kept records and forms, and monitoring of the unit infrastructure
- Security of samples
- Increased patient satisfaction while efficiency of the Unit

Significant benefits also arise for the organization in terms of the relations with its external environment, such as benefits in relation to the transactions of the organization with customers, suppliers etc. which lead to improved competitiveness, prestige and credibility of the organization.

In all QMS the terms goal setting, continuous improvement and improved customer satisfaction are central, that has led to adopt quantitative indicators for monitoring these parameters [19]. In particular, the rate of complaints of customers, the rate of fertilization and pregnancy rates, used as such indicators.

The results indicate statistically significant improvement after the implementation of QMS as shown in the graphs in figure 1.

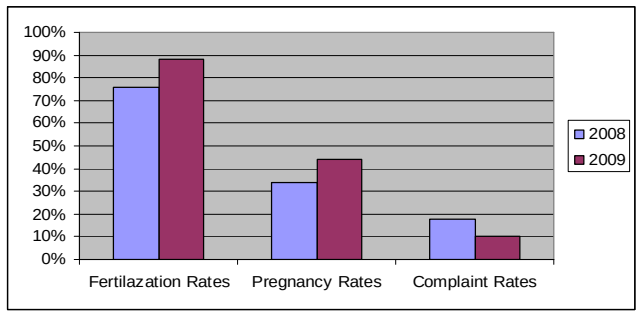

Figure 1. Quantitative indicators after the implementation of QMS

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