

Preface

The objective of this book is to help ART centers comply with the demand to establish a Quality Management System, providing a step-by-step logical sequence to facilitate system implementation. The book covers basic concepts that are part of any model of quality management system chosen and also presents the experience many centers around the world have had in developing and using a quality management system, so as to identify common difficulties, challenges, and successes.

Chapter 1 offers an introduction to quality management in ART clinics. Chapter 2 presents some quality management tools, giving practical examples and explaining how these tools can be used and can help make a quality system work. It will neither focus on a particular tool nor go into extensive details about any of them. The idea is to present readers with what is available and enable them to follow whatever trend they may find suitable for their practices.

Chapter 3 starts with basic concepts to start the process of establishing a quality management system, such as how to define one's mission and quality management policies, how to register and control nonconformities as well as define corrective and preventive actions, and how to use satisfaction questionnaires to set goals and monitor performance.

Chapter 4 focuses on the daily activities of an ART Center, showing ways to have an overview of all activities involved, through flowcharts and interactions, and also showing the importance of standardization to achieve uniformity and guarantee quality. SOP's descriptions, reviews, and controls are also addressed.

Chapter 5 talks about training. The intention is not to present a training program but to suggest training subjects that can be covered for a quality system to be successful. It will also address issues such as internal satisfaction and how to evaluate staff's performance.

Chapter 6 focuses on communication. No quality management system can survive without a proper communication system. It will cover auditing processes, discussion and improvement groups, and the presentation of regular reports and indicators.

Chapters 7–10 provide an overview of how reproductive laboratories (RL), i.e., andrology and embryology clinical laboratories, can be integrated in a quality management system. These chapters define and explain the three pillars of quality for RLs attempting to operate in a quality management philosophy, i.e., (1) Defining what you do; (2) explaining how you do; and (3) making sure that what you do is being done in the proper manner, and provide tools and practical examples that will aid in the development of a quality management plan for reproductive labs. In Chap. 7 we provide an introduction to the role of reproductive laboratories in ART clinics. In Chap. 8, we present an overview of the scope of activities and services performed by typical clinical reproductive laboratories. Chapter 9 discusses what is needed for RLs to perform the procedures under their scope of activity. The role of laboratory manuals, personnel, structure and resources, and laboratory safety is fully covered. Chapter 10 describes and explains the critical quality activities for clinical reproductive laboratories operating in the context of quality management. Quality control (QC), quality assurance (QA), and quality improvement (QI) as key quality management elements should be fully integrated to not only identifying problems but also finding their solutions as well as ensuring and optimizing the quality of laboratory services.

Chapters 11 through 21 present the experience of ART Centers around the world in the establishment of their own quality management systems. The collaborating efforts of contributors in this section geographically span Europe, Latin America, Australia, Africa, Asia, as well as the USA. The idea is not to say what is right or wrong, but to show what worked and what did not work in different countries. Despite their regional and cultural differences, they do have a lot in common, and what they reported may enlighten those who are struggling to succeed. ART Centers will answer the following questions besides addressing issues that were particularly important in their practices:

- In your country, should ART Center legally comply with official regulations? Is having a Quality Management System mandatory?
- What are the key elements of your countries regulations, if any, regarding quality management?
- Which Quality Management System is in place at your center? Why did you decide to use this system?
- Which were the main challenges your ART Center faced to implement the Quality Management System and how were they overcome?
- What are the key elements of your Center's Quality Management System?
- What was gained by implementing a Quality Management System?

The ART Centers participating in these chapters are distributed around the world so as to show how this issue is dealt with in different countries and cultures (Fig. 1).

Each country follows its own regulation and directives, regardless of their being mandatory or simply a matter of choice (Table 1). It is interesting to note that some countries have to follow more than one guideline while others have no mandatory guidelines at all.



Fig. 1 Authors who contributed with chapters on international experience and their locations

Table 1 International guidelines and directives for ART		
Country	Official guidelines and directives—mandatory	Other guidelines—non-mandatory
Australia	Code of Practice for Assisted Reproductive Technology Units, RTAC—Reproductive Technology Accreditation Committee	
Belgium	EU Directive 2004/23/EG EU Directive 2006/17/EG EU Directive 2006/86/EG Belgium Law (BS 30/12/2008)	ISO 9001:2008
Brasil	RDC 33, 17/02/06, ANVISA— Agência Nacional de Vigilância Sanitária CFM 1957/10, 15/12/10, CFM— Federal Medicine Council	ISO 9001:2008 Guidelines and Regulations REDLARA—Latin America Network of Assisted Reproduction
Chile		Guidelines and Regulations REDLARA—Latin America Network of Assisted Reproduction

(continued)

Table 1 (continued)

Country	Official guidelines and directives—mandatory	Other guidelines—non-mandatory
Gulf Countries		American Society of Reproduction Medicine Standards European Society of Human Reproduction and Embryology (ESHRE) Standards U.S. Department of Health and Human Services Standards Australian Council of Healthcare Standards International Organization for Standardization—ISO
India		ICMR—Indian Council of Medical Research National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India—2007
Nigeria		HFEA Code of Practice. 6th edition ISO 9001:2008
Singapore		ISO 9001:2008 Joint Commission Accreditation of Health Care Organization (JJCAHCO)—Joint Commission International (JCI)
South Africa	National Health Act (No. 61 of 2003, Chapters 1–3) Human Tissue Act (No. 65 of 1983) Children's Act (No. 38 of 2005)	American Society of Reproduction Medicine Guidelines and Protocols HFEA Code of Practice. 6th edition Standard Guidelines—SASREG (South African Society of Reproductive Medicine and Gynecological Endoscopy)
The Netherlands	GMP: Good Manufacturing Practice, Dutch Government EU Directive 2004/23/EC, Ministry of Health, Welfare and Sports Artificial Insemination donor information Act Embryo Act Safety and Quality of Body Materials Act Requirements for Body Materials Decree	CCKL Code of Practice ISO 15189:2003
The USA	CLIA for Andrology Laboratories FDA for Cryobiology	CAP Accreditation

Based on this information, we have tried to gather a heterogeneous group to show how a Quality Management System has been applied in different settings. Despite all differences, similar experiences and difficulties are noticed, and much can be learned from this group. Their experience can help both those who already have a system in place, and sometimes struggle to keep it working, and those who are implementing a brand new Quality Management System.

Campinas, SP, Brazil

Campinas, SP, Brazil

Cleveland, OH, USA

Fabiola Bento, B.B.A., M.B.E.

Sandro Esteves, M.D., Ph.D.

Ashok Agarwal, Ph.D., H.C.L.D. (A.B.B.)

<http://www.springer.com/978-1-4419-7138-8>

Quality Management in ART Clinics

A Practical Guide

Bento, F.; Esteves, S.C.; Agarwal, A. (Eds.)

2013, XVIII, 246 p., Hardcover

ISBN: 978-1-4419-7138-8