Second Edition

Quality and Risk Management in the IVF Laboratory

Sharon T. Mortimer and David Mortimer

CAMBRIDGE Medicine

Quality and Risk Management in the IVF Laboratory

Second Edition

Sharon T. Mortimer, PhD
Director, Oozoa Biomedical Inc.
West Vancouver, BC, Canada

David Mortimer, PhD
President, Oozoa Biomedical Inc.
West Vancouver, BC, Canada

CAMBRIDGE
UNIVERSITY PRESS

CAMBRIDGE
UNIVERSITY PRESS

University Printing House, Cambridge CB2 8BS, United Kingdom

Cambridge University Press is part of the University of Cambridge.

It furthers the University's mission by disseminating knowledge in the pursuit of education, learning and research at the highest international levels of excellence.

www.cambridge.org
Information on this title: www.cambridge.org/9781107421288

First published 2005
Second edition 2015

Printed in the United Kingdom by Clays, St Ives plc

A catalog record for this publication is available from the British Library

Library of Congress Cataloging in Publication data
Mortimer, David, 1953- , author.
Quality and risk management in the IVF laboratory / Sharon T. Mortimer, David Mortimer. - Second edition.
p. ; cm.
Authors' names reversed on the first edition.
ISBN 978-1-107-42128-8 (Paperback)
I. Mortimer, Sharon T. (Sharon Tracey), 1961- , author. II. Title.
[DNLM: 1. Fertilization in Vitro-standards. 2. Clinical Laboratory Techniques-standards. 3. Quality Control. 4. Risk Management-methods. WQ 208]
RG135
362.198'1780599-dc23 2014035094

ISBN 978-1-107-42128-8 Paperback

Contents

Chapter 1

Introduction

In the introduction to the first edition of this book we commented that it seemed that we were hearing news reports of disasters in IVF clinics almost weekly, and that public concern over these reports had resulted in governments introducing regulation of IVF labs around the world. We also noted that within our profession there was growing recognition of the need for accreditation of IVF labs to minimize the potential for such errors to occur. In the intervening decade the prevalence of regulation has continued to increase, the acceptance of accreditation has become more widespread – and, gratifyingly, it seems that "IVF disasters" might have become less frequent. National and international professional societies have committees, working groups, special interest groups, and even task forces working in the area of quality management, risk management and safety in assisted reproductive technology (ART), and an increasing number of clinics now employ quality managers.

Quality systems, which have an inherent role in all modern accreditation schemes, are essentially based on the principles of ISO 9000 and related standards. Yet quality management beyond basic assay quality control is still often poorly understood by biomedical scientists, especially outside of clinical chemistry and pathology laboratories. In particular, even though risk analysis and minimization are being demanded of IVF labs, many IVF scientists have only limited understanding of how to go about these tasks. Ten years ago we suggested that this was because the majority of scientists working in clinical IVF labs had come from academic/research backgrounds and, as a consequence, had limited experience of the practicalities of laboratory management. However, it is still very obvious that too many IVF scientists receive little or no formal training in quality management – or even in the basics of laboratory management.

IVF continues its rapid evolution over the last four decades or so: from its beginnings as a highly experimental procedure in the late 1970s, culminating in the birth of Louise Brown on July 25, 1978 (Edwards and Steptoe, 1980) to a rapidly expanding field of research and a clinical practice that swept the world in the 1980s and was consolidated as a routine clinical service in the 1990s. From the mid-1980s we also saw the rapid growth in commercial IVF clinics, to the extent that IVF is often now described as an "industry" and IVF treatment (even ICSI) is increasingly seen by many as a commodity product, especially in the developed world. Over the last 15 years we have seen, at least in countries where the provision of ART services is more advanced, the "corporatization" of IVF clinics, with banks and other financial institutions now owning networks of clinics. Sadly the operation of such clinics now seems prone to being directed by finance professionals whose understanding and "feel" for the provision of quality ART care has been criticized in the mass media as being driven primarily by the motive of profit.

Nonetheless, even in the face of escalating global expansion and commercialization, quality management and risk management continue to increase in importance to those responsible for running IVF clinics, and consequently their understanding and practise by the scientists working in them becomes ever more important.

But quality management and risk management cannot be applied in isolation; they must be integrated within the holistic framework of total quality management, itself essentially synonymous with the goal of "best practice." In this way quality and risk management will not be seen as just additional annoying, expensive regulatory requirements that "don't help the patients get pregnant." The provision of effective and safe IVF treatment depends on achieving improved standards of technical services and medical care. Healthcare is slowly learning the lessons that transformed the manufacturing industries since World War II, and have done the same for service industries more recently. Within this context, calls for IVF centers to operate according to international standards such as ISO 9001 (Alper *et al.*, 2002; Alper, 2013) reflect modern awareness of our professional – and commercial – environment, and should be embraced by all centers that truly care for their patients and employees.

The structure and organization of IVF centers varies widely between small, "sole practitioner"-size clinics and large, corporate IVF organizations that typically operate multiple sites. Figure 1.1 shows a generic concept for viewing the organization of an IVF center by disciplines that is applicable to all clinics, regardless of size. The internal management of an IVF center is illustrated in Figure 1.2, establishing the appropriate levels of control necessary to operate a multidisciplinary organization that expresses mutual respect for all professions involved. IVF labs vary in size between a single scientist (we abhor the word "tech" or "technician" since we believe ardently that anyone performing IVF lab procedures *must* function as an autonomous professional scientist, but more of that later) and a large team that is often sub-divided by functions and responsibilities. These extremes are illustrated in the organization charts shown in Figures 1.3 and 1.4. A full understanding of organizational structure, the hierarchies of authority and responsibility, and lines of communication are essential pre-requisites for anyone embarking upon implementing programs of quality management and risk management.

Fortunately, each center does not need to re-invent the disciplines of quality management and risk management. Not only have numerous IVF centers around the world already achieved ISO 9001 certification, but the basic processes of managing quality improvement and risk management in IVF are not fundamentally different to other areas of business. There are many resources available to centers embarking upon this journey, ranging from "self-help" and reference books at all levels (we still refer to Dale and McQuater, 1998; Heller and Hindle, 2003; Hobbs, 2009), to practical advice from friendly centers, based upon their own experiences, to expert advice and assistance from commercially orientated centers, management companies, or individual consultants.

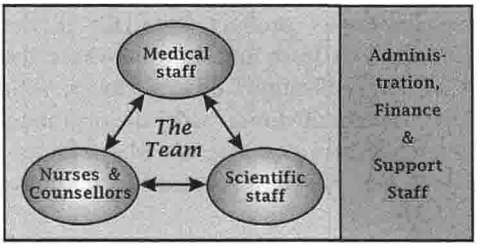

Figure 1.1 Diagrammatic representation of the organization of an IVF center showing the "core team" that must have effective administration, finance, and support teams working alongside it.

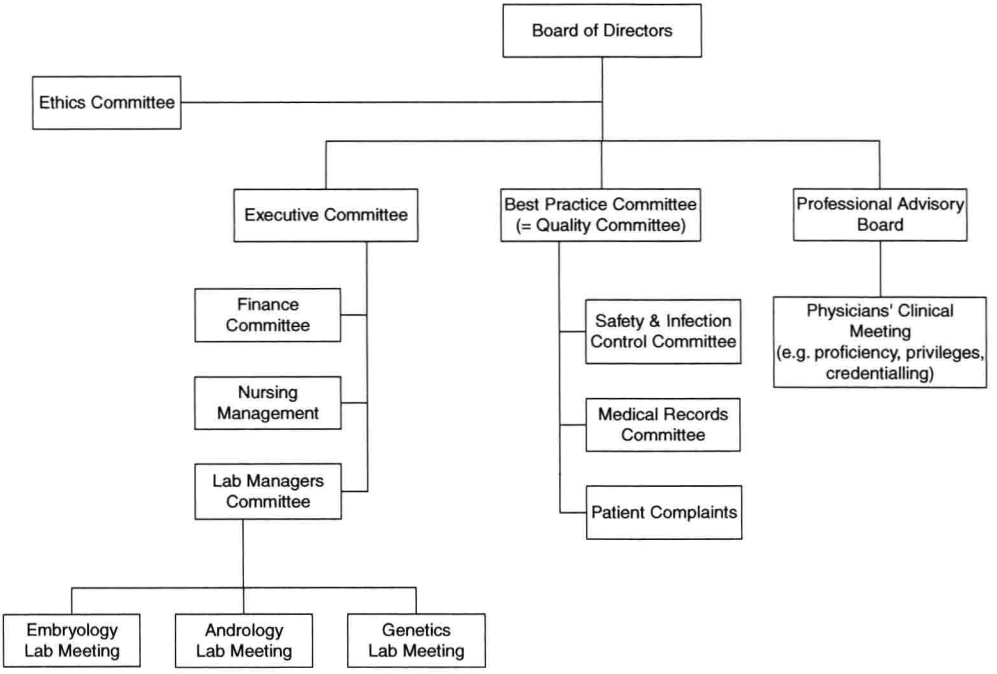

Figure 1.2 Organization chart showing the committee structure that might be required to run a large IVF center according to the principles of total quality management – or a generic accreditation scheme.

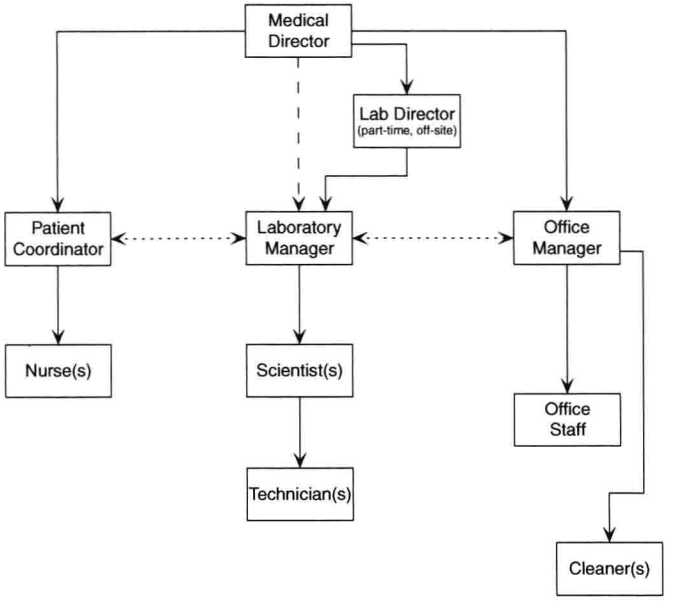

Figure 1.3 Organization chart for a small ("boutique") IVF center.

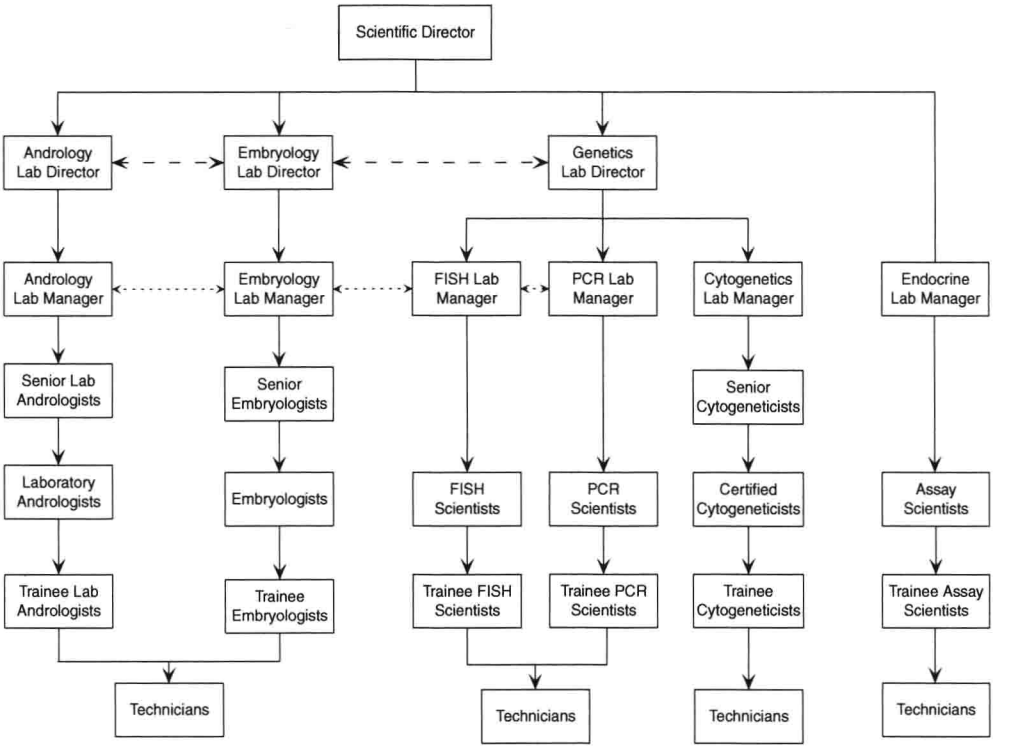

Figure 1.4 Organization chart for the laboratory operations of a large IVF center.

We have written this book to bring together the basics of these essential aspects of laboratory management in the context of IVF labs. The book is aimed at scientists who know their own technical field, but to whom the concepts of process and systems management are less familiar – if not actually alien. We see education as the foundation for bringing about any change or improvement. Simply teaching people how to do a task is not enough: unless people understand the "whys" (and the "why-nots") they are not truly competent to perform a job as complex and responsible as IVF. Therefore, the early chapters provide basic definitions (unfortunately sometimes didactic and boring, but essential nonetheless) and explanations of the concepts and terminology that are used in quality and risk management. Later chapters then go on to demonstrate how quality and risk management are tightly integrated in achieving optimum success rates, avoiding mistakes, and running an efficient – and successful – laboratory service. Finally, there are chapters that provide basic advice and examples on the use of the various quality and risk management tools and techniques in developing and implementing management systems in your own lab.

In this second edition we have significantly expanded Chapter 12, which considers human resource management, added a new chapter (13) that describes an illustrative example of a "well-run" laboratory, and expanded the final chapter (14) to now consider Total Quality Management (TQM) within the context of the entire IVF clinic, including cost-benefit considerations.

Throughout the book we have used illustrative examples from the general world as well as ones specific to the IVF lab. The latter often represent examples of what happens when

things do go wrong: issues such as mis-matched sperm and eggs, transferring the wrong embryos, losing samples from the cryobank, letting cryobank tanks go dry and so on – painful as they might be for any of us to think about. Of course, there are examples of where things went right for us or our colleagues as well.

What happens when an IVF lab is "out of control"? The effects can be very varied, and not all aspects will appear at the same time (or ever), but some, many, or all of the following features will be revealed.

- Unpredictable and inexplicable variations in outcomes (and indicators, if they're being followed), with a likely general downward trend in results. In extreme cases things might deteriorate to such a state that the best description is that "the wheels have fallen off."
- That generalized perception that the feeling of "comfort" that you had when things were running smoothly fades, and ultimately a sense of panic (controlled or not) might eventuate.
- Everyone starts to get "defensive" and this can deteriorate into fault-finding, "finger-pointing," and blame. If this is not checked then a general culture of fear, blame, and retribution can develop, and the lab (and, by then, probably the whole clinic) can become a "toxic workplace."

If you recognize any of these symptoms in your lab or clinic then you should definitely read on!

When we were asked to sum up what the first edition of this book would be about, and what its focus would be, we synthesized our concepts and ideas, our beliefs and attitudes, as well as summarizing our then combined 60 years of practical experience in the field into the simple statement of "taking a holistic approach to prophylactic management" – achieving prevention rather than cure. For the revised and expanded second edition we have retained this basic philosophy, which has only been strengthened over the past decade.

Chapter

2 Regulation, licensing, and accreditation

What's the difference?

Regulation, licensing, and accreditation are often confused with each other, or seen as alternative viewpoints on how IVF labs are governed. In fact, they are different concepts and all three must work together within an integrated system of governance. Let's start with some definitions.

Regulations: These are legal requirements[1] to which an organization or individual must conform in order to operate. Compliance is often verified by inspection (examination for individuals) and confirmed by the issuance of a license. Regulations are typically highly prescriptive as to what an organization or individual must/must not do in order to be compliant.

Accreditation: This is a collegial process based on self- and peer-assessment whereby an authoritative body (usually a non-government organization) gives formal recognition that an organization is in voluntary compliance with one or more Standards set by the authoritative body. Unlike licensing, accreditation is based upon process rather than procedure, and the principles of quality improvement rather than strict obedience of regulations, so that it is not prescriptive in relation to technical procedures or rules. The end result of an accreditation process (being "accredited") is often termed certification or registration by the authoritative body.

Licensing: This is the process whereby an organization (or individual) is identified as being compliant with required regulations. Usually, licensing is a legal requirement under government regulations in order for an organization to be allowed to operate (*c.f.* certification). For individuals, licensing is conferred to denote their competence to perform a given activity (e.g. driving a motor vehicle) in compliance with regulations.

Some other terms that are heard or seen in discussions of regulation, licensing, and accreditation that, unless used properly and not synonymously, include "certification" and "credentialling" (*c.f.* "licensing"), "standards" as compared to "regulations," and "inspection" versus "survey." Again, some more definitions:

---

[1] *A requirement is a need or expectation that can be either stated explicitly, customarily implied, or obligatory (i.e. a regulation).*

Certification: This is the process whereby an organization (or individual) is identified as meeting one or more selected standards. The term is essentially synonymous with "registration" in the ISO system. A certification report will typically highlight any areas of non-conformance and require changes that "must" be made in order to achieve certification, as well as recommendations or suggestions of changes that the organization "should" or "could" make to improve its operations (*c.f.* licensing).

Several national societies have developed certification schemes for clinical embryologists, e.g. the UK Association of Clinical Embryologists, Australia's Scientists in Reproductive Technology, the College of Reproductive Biology (a special interest group within the American Association of Bioanalysts) in the USA, and the ART Lab Special Interest Group of the Canadian Fertility and Andrology Society. These schemes award certificates to personnel based on their competence, evaluated against a set of required competencies developed by their peers, and hence can also been seen as a credentialling process (see below).

Going beyond this, in the Netherlands, only KLEM-certified embryologists can work in a legislated Dutch IVF lab (KLEM = Vereniging voor Klinische Embryologie, the Dutch Society for Clinical Embryology), and some countries have also implemented regulatory schemes that include the certification of clinical embryologists, e.g. the New Zealand Health Practitioners Competence Assurance Act of 2003. In the UK, as of October 2013, the well-developed ACE Certificate scheme was superseded by a Government (NHS) postgraduate entry-only Scientist Training Program, leading to registration with the Health and Care Professions Council.

Credentialling: This is a process for assigning specific responsibilities (or "scope of practice") to individual professionals based on their training, qualifications, experience and current practice (actual expertise) within an organizational framework. It is an employer's responsibility, with a professional development focus, that commences upon appointment and continues throughout each individual's employment. Credentialling is based on verifying that an individual meets an expected set of competencies that have been defined by their peers and are designed to ensure quality of practice and management of risk; in medicine, credentialling is sometimes referred to as "clinical governance."

Inspection: This is a process carried out by one or more authorized inspectors, to determine whether an organization or facility conforms to a defined set of regulations. Inspection is typically a requirement for licensing under regulations.

Standards: These are published documents that contain technical specifications or criteria to be used consistently as rules, guidelines, or definitions of characteristics to ensure that materials, products, processes, and

services are fit for their purpose. Unlike a regulation, a Standard is a "living document" that describes a voluntary agreement between all stakeholders relevant to the product or service, and encompasses everything that can have a profound influence on the product or service, especially its safety, reliability, and efficiency. Compliance with Standards is ascertained through a process of assessment or accreditation, rather than inspection. These Standards are not synonymous with "minimum standards," which, while they define the minimum technical requirements for a process to be performed or undertaken, do not usually consider anything beyond basic quality control (i.e. do not consider quality improvement or the quality cycle, see Chapter 3).

Survey: This is the preferred term for the visit to a facility or organization that is being assessed for accreditation. A survey typically follows a self-assessment process by the organization and is performed by a (typically) multidisciplinary survey team that evaluates the organization's progress towards the goals described in the Standards. (See "A generic accreditation process," below).

Regulation and licensing of IVF

Regulation and licensing are systems that are imposed on an organization, such as a clinical laboratory or an IVF center. These systems, which are not optional, are usually created and enforced via legislation and consequently vary widely between countries, and even between states in countries such as Australia and the USA. Licensing bodies (e.g. the Human Fertilisation and Embryology Authority, the HFEA, in the UK) typically issue a licence after an inspection process to confirm that an organization is, indeed, operating in accordance with the law. While this process does create some sort of minimum standards to which the facility or organization will operate, there is often no consideration of performance standards or quality within the terms of the licensing process.

The European Union Tissues and Cells Directive (EUTCD) 2004/23/EC seeks to set "standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells," with practical matters relating to donation procurement and testing being covered in a 1st Technical Directive (2006/17/EC), and operational technical requirements being covered in a 2nd Technical Directive (2006/86/EC). Together these three directives provide a framework for the operation of tissue banks across the EU, including IVF labs. Member states have since incorporated these directives into their national legal laws, and have each conferred regulatory authority on a national agency for their implementation and operation, e.g. the UK HFEA, the Irish Medicines Board, and the French Agence de Biomédecine.

Regulation and licensing are therefore not particularly relevant to the focus of this book, and will be left for other authors to explore. Instead, our focus will be on the setting of – and complying with – Standards that go beyond meeting minimum standards, an approach that can be described simplistically as seeking to achieve best practice. The formalization of such an approach is usually referred to as certification or accreditation. As defined above,

"certification" is typically used when referring to standards such as ISO Standards (see below), while "accreditation" is a more broad-based approach founded upon a perpetual process of quality improvement.

As a final word, we must all be aware of other regulations that we are obliged to follow in any workplace:

- Regulations that affect the employer/employee relationship, such as those that create statutory requirements pertaining to maximum work hours, statutory holidays, annual leave, etc. Labor relations in general is an area that no employer can ignore – if for no other reason than a disgruntled employee will be sure to remind him/her of them!
- The handling and use of hazardous materials such as flammable solvents, strong acids and alkalis, liquid nitrogen, radioactive materials, etc. All materials used in the IVF lab must be stored, handled, and used correctly for the safety of everyone – and the facility. For example, in Canada the Workplace Hazardous Materials Information System (WHMIS) is designed to reduce the risk from hazardous products in the workplace at all levels (i.e. suppliers, workers, and employers) through proper training and the requirement that a Material Safety Data Sheet (MSDS) for each product must be available to anyone who comes into contact with it.
- General occupational health and safety.
- Fire regulations.
- Building codes.

Add to this the complexities of the EUTCD, for example, and there is a veritable minefield of regulation that affects almost everything we do, from designing a lab to how high a fire extinguisher can be placed above the floor! Just because someone works in a (small) private IVF lab and, in their opinion, "something-or-other doesn't matter here," does not give them any right to break such regulations. Ignore them at your peril!

Accreditation

As defined already, accreditation is a voluntary, collegial process based on self- and peer-assessment whereby an authoritative body (usually a non-government organization) gives formal recognition that an organization is complying to an acceptable degree with one or more Standards set by the non-government body. Accreditation is based on process rather than procedure, and the principles of quality improvement rather than strict obedience of regulations. An accreditation scheme is not prescriptive in relation to any technical procedures or rules.

Accreditation Standards are most definitely not "minimum standards." Minimum standards only define the essential technical requirements for a process to be performed or undertaken, including the basic quality control procedures necessary to ensure that it has been done correctly; they do not usually consider quality improvement or the quality cycle (see Chapter 3).

Accreditation Standards contain the technical specifications or criteria that must be applied consistently – whether as rules, guidelines, or definitions of characteristics – to ensure that materials, products, processes, and services are fit for their purpose. Moreover, an accreditation Standard describes a voluntary agreement between all parties involved in the product or service, and it encompasses every component or factor that can influence the

product or service, especially its safety, reliability, and efficiency. Because our understanding of the processes by which we create a product or provide a service grow with experience, it is vital that an accreditation Standard be a "living document." Processes are dynamic and therefore Standards cannot be embodied within legislation that will probably take years to modify or reform.

Determining whether an organization is complying with an agreed set of accreditation Standards involves a process of assessment and evaluation that typically includes a self-assessment exercise in advance of a *survey* (not an "inspection" or "assessment" site visit) by a multidisciplinary team of surveyors who have received specialized training in reviewing an organization's systems and processes – both as generalized concepts and with specialist, industry-specific knowledge and experience. The organization seeking accreditation is supplied with a set of descriptive Standards against which it can evaluate itself and then submit a preliminary self-assessment. After review of this document, a survey team is sent out to review the organization and its operations and assess their compliance with the Standards and their progress towards achieving their goals.

The following are examples of accreditation schemes:

Australia: The Reproductive Technology Accreditation Committee or "RTAC," which operates under the aegis of the Fertility Society of Australia. RTAC accreditation (now achieved via audit by an independent certifying body under the Joint Accreditation Scheme of Australia and New Zealand [JAS-ANZ]) is required for all IVF units in Australia in order for their patients to receive Medicare rebates for IVF treatment and to access gonadotrophins under the Government's Pharmaceutical Benefits Scheme. IVF centers in New Zealand also participate in the RTAC accreditation scheme.
Australia: The National Association of Testing Authorities or "NATA" accredits all testing facilities including medical laboratories, which are accredited according to ISO 15189. Although IVF units are not required to have NATA accreditation, several have sought this independent accreditation. However, any laboratory performing diagnostic testing (e.g. andrology or endocrine) must be NATA accredited.
Australia: Australian Council on Healthcare Standards or "ACHS" is a non-government organization that accredits hospitals and healthcare organizations.
Canada: Accreditation Canada (previously the Canadian Council on Health Services Accreditation or "CCHSA") is a non-government organization that accredits hospitals and healthcare organizations. An accreditation scheme for IVF clinics was developed jointly with the Canadian Fertility and Andrology Society (CFAS) in the early 2000s within what was then the CCHSA's "AIM" program (Achieving Improved Measurement), and then revised to come under Accreditation Canada's "Qmentum" program in 2010.
UK: Clinical Pathology Accreditation (UK) Ltd or "CPA" is a non-government organization that accredits medical laboratories. It also operates several external quality assurance (EQA) schemes.

With the development of the 7th edition of its code of practice, published in 2007, the HFEA took the unusual step of integrating accreditation principles with its licensing requirements, combining the HFE Act 1990 and the EUTCD, along with embracing the principles of ISO 9001 and ISO 15189.
USA: The College of American Pathologists or "CAP" operates a voluntary Reproductive Laboratory Accreditation Program (RLAP) that was developed in conjunction with the American Society for Reproductive Medicine (ASRM). However, this program only applies to laboratories performing andrology tests regulated by CLIA'88; IVF centers are not accredited by the CAP RLAP.

USA: The Joint Commission on Accreditation of Healthcare Organizations or "JCAHO" is an independent, not-for-profit organization that considers itself to be the nation's predominant standards-setting and accrediting body in healthcare. JCAHO accredits all types of laboratories and healthcare organizations, including IVF labs.

Beyond these national accreditation schemes there is international accreditation by the International Organization for Standardization, commonly known as "ISO," whose Standards are being increasingly seen as the "gold standard" for IVF clinics.

ISO standards

The International Organization for Standardization (www.iso.ch) or "ISO" is based in Geneva and develops standards according to the essential principles of:

consensus – the views of all interested parties are taken into account: manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions, and research organizations;
industry-wide – they are global solutions intended to satisfy industries and customers worldwide; and
voluntary – international standardization is market-driven and therefore based on the voluntary involvement of all interests in the marketplace.

The following ISO standards are relevant to IVF centers and their laboratories.

The ISO 9000 family of standards

The first edition of the ISO 9000 series of standards for quality management and quality assurance was released in 1987, at which time they were known in the various member countries by their own designation (e.g. BS 5750 in the UK). The second edition was introduced in 1994 when most countries made their numbering compatible with the ISO system:

1. ISO 9001:1994 *Quality Systems – Model for Quality Assurance in Design, Development, Production, Installation and Servicing.* This standard was essentially directed towards manufacturers.
2. ISO 9002:1994 *Quality Systems – Model for Quality Assurance in Production, Installation and Servicing.* This standard was very similar to ISO 9001:1994 but had no requirements for design control, being aimed essentially at service organizations.
3. ISO 9003–1994 *Quality Systems – Model for Quality Assurance in Final Inspection and Test.* This standard was intended for quality testing organizations.

For the third (2000) edition, ISO 9002 and ISO 9003 were withdrawn, leaving just one standard for certification: ISO 9001:2000. This single quality management system requirement standard replaced the three quality assurance requirement standards ISO 9001:1994, ISO 9002:1994, and ISO 9003:1994. ISO 9001:2000 was developed to assist organizations of all types and sizes to implement and operate an effective quality management system (QMS) based on a more process-based approach, including an expectation of processes for ensuring continuous improvement.

Therefore, ISO 9001:2000 specifies requirements for a user-defined QMS that will allow an organization to demonstrate its ability to provide products that meet customer requirements and applicable regulatory requirements, and aims to enhance customer satisfaction. Organizations can exclude certain requirements of the standard if some of its clauses are not relevant to their quality systems.

The ISO 9000 family now comprises four core standards that form a coherent set of QMS standards facilitating mutual understanding in national and international trade (see http://www.iso.org/iso/iso_9000):

1. ISO 9000:2005 *Quality Management Systems – Fundamentals and Vocabulary*, covering the basic concepts and language.
2. ISO 9001:2008 *Quality Management Systems – Requirement*, which sets out the requirements of a quality management system. ISO 9001 *Quality Management Systems* is currently under review, with an updated version expected by the end of 2015.
3. ISO 9004:2009 *Managing for the Sustained Success of an Organization – A Quality Management Approach.* This document focuses on how to make a quality management system more efficient and effective. It provides guidelines for both effectiveness and efficiency based upon the fundamental aim of improving the performance of an organization and the satisfaction of customers and other interested parties.
4. ISO 19011:2011 *Guidelines for Auditing Management Systems*, providing guidance on internal and external audits of quality management systems.

ISO standards for laboratories

For laboratories there are other, specific ISO standards that affect them. Until the early 2000s this was the ISO standard applicable to all laboratories (ISO/IEC 17025:2000 *General Requirements for the Competence of Testing and Calibration Laboratories*; now ISO 17025:2005), but for medical laboratories it was superseded by ISO 15189:2003 *Medical Laboratories – Particular Requirements for Quality and Competence*, now ISO 15189:2012. This new standard specifically considers the provision of laboratory-based medical services and is, therefore, the relevant ISO standard for andrology and IVF labs.

Therefore, while IVF centers might choose to be accredited according to ISO 9001:2008, their laboratory activities must (also) comply with ISO 15189:2012.

A generic accreditation process

Accreditation can be viewed as a structured means of achieving positive organizational change, rather than change being enforced through an adversarial process. Usually, the accrediting authority is a non-governmental organization or not-for-profit company that has developed, in consultation with the professional bodies and other stakeholders involved in the particular field, a set of Standards that represent the consensus opinion as to operational standards and performance in the field. Effective accreditation schemes around the world share the same three basic characteristics (see Figure 2.1):

1. Self-study/evaluation/assessment;
2. External assessment via a survey by peers; and
3. Recommendations.

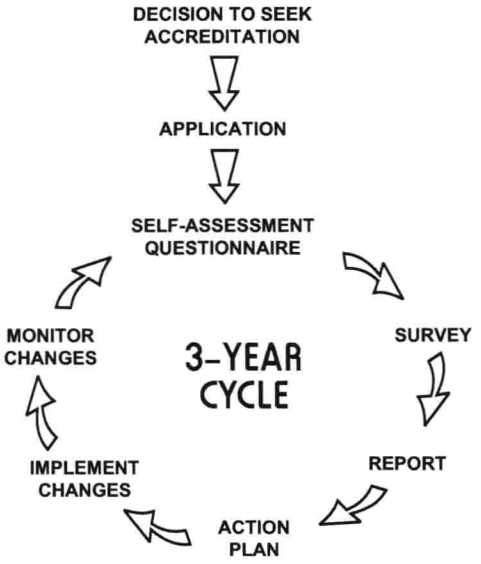

Figure 2.1 A generic accreditation process.

Self-assessment

An initial self-assessment by the organization is at the heart of accreditation. The organization undertakes a comprehensive examination of all aspects of its mission, programs and services, a process that necessarily involves individuals from every area and level of the organization, as well as the organization's customers (patients and referrers) and, ideally, the public. Input from all these "stakeholders" is used to create a detailed self-assessment report documenting the organization's current status quo.

Sometimes, during preparation for the self-assessment phase, on-site focus group consultations might be held that allow surveyors (not necessarily the ones who will undertake the actual formal survey of the organization) to meet with staff, patients, and the organization's community stakeholders. The goal of these meetings is to help increase communication and collaboration throughout the organization, and thereby improve the validity of the self-assessment exercise's findings. The self-assessment process has the following goals:

- to determine compliance with established accreditation criteria or "Standards";
- to assess the organization's alignment with its own stated philosophies and goals, as well as those that might be imposed by any regulatory authority, in terms of patient care and the delivery of service;
- to evaluate outcomes and effectiveness; and
- to identify, and prioritize, areas for improvement.

A major benefit that flows from the self-assessment process is the "buy-in" to the process from everyone involved ("Building a Process Map" in Chapter 5).

Typical accreditation Standards cover the following operational areas of the organization, across which the concepts of "education for life" and "achieving best results" are overarching philosophical principles.