1

Introduction

It seems that we hear news reports of disasters in IVF clinics almost weekly. Public concern over these reports has resulted in governments introducing regulation of IVF labs around the world, and within our profession there is a growing recognition of the need for accreditation of IVF labs to ensure that the potential for such errors occurring is minimized.

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 often poorly understood by biomedical scientists, especially outside clinical chemistry and pathology laboratories. In particular, risk analysis and minimization are being demanded of IVF labs, but many IVF scientists have only limited understanding of how to go about these tasks. Perhaps this is because the majority of scientists working in clinical IVF labs have come from academic/research backgrounds and, as a consequence, many have limited experience of the practicalities of laboratory management – and even fewer have any formal training in it. Certainly IVF has evolved rapidly over the last two-and-a-half decades or so: from its beginnings as a highly experimental procedure in the late 1970s, culminating in the birth of Louise Brown on 25 July 1978 (Edwards and Steptoe, 1980), to a rapidly expanding field of research and 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 intracytoplasmic sperm injection [ICSI]) is increasingly seen by many as a commodity product, especially in the developed world.

As a result of this global expansion and commercialization, quality management and risk management are becoming increasingly important to those responsible for running IVF clinics, and consequently they are fast becoming "hot topics" for scientists working in them.

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 have 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; International Standards Organization, 2000) 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 which typically operate multiple sites. Figure 1.1 shows a generic concept for viewing the organization of an IVF Center by disciplines, which 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

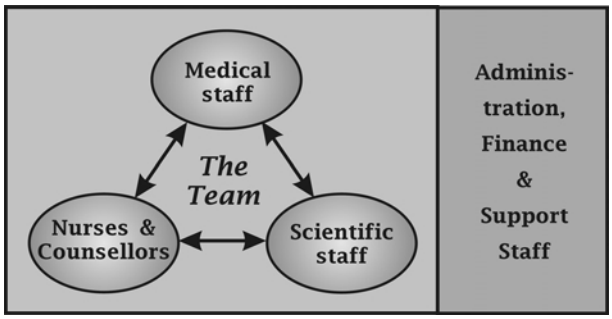

Figure 1.1 Diagrammatic representation of the organization of an IVF Center showing the "core team" that must have effective administration, finance and support teams working alongside it.

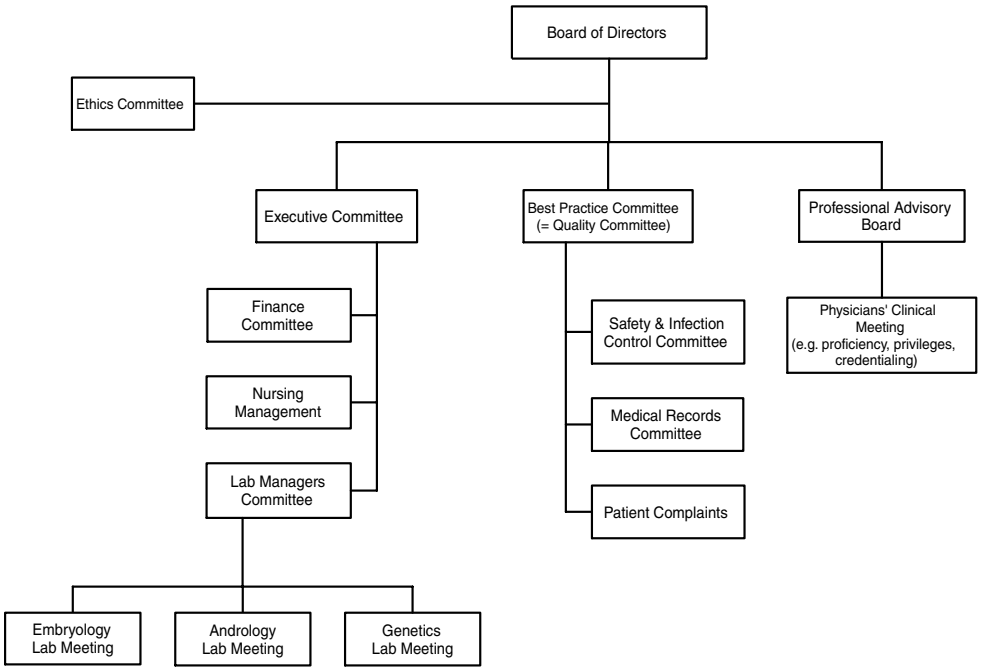

Figure 1.2 Organization chart showing the committee structure that might be required to run a large IVF Center according to the principles of Total Quality Management – or a generic accreditation scheme.

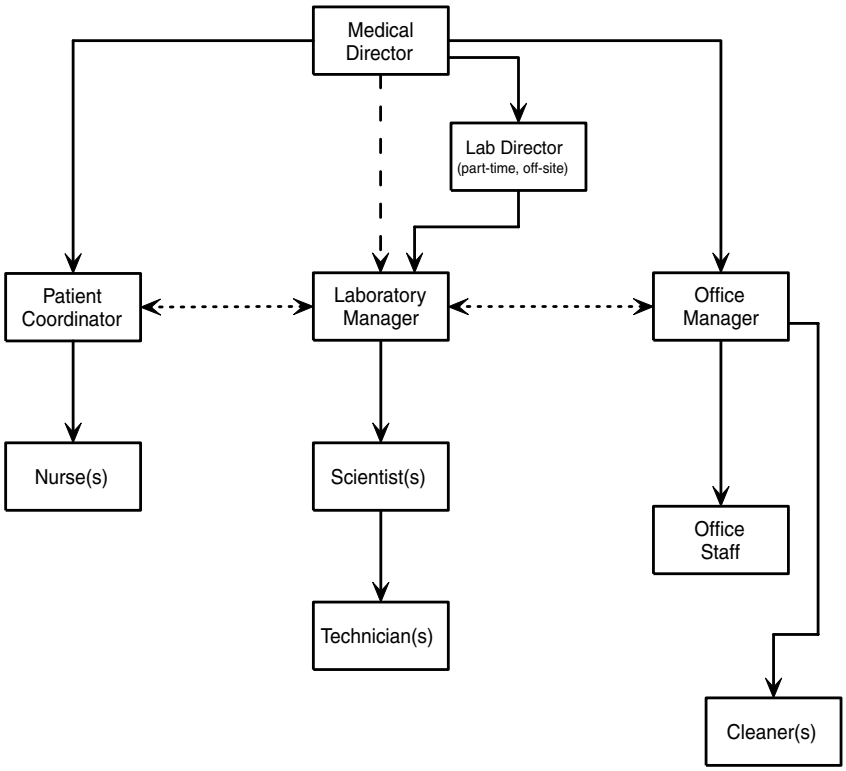

Figure 1.3 Organization chart for a small ("boutique") IVF Center.

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 is an essential prerequisite for anyone embarking upon implementing programs of quality management and risk management.

Fortunately, each Center does not need to reinvent the disciplines of quality management and risk management. Not only have several 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 from other areas of business. There are many resources available to Centers embarking upon this journey, ranging from "self help" and reference books at all

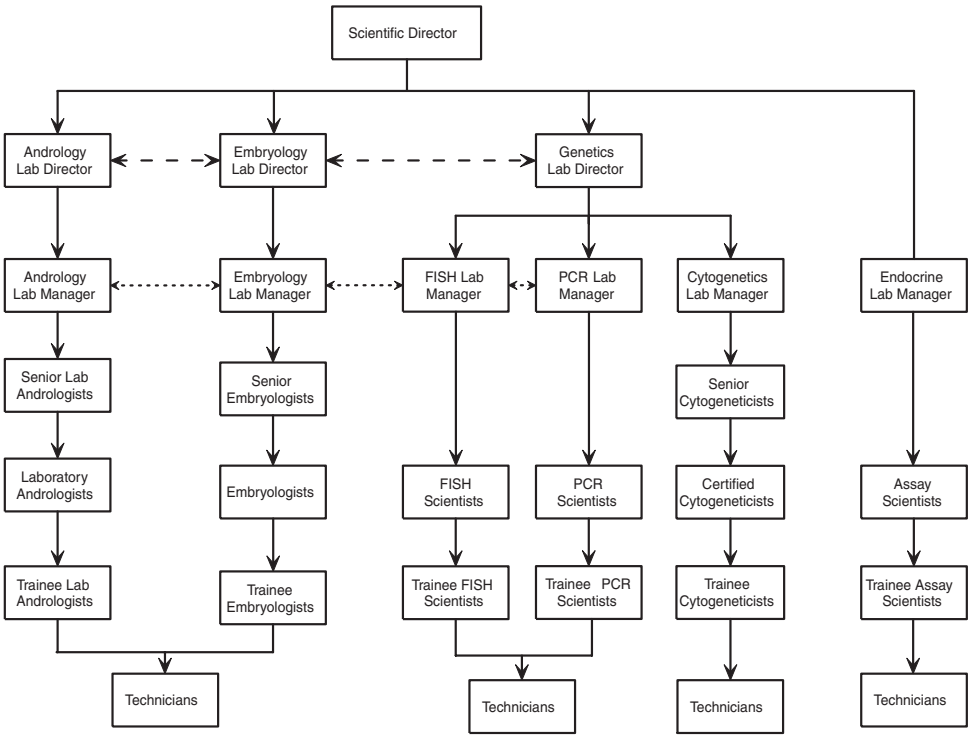

Figure 1.4 Organization chart for the laboratory operations of a large IVF Center.

levels (e.g. Dale and McQuater, 1998; Heller and Hindle, 2003) 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.

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 for developing and implementing management systems in your own lab.

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 this book would be about, what its focus would be, we synthesized our concepts and ideas, our beliefs and attitudes, as well as summarizing our combined 40 years of practical experience in the field into the simple statement of "taking a holistic approach to prophylactic management" – achieving prevention rather than cure.

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* 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.

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

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 [cf. 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.

Other specific terms that are often confused and misused as synonyms when discussing regulation, licensing, and accreditation include: "certification" [cf. "credentialing" and also "licensing"], "standards" as compared to "regulations," and "inspection" as opposed to "survey." Again, some more definitions:

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 nonconformance 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. [cf. licensing]

Credentialing 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. Credentialing is designed to ensure quality of practice and management of risk, in medicine it 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 which 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.