The indispensable role of accreditations in assisted reproductive technology laboratories around the world

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Published: 2025-01-15 | DOI: 10.82098/icmed-mag.2025.01.002

ABSTRACT

Assisted reproductive technology (ART) laboratories have emerged as a key element in supporting the health and well-being of couples facing fertility problems. In this...

Assisted reproductive technology (ART) laboratories have established themselves as a key element in supporting the health and well-being of couples facing fertility problems. In this area of social and clinical relevance, accreditations play a key role, helping to ensure that laboratories operate according to rigorous quality and safety standards. These accreditation schemes define best practices to ensure effective performance, forming a necessary framework for the delivery of patient-oriented services.

However, the path to effective accreditation is not without its challenges. In several countries, accreditation management is still in its infancy and, in some cases, regulatory procedures are insufficient or in the process of being established. This reality limits high-standard integration in health services, creating disparities in access to quality procedures between jurisdictions. Through this article, we will explore the importance of accreditations in ART laboratories, the difficulties that exist and the various approaches taken globally.

The Significance of Accreditations

Accreditation in assisted reproductive technology (ART) laboratories goes far beyond a mere bureaucratic formality; it is, in fact, a guarantee of reliability and a commitment to quality for all patients and their families. This accreditation process involves a series of thorough assessments that examine in detail every aspect of the laboratory's operations, from the rigorous protocols adopted to the qualification and training of staff. These inspections aim to ensure that high and highly desired standards are met, creating an environment conducive to the adoption of state-of-the-art clinical practices and continuous improvement.

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Standardised and well-defined, accreditation protocols promote high quality clinical practices, helping to increase the likelihood of success in fertility-focused treatments. Standardisation allows for uniform procedures and established methodologies, which are essential to ensure consistency and reliability of results. This, in turn, translates into greater safety for patients, as it can mean more effective treatments and fewer complications.

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In addition, accreditation helps to build and strengthen patient confidence in the healthcare system. Knowing that a laboratory operates according to accredited procedures provides patients with the necessary reassurance about the quality of the treatment they will receive. This certainty not only reduces the anxiety associated with the treatment process, but also encourages more informed management of their expectations and decisions.

They also have the confidence to know that a laboratory operates according to accredited procedures.

Finally, accreditation provides important transparency regarding the overall performance of healthcare practices. Performance data, collected and analysed through these processes, provide a clear and quantitative picture of the probability of success and potential complications that may be associated with various treatments. This availability of information not only helps patients to make more informed choices, but also contributes to a direct line of communication between laboratories and the medical community, thus stimulating a culture of accountability and continuous improvement within the industry.

The information is not only available to patients, but also to the medical community.

Difficulties in Accreditation

Although accreditations are fundamental to ensuring quality and safety in assisted reproductive technology laboratories, there are several difficulties that can hinder their effectiveness. One significant issue is the lack of global standardisation. Regulations vary considerably from one country to another, reflecting cultural and legal differences that can make accreditation practices complex. This variability can lead to significant differences in the way laboratories implement quality, possibly resulting in a patchwork of practices that can challenge consistency and uniformity.

In addition, the costs associated with accreditation can be an obstacle, particularly for laboratories in countries with limited economic resources. The investments required for training,

infrastructure and ongoing monitoring practices can be burdensome.

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Another issue is the presence of non-uniform regulations, which may compromise compliance with guidelines due to regulations that are sometimes subjective or deficient. This loosening of regulations does not always encourage laboratories to maintain strict standards, especially where accreditation is not compulsory or strongly implemented.

These regulations are not always uniform.

Finally, in developing countries, accreditation systems are frequently in a state of flux. Here, the transition to more defined accreditations is complex, and economic and logistical challenges may delay progress. Therefore, there is a clear need for improved accreditation procedures and a more coherent approach across the sector so that all ART laboratories can offer high quality services for couples seeking fertility support.

Accreditation Schemes in the World

In **Canada**, accreditation for ART laboratories is rigorous, authorising only those facilities that meet the guidelines dictated by the Assisted Human Reproduction Act to process donated gametes.

- **Scheme:** Licensing for primary facilities producing donor gametes
- **Status:** Mandatory
- **Basis/Origin:** Assisted Human Reproduction Act (S.C. 2004, c.2)
- **Supervisory Body/Authority:** Health Canada.

In **Egypt**, accreditation of ART clinics is compulsory and based on specific national regulations developed by the Ministry of Health, which aim to ensure effective standards of care.

- **Scheme:** Accreditation for ART clinics
- **Status:** Mandatory
- **Basis/Sources:** Local system adapted from international sources

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• **Supervisory Body/Authority:** Ministry of Health and Population.

In **France**, the practice of ART is regulated by bioethical laws. Laboratories are required to be licensed by the public health system and are subject to consecutive inspections, which guarantee access to high quality medical practices.

• **Scheme:** Licensing for ART clinical and laboratory activities

• **Status:** Mandatory

• **Basis/Origin:** Bioethics Law; implementation of the Public Health Code

• **Oversight Body/Authority:** Agence de la Biomédecine (ABM) and Agences Régionales de Santé (ARS).

In **India**, accreditation for ART laboratories is currently being developed through legislation to regulate assisted reproductive practices. The ICMR has provided national guidelines to ensure safety and quality standards in the services offered to patients.

• **Scheme:** Mandatory accreditation system being implemented through the “National ART and Surrogacy Bill”

• **Status:** Mandatory (under implementation)

• **Basis/Origin:** Indian Council of Medical Research (ICMR) guidelines)

• **Oversight Body/Authority:** Governed by the National ART and Surrogacy Bill, supported by the ICMR.

In **Italy**, the accreditation of assisted reproductive technology (ART) laboratories is compulsory and managed at regional level in accordance with national legislation on assisted reproduction. This system aims to ensure that laboratories meet high standards, thus contributing to optimising the quality of services and providing adequate protection for patients.

• **Scheme:** Regional Authorisation/Accreditation

• **Status:** Mandatory

• **Basis / Origin:** National Law 40/2004 and Legislative Decrees 191/2009 and 16/2010; EUTCD

• **Supervisory Body/Authority:** National Transplant Centre.

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In the **Middle East**, many nations are working to establish or improve accreditation schemes for ART laboratories, with progress diverging from accreditation requirements to new facilities requiring decent operations.

• **Scheme:** Evolving Accreditation Schemes for ART Laboratories

• **Status:** Evolving

• **Basis/Origin:** An established regulatory framework requiring ART laboratories to obtain accreditation

• **Supervisory Body/Authority:** Local Government Agencies.

In the **Netherlands**, legislation requires that every reputable ART laboratory adhere to specific recognition standards, such as those described in ISO 15189, thus ensuring high quality practices in fertility care.

• **Scheme:** Accreditation for ART laboratories

• **Status:** Mandatory

• **Basis / Origin:** ISO 15189

• **Supervisory Body/Authority:** RvA (Raad voor Accreditatie).

In the **United Kingdom**, the **Human Fertilisation and Embryology Authority** (HFEA) regulates ART centres, obliging these facilities to follow strict requirements to ensure high standards of medical practice.

• **Scheme:** Licence for ART centres

• **Status:** Mandatory

• **Basis/Origin:** Human Fertilisation and Embryology Act (HFE Act)

• **Supervisory Body/Authority:** Human Fertilisation and Embryology Authority (HFEA).

In **Spain**, ART laboratories are required to obtain a compulsory licence and follow guidelines prescribed by national law to ensure quality and safety standards at treatment facilities.

• **Scheme:** Licence for ART laboratories

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• **Status:** Mandatory

• **Basis/Origin:** Law 14/2006; Royal Decree 1301/2006 and Royal Decree Law 9/2014
• Supervisory Body/Authority: Ministry of Health and local authorities.

In the **United States**, the accreditation system varies significantly between jurisdictions, with a model programme for embryo laboratories. Each state has the authority to implement specific rules, which can lead to significant variations in the quality of services.

• **Scheme:** Model scheme for embryo laboratories (voluntary for the states concerned)

• **State:** Voluntary

• **Basis/Origin:** Fertility Clinic Success Rate and Certification Act (FCSRCA)

• **Supervisory Body/Authority:** Centers for Medicare and Medicaid Services (CMS) and FDA.

In **Turkey**, ART laboratories must obtain a licence from the Ministry of Health, which sets quality and safety regulations. Recently, accreditation under ISO guidelines has grown, contributing to higher standards.

• **Scheme:** Licensing for ART labs

• **Status:** Mandatory

• **Basis/Source:** Quality Management Standard for ART of the Ministry of Health

• **Supervisory Body/Authority:** Ministry of Health.

Conclusions

One of the key recommendations that has emerged in recent years from various international working groups is the need to draw up a universal technical guide for ART accreditation, which could serve as a globally recognised reference point for laboratories and accreditation bodies. This approach would make the adoption of ever-improving quality standards more consistent and address vulnerabilities historically present in current systems, creating opportunities for greater consistency in performance evaluations globally.

They also warned that the use of ARTs would not be consistent with the current system.

In addition, experts warn that even in the absence of full access to accreditation schemes,

laboratories should still engage in peer review of their activities and results. This call for self-auditing and the practice of good laboratory standards is crucial not only to improve continuity of services, but also to pave the way for continuous improvement through mutual learning between laboratories.

The ability to cope with unforeseen events, such as pandemics or natural emergencies, è another key point particularly highlighted after the emergence of COVID-19. This pandemic has revealed the vulnerabilities of health systems and the need for strategic preparedness, making it essential that such considerations become an integral part of accreditation processes. During COVID-19, many assisted reproductive technology (ART) laboratories faced significant disruptions, including temporary suspension of treatments and implementation of strict safety protocols, such as patient screening and staff protection. These experiences have shown that proactive laboratory-led measures—from safety enhancement, emergency planning to cooperation between different centres to rapidly adapt operational practices in extreme cases—are crucial to ensure not only the protection of results, but also to maintain the long-term competitiveness of reproductive care.

In summary, the future of global accreditation schemes for ART laboratories requires a collective effort to innovate, standardise, dialogue and ensure that best practices are adopted, making us feel more confident in interacting with the world of fertility.

Suggested citation:

Iaconianni V. The indispensable role of accreditations in assisted reproductive technology laboratories around the world. ICMED Magazine. 2025;2025(1). doi:10.82098/icmed-mag.2025.01.002

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