

## REVIEW

# Embryologist staffing in assisted reproductive technology laboratories: An international comparative review

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**Abstract**

**Background:** Embryologists are crucial in assisted reproductive technology (ART), yet their duties, education, and licensing requirements vary significantly across countries, complicating the determination of optimal staffing levels in ART laboratories. With anticipated advancements such as automation in ART laboratories, this review comprehensively analyzes factors necessary for appropriate future staffing.

**Main Findings:** A comprehensive literature search was conducted using PubMed to identify relevant articles up to July 2024, employing keywords such as “embryologist,” “staffing,” and “certification.” Articles were evaluated for content related to laboratory operations, and guidelines from five organizations regarding licensing and education were compared.

**Results:** The review revealed significant international differences in embryologist certification, duties, and staffing recommendations. These disparities, along with the integration of advanced ART technologies and regulatory requirements, significantly impact future staffing needs in ART laboratories.

**Conclusion:** The definitions of an ART cycle and required staffing levels vary across organizations, influenced by the certification and duties of embryologists in different countries. Adequate embryologist staffing is essential for ensuring laboratory quality control and impacting patient ART outcomes. As new technologies and automation reshape laboratory workflows, collaborative efforts among organizations, countries, and embryologist associations are essential for developing comprehensive educational curricula and determining appropriate staffing levels.

**KEYWORDS**

ART laboratories, automation in ART, embryologist, embryologist certification, staffing

## 1 | INTRODUCTION

Embryologists are indispensable in assisted reproductive technology (ART) clinics, yet there is no international consensus on optimal staffing levels for ART laboratories. Consequently, various countries

and organizations have independently established their recommendations regarding the required number of embryologists and other specialized personnel.

In Japan, as of April 2022, many ART procedures have been covered by national health insurance. Unlike doctors, nurses, and clinical

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laboratory technicians who hold national licenses, embryologists in Japan are certified privately, either as an “embryologist for assisted reproductive medicine” by the Japan Society for Ova Research (JSOR) or as a “clinical embryologist” by the Japanese Society of Clinical Embryologists (JSCE).<sup>1</sup> Furthermore, it is not mandatory for embryologists in Japan to obtain these private certifications. The presence of multiple certification systems for embryologists within the same country, such as Japan, complicates international comparisons of staffing. Certification is a critical issue in comparing international ART laboratory staffing. Embryologist duties and scope of work vary significantly due to differences in legal systems across countries, which also impact the training curricula for embryologists. These aspects are critical to understanding staffing in ART laboratories. Although several reports discuss the status of embryologists in different regions,<sup>1,2</sup> there has not been a comprehensive examination of the global situation.

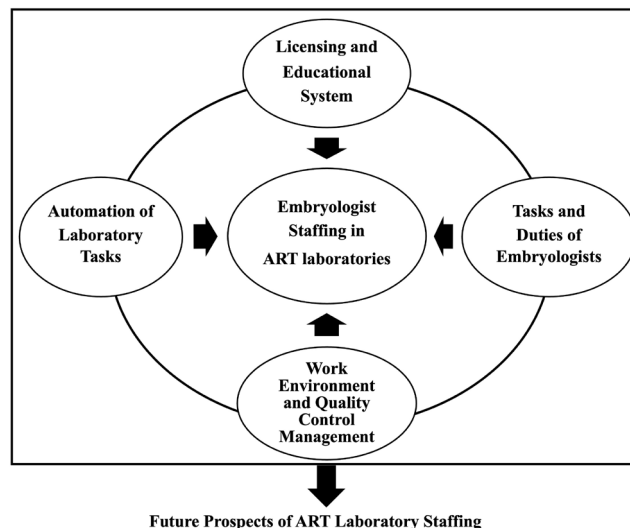
This review provides a comprehensive analysis of ART laboratory staffing, offering an international comparison of embryologist requirements and examining key factors influencing staffing levels. These include task distribution, certification and licensing systems, educational frameworks, and the increasing automation of laboratory tasks. By synthesizing prior research, including recent international reports following the introduction of Japan's national health insurance coverage for ART in 2022, this review offers a distinctive perspective. To the best of our knowledge, this is the first review to investigate the current situation in embryologists' ART environment, incorporating reports published after national insurance coverage.

## 2 | MATERIALS AND METHODS

A comprehensive literature search was conducted using PubMed to identify relevant articles up to July 1, 2024. The search strategy employed the following keywords: “embryologist + laboratory” (214 results), “embryologist + staff” (39 results), “embryologist + staffing” (15 results), “embryologist + certification” (7 results), “embryologist + work” (130 results), and “embryologist + Japan” (24 results).

The search identified 449 articles. After removing duplicates, 336 unique articles remained. While no articles overlapped across all six search strategies, five appeared in five results, seven in four, 12 in three, 48 in two, and 264 were exclusive to a single strategy. Eleven articles were initially selected for this review: five<sup>3-7</sup> identified in all five search strategies and six<sup>8-13</sup> from the seven identified in four strategies, excluding one older article deemed less relevant. These 11 articles addressed embryologist staffing, task distribution, education and certification, laboratory practices, and work-related factors.

The remaining 324 articles, which matched three or fewer search strategies, were also assessed for relevance. Abstracts and full texts were systematically reviewed, and unrelated articles were excluded. Ultimately, three articles<sup>14-16</sup> from the 12 identified by three strategies, 12 from the 48 identified by two, and 29 from the 264 identified by one strategy were included. These articles explored ART



**FIGURE 1** Overview of the six key concepts discussed in this review. The relationships between each section are illustrated. ART, assisted reproductive technology.

laboratory staffing, automation, artificial intelligence (AI), and embryologists' health. A hand search supplemented the findings with additional insights on trends in intracytoplasmic sperm injection (ICSI) and ART procedures, reproductive organization guidelines not indexed in PubMed, unpublished reports from Japan, and topics related to quality management, embryologists' health, and automation. This process added 39 articles, bringing the total to 93.

We systematically reviewed the abstracts and full texts of these articles to extract and identify critical challenges related to embryologist staffing. These challenges were then categorized and examined in detail across several key areas. First, we analyzed existing guidelines on embryologist staffing from various countries and organizations, highlighting differences and commonalities. Next, we compared the expected tasks and duties of embryologists across different countries and organizations, noting differences and similarities. This was followed by an evaluation of education and certification programs for training embryologists in different countries. We then assessed the work environment and quality control practices in ART laboratories, examining their impact on the quality of embryologists' work. Recent trends in the automation of embryologist tasks and associated future challenges were reviewed, followed by a discussion on future directions and potential developments in ART laboratory staffing based on the identified challenges. These concepts are illustrated in [Figure 1](#).

### 2.1 | Ethical considerations

This study is a comprehensive literature search and review and does not fall under the “Ethical Guidelines for Life Science and Medical Research Involving Human Subjects,” thus not requiring approval from an ethics committee.

### 3 | RESULTS AND DISCUSSION

#### 3.1 | Guidelines on embryologist staffing

We examined the factors influencing staffing in ART laboratories and reviewed relevant guidelines across various countries. The factors affecting embryologist staffing are detailed in Table 1. The factors outlined in Table 1 were extracted from the 11 articles that matched at least four search strategies, as described in the Methods section. Additional (add-on) treatments, such as egg donation or preimplantation genetic testing for aneuploidy (PGT-A), significantly increase the time needed for laboratory work.<sup>3</sup> The average time required for an ART cycle was 9 h in the 1980s. However, this figure increases substantially to approximately 20.2 h when PGT-A is performed, significantly affecting staffing estimates based on the annual number of ART cycles and the technologies offered.<sup>3,11,17</sup> Additionally, the adoption of ICSI has risen sharply from around 30% in the late 1990s to 70% by 2012 in Europe and the United States, with some countries achieving a 100% implementation rate.<sup>18–20</sup> Given that ICSI requires three times more time than conventional fertilization methods,<sup>11</sup> verification processes within the laboratory are critical in daily ART tasks. Typically, all tubes and dishes are labeled with names or IDs, and manual or electronic verification processes are conducted, necessitating a minimum of two personnel in the ART laboratory.<sup>21</sup>

In 2015, approximately 7000 staff members were employed in ART laboratories across Europe.<sup>10</sup> However, the definition of staff licenses varies significantly between countries and is often ambiguous. A 2022 survey by the International Federation of Fertility Societies revealed that only eight of 33 participating countries had defined licenses for ART laboratory technical staff.<sup>22</sup> It is crucial to

ensure appropriate staffing for each medical facility, based on the staff licensing requirements.<sup>12</sup>

The staffing requirements of an ART laboratory depend significantly on the volume and types of ART procedures performed.<sup>13</sup> In recent years, the use of ICSI, PGT-A, oocyte vitrification, time-lapse imaging (TLI), and AI has increased, necessitating more time for staff training and compliance with stringent national regulations, thereby increasing the demand for staff.<sup>5,11,23</sup> The introduction of new technologies over time changes how ART laboratories operate, necessitating periodic reassessments of the required number of embryologists. Management must also consider staffing factors, including whether staff work full-time for 7 or 8 h a day, or part-time.<sup>5</sup> Additionally, whether oocyte retrievals, embryo transfer (ET), and vitrification are scheduled on weekdays or weekends impacts staffing needs. There are also reports suggesting a minimal impact on ART procedures' outcomes when scheduling changes from weekends to weekdays, making it important to schedule procedures with staffing levels in mind.<sup>24,25</sup> In cases where an electronic double-check system is not employed in ART processes, at least two staff members are essential even on weekends.<sup>26,27</sup> Recent reports from Japan highlight geographical factors and add-ons such as PGT-A as significant influencers on embryologist staffing requirements.<sup>1</sup>

As previously discussed, determining the staffing levels of ART laboratory personnel is complex and influenced by numerous factors, which has precluded the establishment of a globally unified standard for the number of embryologists. Nevertheless, various organizations have independently recommended the minimum number of embryologists required in ART laboratories. This literature review has identified recommendations from five prominent organizations.

The American Society for Reproduction Medicine (ASRM) established guidelines in 2008, outlining minimum staffing levels for embryologists based on the number of laboratory cycles.<sup>28</sup> These guidelines specified a minimum of two embryologists for 1–150 cycles, three for 151–300 cycles, and four for 301–600 cycles, with an additional embryologist needed for every 200 cycles beyond 600. In 2022, ASRM updated these guidelines to recommend 2–3 embryologists for 1–150 cycles, 3–4 for 151–300 cycles, 4–5 for 301–600 cycles, and one additional embryologist for every 150 cycles beyond 600.<sup>29</sup> The updated ASRM guidelines distinguish between oocyte retrieval and frozen–thawed ET cycles, based on the Society for Assisted Reproductive Technology's definition of these as distinct cycles.<sup>29</sup> Embryologists are categorized into senior embryologists, embryologists, junior embryologists, and embryologist trainees, with laboratory directors and assistants not included in the required number of personnel.

In Japan, the 2022 guidelines from the Japanese Society of Reproductive Medicine (JSRM) mandate that facilities performing more than 150 oocyte retrieval cycles annually must have at least two embryologists, a straightforward requirement without specific qualifications outlined.<sup>30</sup> Similarly, the European Society of Human Reproduction and Embryology (ESHRE) guidelines from 2015 require a minimum of two qualified clinical embryologists for facilities performing up to 150 oocyte retrieval and/or cryopreservation cycles per year.<sup>9</sup> In ESHRE guidelines, for more than 150 cycles, the

TABLE 1 Factors related to embryologist staffing in assisted reproductive technology (ART) laboratories.

Factors	References
Egg donation program	[3]
Preimplantation genetic testing for aneuploidy (PGT-A)	[1,3,5]
Implementation rate of intracytoplasmic sperm injection (ICSI)	[5,11]
Definition of staff licenses	[10,12]
Volume and types of ART processes	[3,11,13,17]
Oocyte vitrification	[11,23]
Use of time-lapse imaging (TLI)	[5,11,23]
Use of artificial intelligence (AI)	[11,23]
Staff training	[11,23]
Compliance with stringent national regulations	[11,23]
Full-time (7 or 8 h daily) or part-time staff	[5]
ART on weekends	[5,24,25]
Double-check system with electronic verification	[5,21,26,27]
Geographical factors	[1]

Abbreviation: ART, assisted reproductive technology.

number of required embryologists should be adjusted based on the number of treatments and the complexity of laboratory procedures and tasks.<sup>9</sup> ESHRE's guidelines also emphasize the qualifications of embryologists.

In 2023, the Asia Pacific Initiative on Reproduction (ASPIRE) issued guidelines utilizing a distinctive scoring system, where each ART procedure is scored individually and evaluated based on the total points.<sup>31</sup> ASPIRE assigns points based on the type of ART procedure, with 1.0 points for each conventional in vitro fertilization (IVF) or oocyte vitrification cycle, 0.5 points for each frozen-thawed embryo (FTE) cycle, 0.1 points for each ICSI case, and 0.5 points for each PGT-A case. Embryologists are classified as junior/trainee embryologists, embryologists, and senior embryologists, with specific requirements outlined for senior embryologists. ASPIRE's minimum standards for embryologists are two (senior embryologists: 1–2) for 1–150 cycle points, three (senior embryologists: 2) for 151–300 cycle points, and 4–5 (senior embryologists: 2–3) for 301–600 cycle points, with an additional embryologist required for every 200 cycle points above 600 (at least 50% of the total embryologists). ASPIRE's guidelines, while similar to ASRM's 2008 standards, require more embryologists due to the inclusion of ICSI and PGT-A scoring.

The staffing guidelines compiled by the Indian Society for Assisted Reproduction (ISAR) in 2021 align closely with the recommendations of ASRM in 2022 and ASPIRE.<sup>15</sup> ISAR's guidelines, akin to ASRM's approach, distinguish between the oocyte retrieval cycle and the frozen-thawed ET cycles. Their minimum staffing standards

for embryologists are two for 1–150 cycles, three for 151–300 cycles, four for 301–600 cycles, and one additional embryologist for every 200 cycles above 600. The recommendations from these five organizations are summarized in Table 2.

When comparing the recommendations from the five organizations, a consistent standard of two embryologists for 150 cycles is evident. However, it is notable that JSRM in Japan and ESHRE lack clear additional recommendations, and only Japan lacks detailed regulations regarding the qualifications of embryologists. This highlights the importance of professional standards and the necessity for clear qualifications for embryologists in the field of reproductive medicine.

### 3.2 | Tasks and duties of embryologists

One of the major challenges in determining the required number of embryologists in an ART laboratory stems from the variability in defining their tasks and duties. In 2023, a study indicated the daily tasks of embryologists as including gamete and embryo manipulation, ET, gamete or embryo freezing and thawing, and gamete and embryo assessment.<sup>32</sup> However, according to the 2015 alpha consensus, the duties of embryologists encompass a broader spectrum of responsibilities encapsulated in the PACER framework: Personal (patient-related), Administrative, Clinical, Education, and Research.<sup>12</sup> The 2023 study also highlighted the multifaceted roles of embryologists

TABLE 2 Recommended embryologists staffing by different organizations.

Organization	Year [ref]	1–150 Cycles	151–300 Cycles	301–600 Cycles	>600 Cycles	Additional notes
ASRM	2008 [28]	2	3	4	+1 per 200 cycles	
ASRM	2022 [29]	2–3	3–4	4–5	+1 per 150 cycles	Distinct cycles for oocyte retrieval and frozen-thawed ET; requires certified embryologists; classifications include Senior, Embryologist, Junior, and Trainee
ISAR	2021 [15]	2	3	4	+1 per 200 cycles	Distinct cycles for oocyte retrieval and frozen ET; requires certified embryologists
ASPIRE	2023 [31]	2 (1–2 senior)	3 (2 senior)	4–5 (2–3 senior)	+1 per 200 cycle points (at least 50% senior)	Points system for different cycle types (IVF: 1.0; FTE: 0.5; ICSI: 0.1; PGT-A: 0.5) Requires certified embryologists; classifications include Junior/Trainee, Embryologist, and Senior
ESHRE	2015 [9]	Up to 150 2	Required embryologists should be adjusted based on the cycles and the complexity of laboratory procedures and tasks			Requires embryologist qualifications
JSRM	2008 [28]	>150 Retrieval	2	No specific qualifications required		

Abbreviations: ASPIRE, Asia Pacific Initiative on Reproduction; ASRM, American Society for Reproductive Medicine; ESHRE, European Society of Human Reproduction and Embryology; ET, Embryo Transfer; FTE, Frozen-Thawed Embryo; ICSI, Intracytoplasmic Sperm Injection; ISAR, Indian Society for Assisted Reproduction; IVF, In Vitro Fertilization; JSRM, Japanese Society of Reproductive Medicine; PGT-A, Preimplantation Genetic Testing for Aneuploidy; ref., reference (indicates the number of senior embryologists).

as professionals, communicators, collaborators, scholars, advocates, and leaders,<sup>32</sup> suggesting that the duties and expected qualities of modern embryologists have significantly evolved. In this section, tasks refer to specific laboratory activities, while duties encompass the responsibilities of embryologists.

Additionally, many countries and institutions categorize embryologists into senior embryologists, junior embryologists, and assistants (technicians) based on their experience and education levels. Technicians, who are not classified as embryologists, often handle routine maintenance tasks such as dish preparation, incubator management, and inventory control of consumables.<sup>12</sup> The coexistence of tasks that only qualified embryologists can perform, tasks that unqualified embryologists can handle, and tasks shared between technicians and embryologists complicates the determination of the optimal staffing levels at ART laboratories. According to the 2021 guidelines from the ISAR, training for embryologists is deemed necessary when implementing add-on procedures.<sup>33</sup> However, current guidelines or recommendations do not mandate additional certification for embryologists when integrating add-ons.

Regarding the calculation of staff requirements, a 2022 study investigated and reported on the time required for daily tasks in the ART laboratory.<sup>5</sup> However, the duties of embryologists extend beyond laboratory tasks to include patient interactions (personal), roles as communicators and collaborators, and responsibilities as researchers, all of which further compound the necessary staffing levels. Additionally, professional duties involve equipment supervision and maintenance to ensure safety and treatment efficacy within ART laboratories, handling of gametes and embryos, documentation of laboratory procedures, and patient care, each carrying significant responsibilities.<sup>34,35</sup> In countries such as Italy, national regulations prohibit the disposal of viable human embryos,<sup>36</sup> highlighting how regulatory frameworks impact the tasks and duties of embryologists and consequently affect staffing in ART laboratories.

In Japan, a joint committee comprising the Japan Society of Obstetrics and Gynecology (JSOG), the Japan Society for Reproductive Medicine (JSRM), and associations of embryologists (JSOR and JSCE) defined in 2024 the tasks of embryologists to encompass handling gametes and embryos, assisting in their assessment and explanation, and ART laboratory operation like managing laboratory equipment, and maintaining documentation.<sup>37</sup> While the duties of embryologists are extensive, as outlined in the PACER framework, there is a lack of international consensus or detailed research on the extent of their patient interaction responsibilities. Furthermore, given the varied tasks and duties assigned to different categories of embryologists, global discussions are imperative for clarifying these roles in the future.

### 3.3 | Embryologist licensing and education systems

Furthermore, the career segmentation of embryologists into senior, embryologist, junior, trainee, and assistant (technicians) varies by country and organization, complicating efforts for global

standardization. Differences also exist in embryologists' certification, education systems, and legal status worldwide.

In North America, regulations regarding embryologist education, training, certification, and licensing are insufficient. In Canada, there are no government regulations concerning embryologist training.<sup>32,38</sup> In the United States, following the enactment of the Fertility Clinic Success Rate and Certification Act of 1992, all ART clinics must report pregnancy rates to the Centers for Disease Control and Prevention, which has established certification standards for laboratories, including criteria for embryologists.<sup>28</sup> ART laboratories in the United States must comply with Food and Drug Administration regulations, which mandate at least two certified embryologists recognized by the American Board of Bioanalysis (ABB).<sup>39</sup> The ABB certification is the sole accreditation recognized by the ASRM. ASRM specifies educational requirements: trainee embryologists must hold a bachelor's or master's degree with less than 1 year of experience, junior embryologists need at least 1 year of experience alongside their degree, embryologists require at least 2 years of experience, and senior embryologists necessitate at least 3 years of experience with their degree.<sup>29</sup>

In Europe, licensing and educational requirements for embryologists vary significantly by country. A 2015 report indicated that only five out of 26 countries had publicly accredited educational programs.<sup>12</sup> Additionally, eight countries lacked specific educational requirements for embryologists.<sup>12</sup> A 2023 report indicated that only 12 out of 31 European countries had mechanisms to verify laboratory skills in ART.<sup>4</sup> Many European countries lack public licensing for ART laboratory staff, and in countries such as Slovakia, the title of embryologist is not officially recognized.<sup>4,40</sup> While ESHRE offers certification for clinical embryologists and senior clinical embryologists, educational accreditation systems differ widely across Europe, highlighting the need for a standardized training curriculum for embryologists.<sup>14</sup>

ESHRE has long implemented a certification program for ART centers<sup>6</sup>; consequently, ESHRE launched a new program in 2023 to certify European ART centers for training clinical embryologists, with 11 clinics being certified as ESHRE Certified ART Centers by June 2024.<sup>4,41</sup> ESHRE's 2015 guidelines stipulate that trainees must accrue at least 3 years of practical experience to work independently in an ART laboratory, alongside holding a bachelor's degree in clinical embryology.<sup>9</sup> Senior clinical embryologists require a master's or doctoral degree and a minimum of 6 years of experience.<sup>9</sup> Only a few countries such as France, Romania, the Netherlands, and the UK have highly formalized education systems for embryologists,<sup>4</sup> with many ART laboratories relying on informal training methods where embryologists gain skills and knowledge from experienced colleagues.<sup>10</sup> The relationship between academic education in medical specialties and the practical skills and competencies of embryologists in ART laboratories remains unclear, necessitating further research.<sup>42</sup>

In the Asia-Pacific region, ASPIRE's guidelines specify that junior/trainee embryologists should hold a bachelor's degree with no specific experience requirements, while embryologists require

TABLE 3 Classification, educational qualification, and years of experience for embryologists by various organizations.

Classification	ASRM	ESHRE	ASPIRE	Japan	ISAR
Trainee embryologist	Bachelor's or master's (<1 year)	No set requirement	Bachelor's (no experience requirements)	No set requirement	No set requirement
Junior embryologist	Bachelor's or master's (≥1 year)	No set requirement	Bachelor's (≥1 year)	No set requirement	No set requirement
(Clinical) embryologist	Bachelor's or master's (≥2 years)	Bachelor's (≥3 years)	Bachelor's (≥1 year)	Bachelor's (≥1 year)	Bachelor's (≥3 years) <sup>b</sup>
Senior embryologist	Bachelor's or master's (≥3 years)	Master's or doctorate (≥6 years)	Bachelor's (≥5 years)	Doctorate (≥5 years after embryologist) <sup>a</sup>	No set requirement
Certifying organization	ABB	ESHRE	Each ASPIRE member organization	JSOR <sup>a</sup> and JSCE	No set requirement

Abbreviations: ASRM: American Society for Reproduction Medicine; ESHRE, European Society of Human Reproduction and Embryology; ASPIRE, Asia Pacific Initiative on Reproduction; ISAR, Indian Society for Assisted Reproduction; ABB, American Board of Bioanalysis; JSOR, Japan Society for Ova Research; JSCE, Japanese Society of Clinical Embryologists.

<sup>a</sup>Certified only by JSOR.

<sup>b</sup>Individuals meeting criteria would be acceptable as a clinical embryologist.

embryologists need a bachelor's degree with a minimum of 5 years of experience.<sup>31</sup> In Japan, embryologist certification was historically managed separately by the JSOR and the JSCE.<sup>1</sup> However, as of 2024, these certifications have been unified under JSOR and JSCE. Both organizations mandate that embryologists hold a bachelor's degree with at least 1 year of experience, without distinguishing between junior and trainee levels. JSOR and JSRM also jointly certify senior embryologists, who must hold a doctorate and have at least 5 years of experience post-certification as an embryologist. As of 2022, only 34 individuals had obtained this senior certification.<sup>43</sup> ISAR's guidelines stipulate that clinical embryologists must possess either a Bachelor of Science or a Bachelor of Veterinary Science degree with at least 3 years of relevant experience.<sup>34</sup>

Therefore, qualifications for embryologists vary significantly by country and region, with notable differences in educational and experience requirements, even for roles such as senior embryologist. The certification requirements of each organization are summarized in Table 3. Understanding these differences is crucial when determining the staffing requirements for ART laboratories, considering the diverse tasks expected at each qualification level.

### 3.4 | Laboratory work environment and quality management

In Europe, implementing a Quality Management System in ART laboratories is essential, encompassing regular inspections for equipment maintenance, management of consumables' batch numbers, and monitoring expiration dates.<sup>3</sup> Maintaining high-quality standards in the laboratory hinges on having a sufficient number of embryologists capable of handling these tasks effectively. The precision and accuracy with which embryologists manipulate and handle gametes and embryos significantly influence the outcomes of infertility treatments.<sup>44,45</sup> Additionally, non-compliance with protocols, procedural errors, and equipment malfunctions in ART laboratories can negatively affect the long-term health outcomes of children born through ART.<sup>46,47</sup> An ongoing international concern in ART laboratory quality management involves the inventory management of cryopreserved gametes and embryos.<sup>48</sup> Effective cryopreservation management is critical and constitutes a core responsibility of embryologists. However, incidents involving the loss of embryos due to improper cryopreservation or tank failures have led to legal disputes and raised serious ethical concerns.<sup>49,50</sup>

Nevertheless, ensuring an adequate staffing level remains challenging given the diverse range of duties assigned to embryologists. Improving the accuracy of tracking and monitoring cryopreserved specimens is essential for laboratory quality management. Proposed solutions include integrating the Internet of Things and robotic systems for enhanced safety and efficiency.<sup>51,52</sup> While current manual confirmation and approval processes in laboratories typically involve at least two personnel, the adoption of electronic witnessing systems could potentially improve operational efficiency, accuracy, and safety in laboratory procedures.<sup>53</sup>

Introducing such automated monitoring and authentication systems may necessitate a reassessment of embryologist staffing and roles in the future.

Ensuring effective quality management in ART laboratories requires a conducive work environment. Given the diverse staff in these facilities, it is crucial to incorporate universal design concepts from the planning stage to ensure optimal usability for all personnel.<sup>54</sup> Managing factors such as light levels, air quality, and gaseous phases is critical for embryo viability and directly impacts ART outcomes.<sup>55,56</sup> While ART laboratories strive to minimize stress on embryos, the demanding nature of working in a controlled environment can lead to significant stress among embryologists. This stress may contribute to issues such as poor mental health, burnout, and depression, which in turn can cause operational errors.<sup>57,58</sup>

To uphold quality in ART laboratories, it is essential to continually monitor the capabilities and performance of embryologists and other staff. Establishing performance indicators (PIs) has been proposed as a method to monitor and enhance performance in ART laboratories.<sup>16,59</sup> Various monitoring parameters have been studied, and key performance indicators (KPIs) are recommended for regular evaluation every 3–6 months.<sup>60,61</sup> Monitoring these indicators allows for ongoing quality assessment in ART laboratories and facilitates the early detection of performance declines and stress among staff due to insufficient staffing levels. Ensuring an adequate number of ART staff,<sup>8</sup> aligning tasks with their qualifications and educational backgrounds, and enhancing the efficiency of laboratory operations are essential steps to maintain high performance and ensure the sustainable operation of ART laboratories.

### 3.5 | Automation of laboratory tasks and its impact on future staffing

The automation of tasks in ART laboratories can be broadly categorized into practical technical tasks and tasks requiring specialized knowledge, such as oocyte and embryo evaluation and selection. Technical tasks in embryology laboratories include routine activities such as preparing cell culture dishes, formulating culture media, and maintaining or calibrating laboratory equipment. These tasks are typically performed by embryologists or laboratory assistants and technicians.<sup>12</sup>

The automation of technical tasks in ART laboratories includes the preparation of dishes and culture droplets. Experiments with mouse embryos have demonstrated that automating these preparatory tasks can reduce preparation time significantly. If implemented in clinical ART laboratories, these technologies have the potential to streamline workflows and prompt a reassessment of staffing needs.<sup>62,63</sup> Research into robotic ICSI has been ongoing, with advancements potentially enabling the automation of ICSI and remote ICSI, where technicians control the process remotely.<sup>64</sup> Techniques such as ICSI involve micromanipulation, where the amount of cytoplasmic suction applied by embryologists can impact outcomes. However, integrating robotic ICSI arms and automation could reduce variability and

improve consistency among technicians.<sup>65</sup> Furthermore, lab-on-a-chip technology utilizing microfluidics is being introduced into ART laboratories.<sup>66</sup> Implementing these technologies in devices could lead to semi-automation or complete automation of procedures such as embryo vitrification in the future.<sup>67</sup> Automating these technical tasks holds the promise of standardizing laboratory workflows and reducing the time embryologists spend on routine tasks.

The automation of gamete and embryo evaluation and analysis has also been widely adopted in recent years. However, it may not necessarily reduce embryologists' work hours. The first automated embryo analysis system using TLI, Eeva® (Early Embryo Viability Assessment), was reported in 2014.<sup>68</sup> Recent developments have focused on combining dynamic behavior observed through TLI with PGT-A results to develop predictive algorithms for detecting chromosomal aneuploidy, which has increased the demand for TLI.<sup>69,70</sup> Despite its potential, utilizing TLI data requires a qualified team, and manually annotating the data may require more time than current methods, potentially increasing the workload.<sup>71,72</sup>

Nevertheless, the potential of AI and deep learning in ART laboratories is significant. Recent developments in TLI scoring and evaluation involve new-generation models that use machine learning and deep learning tools based on neural networks, which could fully automate these processes and eliminate the need for manual evaluation, thereby changing laboratory workflows.<sup>73–77</sup> The use of AI and deep learning in ART laboratories is expected to continue, supporting doctors and embryologists in selecting high-quality embryos and revolutionizing the field.<sup>78–81</sup>

Predicting the future state of ART laboratories by 2030 is challenging, but increased automation and the further use of lab-on-a-chip technology are anticipated.<sup>82</sup> The use of add-on technologies such as in vitro maturation and PGT-A may also become more common in general clinics, although patient costs and workflow improvements due to automation will influence future adoption rates.<sup>83–85</sup> Given the rapid introduction of new technologies and add-ons in ART laboratories, defining embryologists' duties, and developing appropriate educational systems will become increasingly challenging. These factors will significantly impact the determination of necessary staffing levels in ART laboratories, making continuous reassessment essential to stay at the forefront of the field.

### 3.6 | Future prospects of ART laboratory staffing

Academic organizations in each country and region must set standards reflecting their specific legal and practical contexts and periodically review and update these standards. It is essential to develop educational institutions for embryologists tailored to each country's specific context. Furthermore, establishing educational systems that address global needs is equally important. To establish optimal staffing in ART laboratories, it is crucial to consider the rapidly evolving laboratory processes and long-term issues related to the training and certification of embryologists. Educational systems that consider special circumstances, such as infectious diseases,

will be increasingly important in the future. The global pandemic caused by Coronavirus Disease 2019 (COVID-19) since late 2019 has somewhat subsided by 2024. However, during the peak of the pandemic, ART laboratories implemented measures such as smaller team configurations and restricted patient interactions to prevent the spread of infection.<sup>86</sup> Additionally, supply chain restrictions led to conserving consumables.<sup>87</sup> Future pandemics may occur, necessitating traditional infection control measures in laboratories. It may also be necessary to prepare for and educate staff on remote oocyte retrievals and the transportation of eggs and embryos.<sup>88-90</sup>

The varying global certification standards for embryologists make it challenging to set unified criteria for laboratory tasks and responsibilities. This review summarizes the staffing standards of five organizations in Tables 2 and 3. In Europe, only a few countries have legal regulations on educational standards and required skills for ART laboratories.<sup>7</sup> Embryologists are involved in tasks and duties such as the disposal of gametes and embryos, which require skilled judgment and a high level of ethics.<sup>91</sup> Leaders in ART laboratories must possess strong leadership skills to manage embryologist teams effectively, as the quality of their leadership can impact ART outcomes for patients.<sup>92,93</sup> Consequently, it is essential to provide continuous educational opportunities for laboratory staff to update their knowledge and skills.<sup>12,57</sup> It is essential to address legal regulations on certification, including national certification, based on the issues highlighted in this review, while considering the specific circumstances of each country.

## 4 | CONCLUSION

We conducted a multifaceted examination of appropriate staffing levels in ART laboratories and the various issues related to staffing. To date, no detailed report from Japan has examined changes in the number of embryologists following the introduction of insurance coverage for ART in 2022, underscoring the need for further research. The definition of an ART cycle and the required number of staff vary across organizations, primarily influenced by differences in embryologist certification and scope of work in each country. Appropriate staffing of embryologists is essential for laboratory quality control and significantly impacts patient ART outcomes. Only some countries worldwide have national certification for embryologists, and there are also few countries with legal regulations in place, making self-regulation by each country and organization important. However, the introduction of new technologies and automation in the future will significantly impact laboratory workflows. Therefore, creating long-term educational curricula for embryologists and setting the number of training personnel will require joint consideration by each organization, country, and embryologist association.

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

## HUMAN/ANIMAL RIGHTS

This article does not contain any studies with human and animal subjects performed by any of the authors.

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