ORIGINAL ARTICLE: ASSISTED REPRODUCTION

A comprehensive evaluation of contemporary assisted reproduction technology laboratory operations to determine staffing levels that promote patient safety and quality care

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Objective: To consider how staffing requirements have changed with evolving and increasingly more complex assisted reproduction technology (ART) laboratory practice.
Design: Analysis by four laboratory directors from three different ART programs of the level of complexity and time requirements for contemporary ART laboratory activities to determine adequate staffing levels.
Setting: Two university-based and one private ART program.
Patient(s): None.
Intervention(s): None.
Main Outcome Measure(s): Human resource requirements for ART procedures.
Result(s): Both complexity and time required for completion of a contemporary ART cycle have increased significantly compared with the same requirements for the "traditional cycle" of the past. The latter required roughly 9 personnel hours, but a contemporary cycle can require up to 20 hours for completion. Consistent with this increase, a quantitative analysis shows that the number of embryologists required for safe and efficient operation of the ART laboratory has also increased. This number depends on not only the volume but also the types of procedures performed: the higher the number of complex procedures, the more personnel required. An interactive Personnel Calculator is introduced that can help determine staffing needs.
Conclusion(s): The increased complexity of the contemporary ART laboratory requires a new look at the allocation of human resources. Our work provides laboratory directors with a practical, individualized tool to determine their staffing requirements with a view to increasing the safety and efficiency of operations. The work could serve as the basis for revision of the 2008 American Society for Reproductive Medicine (ASRM) staffing guidelines. (Fertil Steril® 2014;■:■–■. ©2014 by American Society for Reproductive Medicine.)
Key Words: ART complexity, embryology laboratory, patient safety, PGD/PGS, staffing

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The past decade has seen dramatic changes in assisted reproduction technology (ART) practice, including the addition of many new technologies and increased oversight (1). As a result, safe and efficient operation of the ART laboratory has become increasingly complex, requiring a deep understanding of laboratory activities

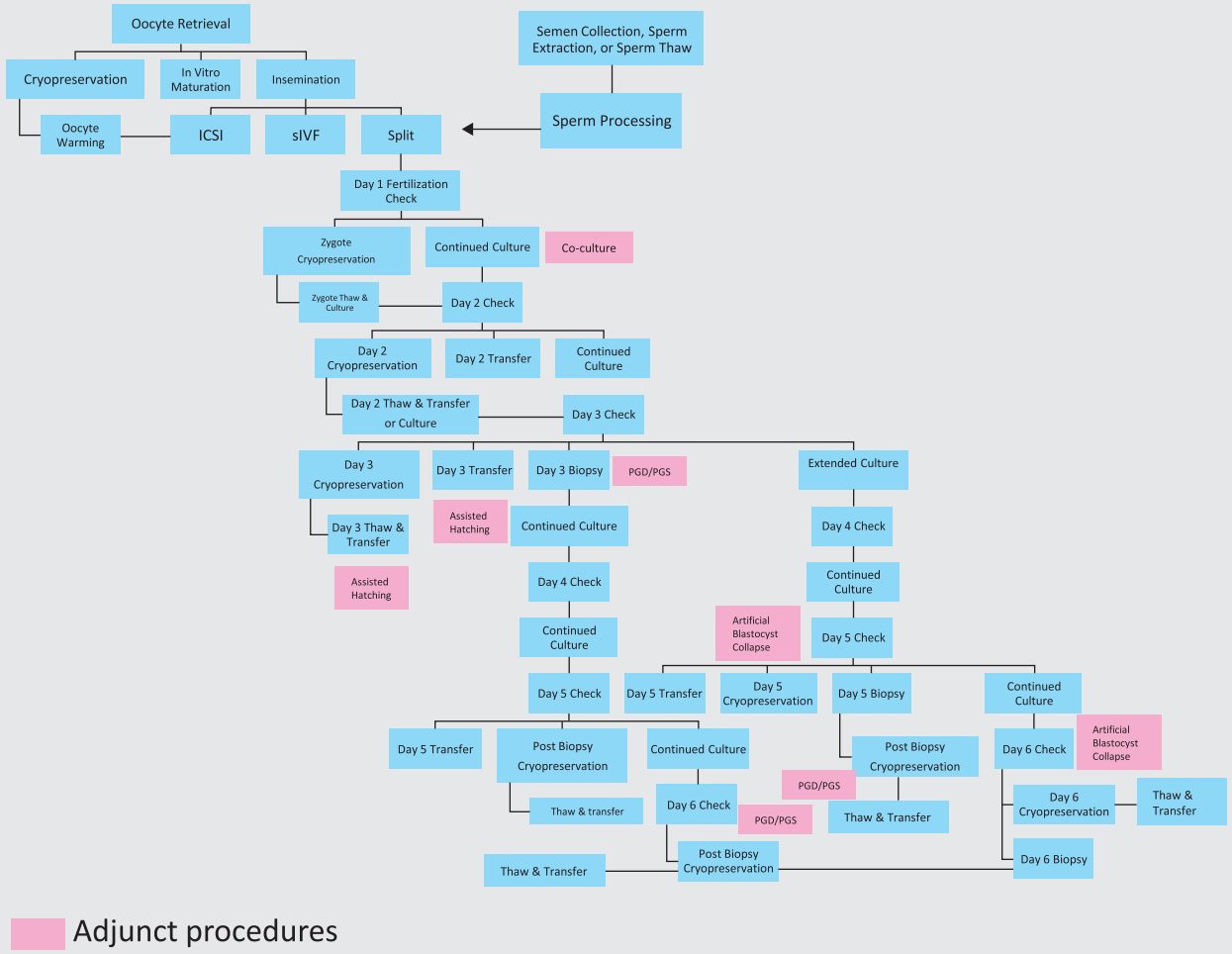
and the proper allocation of resources to support those activities. Different approaches to calculating staffing needs have been proposed (1). One approach used the number of in vitro fertilization (IVF) cycles, where each cycle was taken as the sum of oocyte retrieval, insemination/intracytoplasmic sperm injection (ICSI), embryo culture, and embryo transfer; another considered each laboratory cycle as consisting of a full spectrum of individual embryology subprocedures, including oocyte retrieval, sperm preparation, embryo transfer, or cryopreservation. However, the most recently published guidelines on allocation of human resources in embryology laboratories date back to 2008 (2). The guidelines are based on the number of "laboratory cycles" performed. Although the term *laboratory cycle* is not specifically defined, it can be reasonably assumed to refer to a "traditional" treatment cycle that typically involves an oocyte retrieval procedure, insemination of the oocytes, intrauterine transfer of the resulting embryos, and cryopreservation of surplus embryos when appropriate.

This traditional laboratory cycle, however, only applies to a small proportion of current ART cycles. Thus, a reevaluation of this concept is needed. We present a new approach to assessing staffing needs based on a detailed analysis and offer a logical and quantitative method for laboratory directors to determine minimum staffing requirements for their laboratories.

MATERIALS AND METHODS

A list of all activities in the contemporary ART laboratory was compiled. Four laboratory directors, representing or having substantial experience with small, medium, and large programs discussed and agreed on time requirements as well as the level of complexity of the various procedures on the list. Level of complexity refers to level of skill required and the number of steps involved in each procedure; this definition may or may not conform to the categories defined by Clinical Laboratory Improvement Amendments (CLIA) (3).

FIGURE 1



A flowchart representing complexity of the contemporary ART laboratory operations. This is a representative figure and does not depict all practiced variations on treatment approaches. sIVF = standard insemination.

Alikani. Staffing the contemporary IVF laboratory. Fertil Steril 2014.

TABLE 1

Technologies, procedures, and processes that have added significant complexity to the ART laboratory.

- Increasingly frequent and rapid integration of new, specialized techniques into daily use
- Intracytoplasmic sperm injection (ICSI) for treatment of (increasingly more challenging) male factor and non–male factor infertility
- The use of the laser for assisted hatching and the associated instrument maintenance and calibration requirements
- Embryo biopsy and all its associated administrative tasks, such as management and communication of results and maintenance of records and data
- Blastocyst biopsy, possibly requiring embryo assisted hatching on day 3 and biopsy on day 5, day 6, and even day 7 of development as well as possible requirement for immediate vitrification of embryos after biopsy, and the imperative processing of individually identified and vitrified embryos and witnessing of the entire process
- Increased requirements for witnessing to provide patients with the assurance that gametes and embryos are always tracked individually and accurately through all the treatment steps in the laboratory
- Challenging cytogenetic techniques like nuclear fixation for fluorescent in situ hybridization (FISH) or, more recently, preparation and loading of biopsied tissue in microtubes for sample shipment and the imperative witnessing of these procedures
- Vitrification in addition to slow cooling as a method of cryopreservation
- Use of multiple varied vessels with different requirements for vitrification and the need for knowledge of devices and handling after transport of embryos between programs
- Oocyte vitrification for fertility preservation for medical and nonmedical reasons
- Thawing of oocytes and/or embryos in cycles where treatment modalities/plans are often combined adding to the complexity of each case
- Time-lapse microscopy and incubation equipment with significant operational time requirements and training, frequent service visits, maintenance, and software updates
- Use of commercial egg banks requiring high level of coordination, data sharing, and reviewing
- Administration of cryopreserved gametes and embryos, including a rapidly increasing inventory, import, export, and donation
- One on one interaction between embryologists and a better-informed and increasingly more involved patient population
- Increased oversight and regulations requiring inspections (CAP, JCAHO, state departments of health, FDA, SART) leading to additional quality control and quality assurance activities, including proficiency testing, structured documented training of personnel, testing of contact materials or media products, updating of laboratory manuals, and commitment to continued education and training
- Requirement for training and mentoring of fellows and teaching of medical students in academic centers
- Requirements for data collection, analysis, and publication
- Administration of randomized controlled trials requiring significant investment of time for patient and data management
- Conducting institutional review board approved research studies in academic centers along with the accompanying documentation

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To calculate the time required for different procedures, a detailed table was constructed by one director (MA) then evaluated, discussed in detail, and revised as agreed upon unanimously by all four directors with current hands-on laboratory experience. An Interactive Personnel Calculator was developed based on this evaluation, and it was validated by application to several facilities. The calculator was designed to generate minimum staffing requirements based on the main procedures handled by the laboratory. We opted to exclude a detailed accounting of peripheral activities in the calculator to ensure its utility, keeping in mind that different laboratories handle those tasks differently. Nonetheless, it should be noted that time required for activities such as reviewing treatment plans with physicians and patients, importing and exporting samples, data entry, consent checks, and other similar tasks were considered when total time required for different procedures was assessed. For example, a review of the treatment plan is part of the preparation for all cycles; data entry is included in the document management portion in the calculator. Furthermore, the estimation of time required is based on performance of procedures by reasonably well-trained embryologists. However, it is important to acknowledge that a substantial amount of time and resources are required for training of embryologists.

Additionally, this analysis is limited to the embryology laboratory and does not include the time required for diagnostic semen analysis, processing of semen for intrauterine insemination, cryopreservation of sperm for later use, or endocrinology testing. We chose to restrict our calculations to embryology tasks only (including sperm preparation for IVF-ICSI). The addition of other tasks would naturally increase the workload and personnel time required to perform all tasks.

The Interactive Personnel Calculator is presented as a Supplemental Calculator (available online). The formulae used to devise the calculator are presented in the *Results* section. The calculator determines the number of personnel necessary by assessing six different activity types: [1] daily quality control tasks (QC); [2] IVF with embryo transfer and cryopreservation but without preimplantation genetic screening/diagnosis (PGS/PGD) (IVF); [3] IVF with embryo/blastocyst biopsy for PGS/PGD and cryopreservation (IVF-PGD); [4] oocyte retrieval with oocyte cryopreservation (oocyte freeze); [5] cryopreserved embryo thaw/warming with embryo transfer (FET); and [6] cryopreserved oocyte thaw/warming with ICSI, culture, and embryo transfer (OOT).

The sum of the products of personnel time for each procedure and the number of procedures performed determined the total personnel time required for these procedures. Division of this time by the number of personnel hours available per year for one person (accounting for 5 days per week, 8 hours per day, time for lunch and breaks, as well as 10 vacation days per year) yielded an estimate of the number of personnel needed. Further, we stipulated that because of witnessing needs and to ensure safety, no fewer than two people must be present (during most days of operation) when procedures are performed. A witness can be anyone trained to witness the procedures, but this is often another embryologist. Alternatively, andrologists, medical or laboratory assistants, or even personnel expressly hired for the purpose of witnessing may perform these tasks. It should be stated that, to our knowledge, there is no "requirement" for witnessing as

such, but to ensure safety and minimize unfortunate incidents of misidentification (4–8), procedures must be witnessed whenever the possibility of an identity error exists.

RESULTS

The complexity of the contemporary ART laboratory operations is depicted in a flow chart in Figure 1. The flow chart does not detail all possible practice variations but represents a majority of common practices.

Table 1 lists technologies, procedures, and processes that are currently part of routine practice in many laboratories, adding significant complexity to their operations. These vary from time- and labor-intensive procedures such as PGS/PGD with cryopreservation of biopsied embryos for later thaw/warming and transfer, to substantial time that must be dedicated to administrative work related to increased oversight by governmental entities (e.g., the U.S. Food and Drug Administration [FDA], the Centers for Disease Control and Prevention [CDC], or the New York State Department of Health) and nongovernmental and professional organizations (e.g., Joint Commission on Accreditation of Healthcare Organizations [JCAHO], Society for Assisted Reproductive Technologies [SART], or College of American Pathologists [CAP]).

Table 2 compares the numbers of personnel hours estimated to be required to complete different types of cycles, accounting for the procedure and witnessing time requirements. The number of hours for a traditional cycle, a contemporary cycle, and a contemporary cycle that integrates PGS/PGD were compared. Whereas in earlier years of IVF, a typical IVF cycle required roughly 9.1 personnel hours, a standard IVF cycle now requires substantially more time (roughly 12.6 person hours). More complex cycles, such as those involving PGS/PGD require even more personnel time, amounting to some 20.2 hours of work.

Table 3 is an analysis of different components incorporated in each type of activity in the contemporary ART laboratory. Each activity has also been assigned a complexity level. Complexity was calculated based on five elements: [1] time restriction, [2] requirement for intense/prolonged focus, [3] multiple complex steps, [4] potential irreversible harm to gametes/embryos, and [5] potential serious harm to the patient. Harm to the embryo is defined as any manipulation that impedes development, implantation, or progression toward delivery of a healthy infant. Harm to the patient encompasses both psychological and physical harm that would result as a consequence of inadvertent errors that lead to failure of the treatment or misidentification of gametes or embryos. It should be noted that the last two elements are present during virtually all manipulations in the laboratory, but they were only included when the chances were increased or substantial. For example, case setup on the day before procedures was given a complexity level of 2 for time restriction and intense, prolonged focus, but a procedure such as embryo transfer was given a complexity of 4 because all but (possibly) one element (potential harm to gametes/embryos) apply to that procedure.

TABLE 2

A comparison of the estimated number of person hours required for completion of a traditional versus contemporary versus contemporary with PGD/PGS cycles (the latter requiring almost three times as many person hours as the traditional model).

	IVF traditional		IVF contemporary		IVF/PGS/PGD	
	Procedure time (min)	Witness (min)	Procedure time (min)	Witness (min)	Procedure time (min)	Witness (min)
Preparation all	30	0	60	0	80	0
Oocyte retrieval	60	10	60	10	60	10
Sperm preparation	60	10	60	10	60	10
Insemination/ICSI	20	10	40	20	40	20
Fertilization check	40	10	40	10	40	10
Day 2 check	20	0	20	0	20	0
Day 3						
Check	20	0	20	0	20	0
Transfer	40	10	0	0	0	0
Cryo	40	10	0	0	0	0
Assisted hatching	20	0	20	0	60	0
Extended culture	0	0	40	10	40	10
Day 5						
Check	0	0	20	0	20	0
Transfer	0	0	40	10	0	0
Biopsy	0	0	0	0	80	40
Cryo	0	0	40	20	80	40
Day 6						
Check	0	0	20	0	20	0
Biopsy	0	0	0	0	80	40
Cryo	0	0	40	20	80	40
No. of minutes	350	60	520	110	780	220
No. of hours	5.83	1.00	8.67	1.83	13	3.67
Total time (h)	6.83		10.50		16.67	

Note: Cryo = cryopreservation (primarily vitrification); ICSI = intracytoplasmic sperm injection; PGD = preimplantation genetic diagnosis; PGS = preimplantation genetic screening.

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The Interactive Personnel Calculator is based in part on operational details presented in Tables 2 and 3. The calculator operates on two levels: First, it provides a minimum of two staff members for every day of operation in the embryology laboratory. However, two individuals working simultaneously can only provide coverage for 250 days per year (50 weeks × 5 days per week = 250 days). Therefore, a third person is required if the number of days of operation exceed 250 days—that is, nearly three people are required to operate the laboratory for 351 days (allowing for 2 weeks of down time). When the number of days of operation is 125 days or fewer, the calculator estimates the need as one person or fewer. However, it should be noted that two personnel are still required to perform procedures and witnessing. In such cases, the 1 (or fewer) person-year must be divided between no fewer than two personnel.

At the second level, the calculator calculates the number of staff required to perform five different procedure types, including IVF (requiring 12.6 personnel hours); IVF/PGD (requiring 20.2 personnel hours); frozen-thawed embryo transfer (FET) (requiring 3.6 personnel hours); oocyte freeze (requiring 5.6 personnel hours); and oocyte thaw (requiring 12.9 personnel hours). Additionally, the number of days of QC encompassing the number of incubators and the time requirements for these activities are incorporated in this calculation.

Finally, the two values generated from the two calculations we have described are compared, and the larger number is given as the minimum staffing requirement. The number of personnel increases above three with greater than 425 IVF cycles (when only IVF is performed using a 351 days per year schedule). The number then increases according to the estimated time demand per procedure. The formulae are as follows:

Minimum Personnel Required (MPR)

$$= \text{The greater of MPR (procedures) and MPR (2 per day)},$$

where:

$$\begin{aligned}
\text{MPR (procedures)} = {} & \text{No. of IVF procedures (without PGS/PGD)} \times 0.00672 \text{ person} - \text{years/procedure} \\
& + \text{No. of IVF procedures (with PGS/PGD)} \times 0.01077 \text{ person} - \text{years/procedure} \\
& + \text{No. of FET} \times 0.00192 \text{ person} - \text{years/procedure} \\
& + \text{No. of oocyte freezing procedures} \times 0.00299 \text{ person} - \text{years/procedure} \\
& + \text{No. of oocyte thaw procedures} \times 0.00686 \text{ person} - \text{years/procedure} \\
& + \text{Days of operation (Days of QC activity)} \times [(\text{No. of Incubators requiring QC} \\
& \times 0.0000347 \text{ person} - \text{years/incubator QC/day}) + 0.000267 \text{ person} \\
& - \text{years/day}] \\
\text{MPR (2 per day)} = {} & \text{Days of procedures} \times 0.008 \text{ person} - \text{years/day}
\end{aligned}$$

It should be noted that the number of personnel required for smaller programs with lower numbers of procedures is facility-dependent because different facilities may choose to provide witnessing of procedures in different ways. However, as may be deduced from the American Society for Reproductive Medicine (ASRM) guidelines (2008), the number of people available must always be at least two, even if the program operates for only 1 week out of the year.

DISCUSSION

The evaluations presented here detail the increased complexity of contemporary ART practice and demonstrate how this increased complexity translates into increased time requirements for proper and safe completion of laboratory tasks. As shown in Table 2, the traditional IVF cycle of the 1980s and 1990s required roughly 9.1 person hours for completion, but a contemporary IVF cycle requires about 12.6 person hours; a cycle including PGS/PGD, whether by blastomere or trophectoderm biopsy, may require more than 20.2 person hours, thanks to significantly more procedural steps, including strict requirements for witnessing at all stages of the process.

We are aware of two sources of staffing guidelines for ART laboratories. The first is an unpublished, word-of-mouth standard that has circulated in the ART community for nearly 20 years. It suggests that one embryologist is needed for every 100 IVF cycles annually. The second source—and the only published guidelines currently available to laboratory, medical, and administrative directors for allocation of human resources to the ART laboratory—is the guidelines published in 2008 by the Practice Committee of the ASRM in 2008. Both of these sources provide estimates of the minimum staffing that fall short of average staffing levels determined using surveys and systematic analyses of facilities in the United States (1). Furthermore, although these guidelines may address the needs of programs that perform up to 300 traditional cycles annually—where, according to the scale, each embryologist would be expected to handle a maximum of 100 cycles—for programs performing 600 or more cycles or more complex cycles, the given scale of one embryologist for every 200 cycles is impractical and unrealistic. It is also inherently risk-laden.

Manipulating tens of gametes and embryos on a daily basis while cognizant of the potentially grave consequences of errors is mentally exhausting, particularly in a complex laboratory environment. Mental exhaustion leads to loss of focus and generates disinterest. Exhaustion is also a contributor to decreased productivity. It is therefore imperative that staffing

TABLE 3

Activities in the IVF laboratory including components and estimated complexity level.

Activity	Component 1	Component 2	Component 3	Component 4	Component 5	Component 6	Complexity
Day -1 case set-up	Record review	Need assessment	Dish labeling	Media preparation	Dish preparation		2
Day- 0 oocyte retrieval, 12 oocytes	Laboratory preparations	Follicular fluid search	Cumulus dissection/wash	Oocyte Culture	Witnessing		2
Oocyte cryo, 10 oocytes	Record review/Pt ID	Media/Dish Preparation	Cryo container preparation	Denuding/evaluating eggs	Vitrification	Witnessing	4
Oocyte thaw, 10 oocytes	Record review/Pt ID	Media preparation	Dish preparation	Oocyte warming	Oocyte culture	Witnessing	4
Surgical sperm retrieval	Laboratory preparations	Operating room procedures	Tissue/sample processing	Tissue/sample cryo	Witnessing		2
Sperm preparation, Simple	Semen analysis	Gradient preparation	Sample preparation	Analysis	Witnessing		1
Sperm preparation, Complex	Semen analysis	Special treatments	Sample preparation	Analysis	Witnessing		1
Insemination, standard	Record review/Pt ID	Oocyte preparation	Insemination prop preparation	Insemination	Witnessing		2
ICSI, simple, 12 oocytes	Record review/Pt ID	Oocyte preparation	Dish preparation	Microinjection	Witnessing		4
ICSI, complex, 12 oocytes	Record review/Pt ID	Oocyte preparation	Dish preparation	Sperm search	Microinjection	Witnessing	4
ICSI	Record review/Pt ID	Oocyte preparation	Dish preparation	Sperm search	Microinjection	Witnessing	4
Insemination, split ICSI/ standard	Record review/Pt ID	Oocyte preparation	Insemination	Dish preparation	Microinjection	Witnessing	4
Fertilization check, standard	Oocyte denuding	PN assessment	Zygote culture	Witnessing			2
Fertilization check, ICSI	Pronucleus assessment	Zygote culture	Witnessing				1
Day-2 check, 10 zygotes	Morphology assessment	Micrographic record					1
Day-3 check, 10 zygotes	Morphology assessment	Micrographic record					1
Day-3 AHA, laser	Record review/Pt ID	Dish prep	Laser alignment	Assisted hatching	Embryo culture		2
Day-3 AHA, chemical	Record review/Pt ID	Dish prep	Microtool placement	Assisted hatching	Embryo wash	Embryo culture	2
Day-3 transfer	Record review/Pt ID	Micrographic record	Catheter preparation	Catheter loading	Catheter check	Witnessing	4
Extended culture	Changeover of embryos	Witnessing					1
Day-3/-5 cryo, 4 embryos	Record review/Pt ID	Media/dish preparation	Cryo container preparation	Vitrification	Witnessing		2
Day-3 biopsy	Day-3 check	Day 3 AHA	Blastomere biopsy	Embryo wash and culture	Sample loading	Witnessing	4
Day-4 check	Morphology assessment	Micrographic record					1
Day-5 check	Morphology assessment	Micrographic record					1
Day-5 transfer	Record review/Pt ID	Micrographic record	Catheter preparation	Catheter loading	Catheter check	Witnessing	4
Day-5 cryo	Record review/Pt ID	Media/dish preparation	Cryo container preparation	Vitrification	Witnessing		2
Day-5 biopsy	Day-3 assisted hatching	Day-5 check	Dish preparation	TE biopsy	Sample loading	Witnessing	4
Day-6 check	Morphology Assessment	Micrographic record					1
Day-6 biopsy	Day-3 assisted hatching	Day-6 check	Dish preparation	TE biopsy	Sample loading	Witnessing	4
Embryo thaw	Record review/Pt ID	Media/dish preparation	Embryo thaw	Micrographic record	Witnessing		3
Frozen embryo transfer	Record review/Pt ID	Micrographic record	Catheter preparation	Catheter loading	Catheter check	Witnessing	4

Note: Complexity was calculated based on five elements: time restriction; requirement for intense/prolonged focus; multiple complex steps; potential irreversible harm to embryos; potential serious harm to patient. AHA = Assisted Hatching; Cryo = cryopreservation (primarily vitrification); ID= identification; PN = pronuclear; Pt = patient; TE = trophectoderm.

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needs are assessed based on a careful breakdown of the numbers and types of procedures performed in the laboratory. The Interactive Personnel Calculator introduced here provides just such an opportunity.

We believe that it is important to acknowledge the increased complexity of more recently adopted embryology procedures. More extensive witnessing and more individualized treatment/tracking of embryos have become necessary in association with the testing and screening of embryos for embryo selection. Laboratories considering the adoption of these new techniques should be aware of the increased personnel time requirements.

We expect that the suggested staffing requirements will be universal because the time requirements for the embryology tasks are anticipated to be uniform whether they are performed in North America, South America, Europe, Asia, Australia, or elsewhere in the world. However, we acknowledge that there are some differences in personnel utilization/responsibilities from practice to practice, state to state, country to country, and continent to continent. So it is reasonable to assume that there will be some differences in staffing allocation depending on differences in personnel utilization.

What is certain is that administrators should be aware of the increased personnel time requirements for procedures that have been available for decades. Whereas the names and acronyms for these procedures may not have changed, there have been substantial increases in time requirements over the years as the standard of care has evolved in association with extended culture durations and more cryopreservation events per patient treatment cycle.

Although it is anticipated that efficiency should improve as more procedures are performed, it is also true that embryologists are faced with increasing responsibility for diligence, as higher volumes also increase the risk of catastrophic errors of misidentification. This reevaluation of ART laboratory activities should encourage a new set of guidelines for laboratory staffing that better reflect both the new complexities of the IVF laboratory operation and its central role in safe and successful treatment of ART patients.

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