Comparison of electronic versus manual witnessing of procedures within the in vitro fertilization laboratory: impact on timing and efficiency

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Objective: To evaluate the impact of an electronic witnessing system (EWS) on witnessing standard operating procedures and to assess embryologist perceptions of the EWS.
Design: Prospective cohort study.
Setting: Private in vitro fertilization laboratory network.
Patient(s): None.
Intervention(s): None
Main Outcome Measure(s): The time difference between manual and electronic double-witnessing procedures, and embryologist perceptions of the EWS.
Result(s): From 342 witnessing times analyzed (114 EWS, 114 manual, and 114 interruptions to witnesses), the EWS reduced mean (SD) total witnessing time (in seconds) by 91.5 (23.6) for intracytoplasmic sperm injection, 62.0 (17.9) for Day 3 embryo assessment, 58.3 (18.9) for fresh embryo transfer, and 59.4 (13.3) for frozen embryo transfer. This time reduction significantly decreased the overall time required for double-witnessing by 3.1- to 5.2-fold. A survey with 50 embryologists within the laboratory network indicated that most embryologists considered the EWS to improve sample traceability (78.3%), reduce errors in labeling issues (80.4%), and reduce the risk of sample mismatch errors by minimizing disruptions (60.9%). Furthermore, 82.6% thought that visual completion of the EWS dashboard provided peace of mind when leaving work and 84.8% were more confident knowing that all procedures were completed according to the EWS.
Conclusion(s): An EWS can improve laboratory efficiency by significantly decreasing the time required for witnessing procedures and by minimizing interruptions. The EWS was well perceived by embryologists and laboratory managers and enhanced their confidence and peace of mind with regard to witnessing compliance and safety/accuracy. (Fertil Steril Rep® 2021;2:181–8. ©2021 by American Society for Reproductive Medicine.)
Key Words: Embryologist's perspective, electronic witnessing system, IVF laboratory witnessing, laboratory efficiency, quality management

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Infertility affects approximately 50 $\times 10^6$ couples globally, and patients are increasingly seeking medical intervention to conceive, particularly with in vitro fertilization (IVF) (1). Success rates for infertility treatments depend on several patient-related variables (e.g., age and diagnosis) and type of assisted reproductive technology (ART) cycle (e.g., fresh vs. frozen embryo transfer, insemination method), but also vary between fertility clinics (1). Some interclinic variation in

success rates can be attributed to the diverse set of practices and technologies used to perform complex procedures. IVF laboratories have a high degree of complexity in terms of the technology and equipment used and the type and number of tasks being performed simultaneously. Recommendations for best practices or guidelines in IVF laboratories are active areas of discussion (2–5).

Dramatic changes in ART practice, including the addition of many new technologies, have occurred in recent years. As a result, operation of the IVF laboratory has become increasingly complex; with increased complexity comes increased risk (6). Many procedural steps within the IVF laboratory are susceptible to variation and human error, with potentially deleterious consequences. Important steps in the IVF process during which errors are most likely to occur have been identified and include initial gamete collection, mixing of gametes by either conventional IVF or IVF with intracytoplasmic sperm injection (ICSI), gamete or embryo transfer between tubes or dishes, freezing and thawing of gametes, and embryo transfer into patients (7). Gametes and embryos belonging to a particular patient or couple may be manipulated at various times by different embryologists, which introduces further potential for error. Errors in any of these steps could lead to loss or mismatch of gametes and/or embryos.

As the number and complexity of procedures increase, embryologists are exposed to increased sample mismatching risk during manipulation of biologic materials. Therefore, IVF laboratories have implemented required verification by a second person (double-witnessing) to minimize the potential for human error associated with key steps in the IVF process (8, 9). Although double-witnessing is mandated in many countries (10), others have not made it compulsory. IVF laboratories need to define and implement their own double-witnessing standard operational procedure (SOP) (11), which can be challenging given its interdependency with human and equipment resources and the lack of specific guidelines. In addition, double-witnessing protocols can be difficult to implement and new human errors may be introduced, with variation occurring across laboratories (12).

To best serve patients and achieve consistently high success rates, technologic advancements in the laboratory setting need to be standardized (4). Electronic witnessing systems (EWSs) have emerged as a new technology with the potential to standardize IVF witnessing procedures. It may optimize laboratory efficiency by helping embryologists monitor the sequence, timing, and completion of procedures and by minimizing interruptions. EWSs may be able to alleviate some of the current witnessing challenges by mitigating sample mismatch risk, improving sample management and traceability, and eliminating the need for a second human witness. However, the actual impact of EWSs on double-witnessing SOPs with regards to system implementation, time savings, and embryologist perceptions has not been previously described. Furthermore, there have been no head-to-head comparisons of manual witnessing vs. EWSs that include the interruption time imposed on the second witness.

This is the first study to investigate the total time saved using an EWS in the IVF laboratory, taking into account times for both the performer and the second witness, and to seek embryologists' opinions on using this technology.

MATERIALS AND METHODS

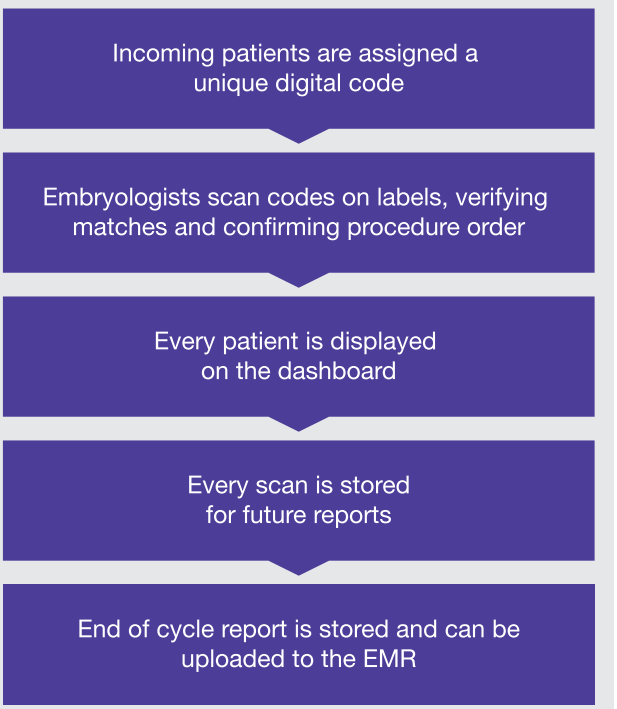
This study evaluated a specific EWS (Gidget; Genea Biomedx, Sydney, Australia) that allows electronic witnessing and workflow visualization with handheld scanners and a centralized computer (Fig. 1). This system uses unique patient bar codes printed on labels and attached to patient specimen containers and paperwork.

The study was determined to be exempt from review by the institutional review board (Western Institutional Review Board, Puyallup, WA). Data were collected over a 3-month period from August to October 2019.

Quantitative Assessment

Study design and data collection. At a single IVF laboratory site (CCRM Boston, Boston, Massachusetts, USA), three procedures of varying complexity – ICSI, Day 3 embryo assessment, and embryo transfer (fresh or frozen) were double-witnessed both manually and electronically during 2 weeks of each month. Five embryologists double-witnessed procedures manually (performer), second-witnessed procedures performed by a second person (witness), and also used the EWS. The duration of all witnessing sessions (initial and final time) was tracked for both the performer and the witness. To account for the interruption time imposed on the witness, the witness recorded how long he/she was kept away from an

FIGURE 1



The electronic witnessing system. EMR = electronic medical record.

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initial task (initial time was recorded when the second witness was requested and final time was recorded when the witness returned to the interrupted task). Large display digital wall clocks were installed at laboratory workstations to optimize time tracking and avoid the need to click on laboratory bench timers. Study procedures occurred over six independent weeks, selected a priori to capture different workloads (low/medium/high) and staff availability. The day of the week (weekend/weekday), number of procedures performed down to the number of oocytes and embryos, and staff available were recorded and evaluated to account for workload variability and its potential impact on the results obtained (Supplemental Table 1, available online). To address potential bias, the sequence of witnessing sessions was alternated. For instance, during one week, embryologists would perform manual witnessing followed by electronic witnessing and then switch to electronic witnessing followed by manual witnessing in the following week. None of the embryologists participating in the study had access to the cumulative raw data to prevent any potential biases towards either of the two types of assessments.

As of April 2018, this EWS had already been implemented as a standard procedure for CCRM Boston; therefore, an additional manual witnessing procedure was performed to prospectively collect the study data. All witnessing steps were performed in isolettes per normal protocols to avoid potential detrimental environment exposure imposed by the additional witnessing procedures.

EWS procedure—creating labels. A laboratory administrator entered patient information into the EWS software. Enough labels—containing patient name, medical record number (MRN), and date of birth—were printed for both paperwork and each dish/tube from Day 0 to Day 7. The number of labels varied depending on the patient treatment (e.g., cycles with preimplantation genetic testing [PGT] would require more labels). The cohort labels were kept with the patient paperwork in the lab. When dishes/tubes were created each day/before each procedure, a label was placed on the side wall of the dish/tube. The process of entering patient information into the EWS system and printing labels usually took around 60 seconds. EWS labels were used for both EWS and manual assessments. During electronic witnessing, paperwork and dishes/tubes were scanned to confirm matching shortly before gametes were handled.

Manual procedure. During manual witnessing, paperwork was checked to verify patient name, MRN, and date of birth against the dishes that were about to be handled. In the case of ICSI, the sperm tube was examined for both male and female patients' name and MRN and compared with the egg, ICSI, and culture dishes. The second witness initialed the paperwork to document witnessing.

Outcome measures. The primary outcome was the time difference between the manual and electronic double-witnessing procedures. A key secondary outcome was a comparison between the number of double-witnessing procedures before and after implementation of the EWS. Other secondary outcomes were numbers of potential mismatches identified by the system since its implementation in April 2018.

Statistical analysis. Categorical data are expressed as absolute counts and percentages. Continuous measurements are expressed as mean (SD), with 95% confidence intervals (CIs) or ranges as appropriate. The analysis of time to double-witness was performed using a linear regression model for manual vs. electronic witnessing, including factors for type of procedure (e.g., ICSI, Day 3 assessment, and embryo transfer), week of data collection (to assess different workloads and staffing), and individual embryologist.

Qualitative Assessment

Study population and survey design. A web-based survey was developed and administered to embryologist staff via email at eight CCRM laboratories across the US and Canada to gather information on attitudes and perceptions regarding the EWS. The survey questions were written and validated by eight embryologists (two independent groups of four each) and one epidemiologist (Ph.D.) for clarity and to ensure that there were no double-barreled questions or other confusing or ambiguous statements. CCRM embryologists provided consent before answering the questionnaire. Questionnaires (Supplemental Fig. 1) were administered to two groups of embryologists among all laboratories: managers (directors/supervisors) and non-managers. The manager survey had the same 53 questions as the non-manager survey but also included an additional 20 questions regarding managerial tasks. Questionnaires were composed of Likert-scale statements, open-ended questions, and ranking questions related to the EWS. Some questions asked as a negative were included to ensure that the survey taker reflected on each question and answer (i.e., "It takes me longer to double-witness a sample using Gidget [compared to manual double-witnessing]", "I was concerned when I heard CCRM was implementing electronic double-witnessing"). Questions addressed the following specific topics: sample identification, traceability, and matching; patient mismatch prevention; critical procedures and deviation; workload interruptions; laboratory efficiency; managerial tasks (i.e., workflow management, audit, and record keeping); EWS implementation (i.e., training, impact on existing SOP, and potential concerns). The values corresponded to categorical variables (strongly disagree [1], disagree [2], neutral—neither agree nor disagree [3], agree [4], and strongly agree [5]), with an option for "no viewpoint" or "choose not to answer" for some of the questions. The survey was used to evaluate the individuals' perceptions and beliefs about the EWS device in the workplace and was not meant to assess their knowledge about the advantages or disadvantages of electronic vs. manual witnessing.

Outcome measures. The primary outcome was to evaluate the embryologists' perceptions on specific domains of interest related to the EWS, adjusted by sex, race, age, and years of IVF laboratory experience.

Data collection. Before the start of the formal data collection, the questionnaires were validated using the following steps: establishing face validity, pilot testing with experienced embryologists, revision, and retesting. Data were deidentified, consolidated, and summarized to describe demographics

and embryologist perceptions. For the open-ended and free-text questions, unique themes on the basis of word and phrase choice and frequency were identified using grounded theory methodology to find patterns and trends in the data (13).

Statistical analysis. Analysis of each categorical survey question was performed using a logistic regression model for the proportion of participants with favorable perception (e.g., "agree" or "strongly agree") adjusted by sex, race, age, education level, and years of IVF laboratory experience. A sensitivity analysis was conducted with months of experience with the EWS added to the model. Binomial CIs for the proportion positive were calculated using the Clopper–Pearson method.

RESULTS

Quantitative Study

Number of witnessing sessions. A total of 342 witnessing sessions were analyzed (114 EWS, 114 manual, 114 interruption times of witness). Overall, 49/64 (76.6%) ICSI procedures, 32/72 (44.4%) Day 3 fertilization assessments, 2/2 (100%) fresh embryo transfers, and 31/33 (93.9%) frozen embryo transfers (FETs) were witnessed manually and with the EWS during the 6-week study period.

Time savings for the performer. For the embryologists performing the procedure to be witnessed (performers), the EWS reduced the mean (SD) time to witness by 29.7 (38.8) seconds per ICSI procedure. For Day 3 embryo assessment, the EWS saved a mean (SD) of 16.8 (26.5) seconds per procedure. The EWS saved a mean (SD) 27.0 (19.8) and 18.5 (15.0) seconds for fresh embryo transfer and FET, respectively. Overall, witnessing using the EWS saved the performer 25.3 seconds per procedure compared with manual witnessing (95% CI −36.70, −13.84; $P<.001$).

Time interruption imposed on second witness. The amount of interruption time required for embryologists to manually double-witness procedures ranged from 31 to 62 seconds (Table 1). The amount of time did not differ by embryologist, sequence of double-witnessing, or period of data collection.

Time savings when combining the performer's and second witness' time. When the performing embryologist's time and the witnessing embryologist's interrupted time were included, the EWS reduced the mean manual witnessing total times (performer waiting and second witness interruption) by 58 to 92 seconds per procedure (Table 1, Fig. 2). The amount of time saved did not differ by embryologist, sequence of double-witnessing, or period of data collection, indicating that time savings were independent of workload and staff availability.

EWS implementation and standard witnessing procedures. When comparing the SOP for double-witnessing procedures at CCRM Boston before and after the implementation of the EWS, there was an increase in the number of procedures and sub-procedure steps being witnessed: 8 procedures and 15 steps involved witnessing sessions before the EWS compared with 13 procedures and 33 steps after EWS implementation (Supplemental Table 2, Supplemental Fig. 2).

Identification of potential mismatches. Since the implementation of the EWS at CCRM Boston (April 13, 2018) until the end of the study (October 31, 2019), a total of 20 potential mismatches were identified among 9,762 scans (0.2%). On review, these mismatches would be considered minimal if not prevented and would likely not result in harm on the basis of the grade of IVF laboratory nonconformances described by Sakkas et al. (14). Most incidents were caused by paperwork scanning mistakes (e.g., embryologists picking the wrong clipboard). Out of 20 potential mismatches, 5 near

TABLE 1

Time differences in double-witnessing between EWS and manual witnessing.

	Time in seconds, mean (SD); 95% confidence interval				
	Manual procedures				
Procedure	Witness	Performer	Total	EWS performer	Time difference (manual total minus EWS performer)
ICSI	61.7 (24.9); 54.7–68.7 (n = 48)	64.2 (36.1); 54.1–74.3 (n = 49)	125.9 (31.0); 117.2–134.6	34.4 (12.4); 30.9–37.9 (n = 49)	91.5 (23.6); 84.9–98.1
Day 3 embryo assessment	44.6 (16.4); 39.1–50.1 (n = 34)	47.6 (16.1); 42.0–53.2 (n = 32)	92.2 (16.2); 86.7–97.7	30.2 (19.4); 23.6–36.8 (n = 33)	62.0 (17.9); 55.9–68.1
Fresh embryo transfer	31.3 (25.0); 3.0–59.6 (n = 3)	41.0 (22.6); 9.6–72.4 (n = 2)	72.3 (24.2); 42.3–102.3	14.0 (2.8); 10.1–17.9 (n = 2)	58.3 (18.9); 33.7–82.9
Frozen embryo transfer	40.9 (21.2); 33.2–48.6 (n = 29)	35.1 (13.8); 30.2–40.0 (n = 31)	76.0 (17.8); 69.6–82.4	16.6 (6.6); 14.3–18.9 (n = 31)	59.4 (13.3); 54.7–64.1
All procedure types	50.5 (23.5); 46.2–54.8 (n = 114)	51.2 (28.8); 45.9–56.5 (n = 114)	101.7 (26.3); 96.9–106.5	28.1 (15.5); 25.3–30.9 (n = 115)	73.6 (21.6); 69.6–77.6

Note: EWS = electronic witnessing system; ICSI = intracytoplasmic sperm injection; SD = standard deviation.

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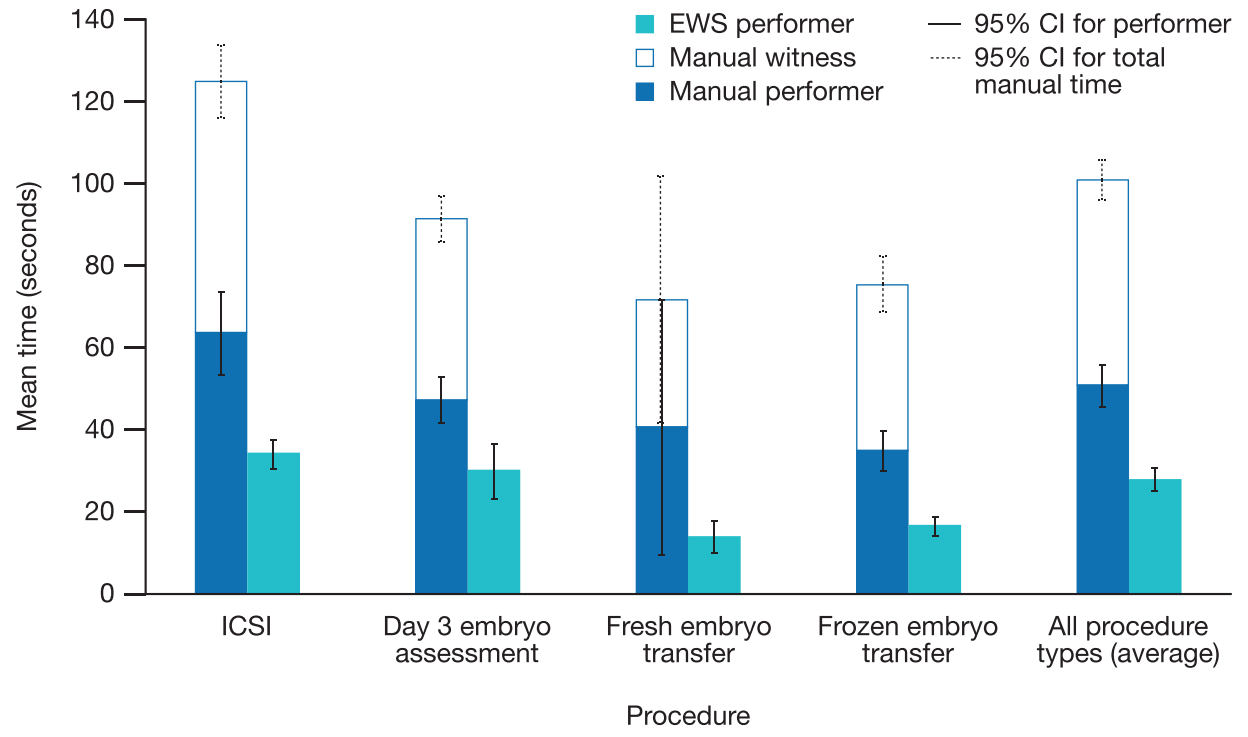
FIGURE 2



Comparison of witnessing times with EWS and manual witnessing by procedure, including witness (interruption) time—interruption time when the second witness was kept away from an initial task. The mean difference in overall time to witness for the performer was significantly shorter with the EWS than with manual witnessing (–25.3 seconds, $P<.0001$ from a linear regression model for difference in time needed to witness for manual vs. electronic double-witnessing across all procedures, with fixed effects for type of procedure, week of data collection, and embryologist). EWS = electronic witnessing system; ICSI = intracytoplasmic sperm injection.

Holmes. Electronic vs. manual double-witnessing. Fertil Steril Rep 2021.

misses could have led to a major nonconformance if not prevented by the EWS. Near misses were defined as events that could have negatively impacted clinical care. For example, one of multiple sperm tubes (from the same patient) was placed in the wrong rack; in this case, the embryologist did not check all tube IDs correctly. Potential contributing factors may include high patient volume and new staff. In this case, the EWS helped to identify a potential error before the sample was used.

Qualitative Study

Demographics and baseline characteristics. Fifty embryologists in total and a subset of 15 managers took part (Table 2). The mean (SD) age was 41.7 (10.9) years for the embryologists and 49.0 (9.3) years for the managers. The mean (SD) number of years of experience working in a clinical IVF laboratory in any capacity was 12.9 (8.7) years for the embryologists and 18.7 (6.8) years for the managers. Embryologists had a mean (SD) 10.9 (6.3) months of experience working with the specific EWS, and managers had 12.4 (5.5) months.

Survey responses. The questionnaire response rate was 96.2% (50/52). Implementation of the EWS was well perceived by most embryologists; 78.3% of the respondents agreed that it improved sample identification and traceability, 80.4% agreed that it reduced errors in labeling, and 60.9% agreed that it reduced the risk of sample mismatch errors by minimizing disruptions.

With regard to embryologist confidence, 82.6% of the respondents agreed that visual completion of the critical mandatory laboratory procedures checklist visible on the EWS dashboard provided peace of mind when leaving work, and 84.8% were more confident knowing that all procedures were completed according to the EWS. Common reasons given for increased confidence levels with the EWS use included reduced likelihood of errors at each step and increased traceability. Responses included "adding an extra layer of protection to ensure samples aren't mismatched", "providing a timeline for the day of procedures performed by each technician. This won't prevent an error but it can assist in light of poor recall of events", "having a traceable accountability log", "providing an audible alarm when names don't match", and "provides an independent witness". A common reason for decreased confidence levels was greater complacency with the EWS than with manual assessments: "making it easier to forget to read the dish labels manually",

TABLE 2

Demographics and baseline characteristics

Characteristic	All embryologists (N = 50)	Managers[a] (n = 15)
Age, years, mean (SD), range	41.7 (10.9), 23–64	49.0 (9.3), 35–64
Age categories, years, n (%)		
<30	7 (14.0)	0 (0)
30–39	12 (24.0)	1 (6.7)
40–49	19 (38.0)	8 (53.3)
50–59	8 (16.0)	3 (20.0)
≥60	4 (8.0)	3 (20.0)
Female, n (%)	31 (62.0)	7 (46.7)
Male, n (%)	19 (38.0)	8 (53.3)
Educational level, n (%)		
Bachelor's degree	27 (54.0)	4 (26.7)
Master's degree	12 (24.0)	4 (26.7)
M.D.	0 (0)	0 (0)
Ph.D.	11 (22.0)	7 (46.7)
Years of experience in clinical IVF laboratory (any capacity)		
n (missing)	45 (5)	15 (0)
Mean (SD), range	12.9 (8.7), 2–32	18.7 (6.8), 10–32
Experience as clinical embryologist, years		
n (missing)	46 (4)	15 (0)
Mean (SD), range	11.7 (8.1), 1–30	17.9 (6.5), 10–30
Experience working with Gidget® EWS, months		
n (missing)	50 (0)	15 (0)
Mean (SD), range	10.9 (6.3), 0–25	12.4 (5.5), 1–25

Note: EWS = electronic witnessing system; IVF = in vitro fertilization; MD = doctor of medicine; Ph.D. = doctor of philosophy; SD = standard deviation.

[a] The subgroup of "All embryologists" who answered "yes" to the question "At this time, I am a lab manager, lab supervisor, or lab director."

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"having one set less of eyes. I read the labels less counting on 'the EWS'"; other reasons included "audible alarms are similar" (for warnings and critical errors), "labels are tiny and sometimes difficult to read", and "adding more steps to what we do" (Supplemental Table 3). When asked how the live dashboard on the EWS helps embryologists, many responses related to help with organizing the day and planning procedures for the following day.

In addition, the EWS increased efficiency by allowing labeling standardization according to 84.8% of the respondents. Most respondents (73.9%) agreed that the EWS allowed double-witnessing procedures to be conducted more quickly than manual witnessing procedures, as a second person is not required (Supplemental Figure 3A).

Overall, 78.3% of the respondents considered EWS training easy, whereas only 26.1% showed concern with the transition from manual witnessing to the EWS. Most embryologists (88.9%) would recommend the EWS to another embryologist (Supplemental Figure 3B). Among managers, 93.3% agreed that the sample chain of custody was easy to follow when using the EWS audit reports.

Survey responses were not influenced by the respondent's age, sex, or years of laboratory experience. Sensitivity analyses, which added the number of months of prior experience with the EWS to the model, also found that prior experience did not impact survey responses.

DISCUSSION

For the first time, these data represent a comparison between manual double-witnessing and an EWS in the IVF laboratory that includes accounting for second-witness interruption time. Overall, using the EWS saved an average of 73.6 seconds (1.23 minutes) per studied procedure compared with manual witnessing. The amount of time saved depended on the procedure but did not differ by embryologist, study period, or sequence (e.g., EWS first, manual second; or manual first, EWS second), showing that, overall, the EWS can significantly reduce the time required for double-witnessing by 3.1- to 5.2-fold when including the second-witness interruption time.

Extended culture and PGT, which currently may involve evaluating and biopsying embryos through Day 7, have added both complexity and time required for completion of ART cycles (4). Alikani et al. (6) estimated that more complex cycles, such as those involving PGT, could require 20.2 hours of personnel time, including 3.67 hours related to manual witnessing of nine procedures (average of 24.4 minutes per procedure). Our study evaluated the actual witnessing time for three procedures of different complexity and showed a much lower average of 101.7 seconds (1.69 minutes) when using manual witnessing (Table 1). This time was considerably reduced to an average 28.1 seconds (0.47 minutes) when using the EWS. Understandably, estimations such as the one described by Alikani and colleagues usually tend to account for worst-case scenarios. The actual time dedicated to manual witnessing procedures will vary on the basis of each laboratory's SOP (i.e., the number of procedures to be witnessed) but in addition on laboratory logistics and staffing. In the present study, however, staffing and workload did not affect manual witnessing time.

The results showed that a witnessing session can average 0.47 minutes using the EWS. Small increments of time savings could represent several hours of embryologists' work considering the annual volume of ART cycles. We estimated the average time savings per day, week (7 days), month (30.45 days), and year (365.25 days) using the average of procedures performed in our lab during the study period: 14.73 minutes per day, 103.9 minutes per week, 7.47 hours per month, and 89.66 hours per year, respectively (Supplemental Table 2). At CCRM Boston, the number of types of witnessing sessions per patient increased from 15 to 33 after the implementation of the EWS. However, when summing up the total time required to double-witness, 33 sessions is estimated to take less time than performing manual witnessing on 15 sessions (10.42 vs. 19.67 minutes; Supplemental Table 2). Although increasing the number of types of witnessing sessions potentially represents additional work for embryologists, the simplicity of the witnessing steps with the EWS enabled additional checks to be built into the workflow in a seamless manner, as indicated by the survey results. Importantly, the improved SOP allowed increased sample identification and traceability and additional checkpoints to prevent potential mismatches. Although these changes are feasible with an EWS, implementing such a robust witnessing SOP relying on manual witnessing can be challenging. In addition, the

potential detrimental effect caused by increased exposure to a suboptimal environment (such as variations in pH or temperature) while dishes might be outside the incubator for double-witnessing and oocyte/embryo assessment cannot be dismissed.

Although manual double-witnessing is perceived as a safeguard, some disadvantages have been noted; these include independent redundancy (double checkers do not behave independently as predicted, and failures are not identified), inattentional blindness (discrepant information not perceived because of limited cognitive resources), and ambiguous accountability (unclear which staff member is responsible for checks, and checks are unintentionally omitted) (15, 16). Evidence suggests that manual double-witnessing is not as safe and effective as it could be, and it has the unintended consequence of increasing risk by creating distractions and interruptions to the process and introducing additional witnessing paperwork and staffing challenges (17). The interruption factor—defined as work interruptions occurring when an embryologist needs to stop a task to be the second witness for another colleague—is usually underestimated. Interruptions imposed on the embryologist staff could potentially offer more opportunities for human errors. However, the importance of double-witnessing is generally acknowledged: the European Society of Human Reproduction and Embryology and the Human Fertilisation and Embryology Authority strongly advise using a system of codes and checks such as double-witnessing or an electronic identification system during critical steps in ART (3, 10).

The EWS can address interruptions and may help to reduce sample mismatches. In addition, however, it may introduce new risks such as errors in printing labels and overconfidence in the witnessing system technology. Most of the potential mismatches identified by the EWS at CCRM Boston were minimal nonconformancies related to paperwork scanning. This could be potentially attributed to a "relaxation" of reading labels and the confidence on the EWS used. Although the technology will safeguard the relaxation aspect, it may not circumvent initially printing and attaching the wrong label to a tube. However, the same risk applies to manual witnessing processes. It is important to mention that no EWS provides a foolproof system, as it cannot completely eliminate user error, although it does provide another level of checkpoints where potential mismatches can be identified, prevented, and, importantly, documented. The mismatches identified since the implementation of the EWS at CCRM Boston would have likely been caught by manual witnessing as well, but the EWS helps to track and quantify these issues, leading to increased documentation to support changes to workflow to minimize risk. Many challenges, such as staff availability, workflow, implementation, standardization across laboratories, traceability, and prevention of errors, can be at least partially addressed through the use of an EWS, which may in addition have the potential to reduce the embryologists' inattentional blindness and stress related to the risk of mismatches.

A prior report presented a patient's perception of the use of an EWS within the IVF laboratory (12). The current study represents the first evaluation of embryologists' opinions on EWS value. Survey results showed that embryologists' perceptions of the EWS were positive, with most embryologists recommending using one in their laboratories. Sample identification, traceability, mismatch prevention, laboratory efficiency, and embryologist confidence were perceived to be improved. Although not all aspects were evaluated in our study, the overall effect of EWSs on embryologists' reported confidence and stress suggest that the specific EWS may have additional positive effects that have been observed in previous studies, such as increased patient satisfaction and reduced mismatches in the laboratory (12, 17).

An important consideration related to the implementation of new technologies in an IVF laboratory is the cost factor. Potential cost savings related to EWS might be different for each clinic as it may be influenced by different aspect, such as time savings, lab staffing, and logistics, as well as risk mitigation. As such, there is the possibility that this technology might not demonstrate any cost savings for some clinics. In this study, we did not evaluate the potential impact of cost savings and financial aspects related to this technology.

A potential limitation of the quantitative study is that our findings may not be generalizable to other laboratories. Our results are restricted to a single clinic with approximately 1 year of experience using a specific EWS—Gidget was adopted by CCRM in April 2018 and study data collection occurred from August to October 2019. Furthermore, clinics that have recently introduced this system or a different EWS may not observe time savings that are as extensive as the savings seen here. Embryologist perceptions may additionally be influenced by the length of experience with a particular system and by general embryology experience and knowledge. Before implementing an EWS, clinics should evaluate the system, its functionality, and the context of the IVF laboratory in which it will be used (16). CCRM Boston evaluated two other systems—IMT Matcher and RI Witness—before selecting the EWS used in this study. The final choice of EWS was on the basis of pricing, ease of hardware integration within our laboratory set-up, and positive user interface experience with the software. This facilitated the implementation of the technology across all CCRM laboratories, demonstrating widespread acceptance, standardization, and adoption within this laboratory network.

CONCLUSION

In conclusion, an EWS may help improve laboratory efficiency and workflow by saving time and minimizing interruptions, which have long been underestimated in current complex IVF laboratory practice. In addition, the EWS was generally well perceived by most embryologists across the evaluated domains, where it enhanced confidence and peace of mind for embryologists at the end of a workday.

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