

Electronic witness system in IVF—patients perspective

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Received: 25 March 2016 / Accepted: 15 June 2016 / Published online: 7 July 2016
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Abstract

Objective The objective of this study is to evaluate patient concerns about in vitro fertilization (IVF) errors and electronic witness systems (EWS) satisfaction.

Design The design of this study is a prospective single-center cohort study.

Setting The setting of this study was located in the private IVF center.

Patient(s) Four hundred eight infertile patients attending an IVF cycle at a GENERA center in Italy were equipped with an EWS.

Intervention(s) Although generally recognized as a very rare event in IVF, biological sample mix-up has been reported in the literature. For this reason, some IVF laboratories have introduced EWS with the aim to further reduce the risk of error during biological samples handling. Participating

patients received a questionnaire developed through a Likert scale ranging from 1 to 6.

Main outcomes measure(s) Patient concerns about sample mix-up without and with an EWS were assessed.

Result(s) 90.4 % of patients expressed significant concerns relating to sample mix-up. The EWS reduced these concerns in 92.1 % of patients, 97.1 % of which were particularly satisfied with the electronic traceability of their gametes and embryos in the IVF laboratory. 97.1 % of patients felt highly comfortable with an IVF center equipped with an EWS. Female patients had a significantly higher appreciation of the EWS when compared to their male partners ($p = 0.029$). A significant mix-up event occurred in an Italian hospital during the study and patient's satisfaction increased significantly towards the use of the EWS after the event ($p = 0.032$).

Conclusion(s) EWS, by sensibly reducing the risk for sample mix-up in IVF cycles, has been proved to be a trusted strategy from patient's perspective.

Capsule EWS is able to contain patient concerns about possible errors in biological sample manipulation and will increase patient satisfaction towards the IVF Clinic, especially after of the embryo exchange that happened at an Italian Hospital in 2013.

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Keywords Embryo labeling · IVF mix-up · Traceability · Witnessing system · Patient's perspective

Introduction

The introduction of the electronic witness system (EWS) in the in vitro fertilization (IVF) clinical practice is a recent innovation. Its use is especially prevalent in the UK where it is mandated by a specific legislation. Although electronic witnessing has been recommended to improve traceability and reducing IVF mix-ups [1], only a few centers have implemented the technology to this point all around the world.

Without an EWS, embryologists are exposed to increased mismatching risks during the manipulation of biological material. In fact, since the first known case of an assisted

reproductive technology (ART) mix-up in 1987 in Manhattan, USA [2], the accidental use of incorrect gametes or embryos during ART procedures has been reported in several centers in different countries [3, 4]. Many of these mix-ups were detected because couples gave birth to babies of different skin color to their own or because fertility clinics later informed patients of the mistake. It is therefore possible that other cases could have gone unnoticed. In an IVF center, a biological sample misidentification could potentially be catastrophic for the clinic, clinic staff, and especially patients.

Embryologists could face legal challenges and regulatory sanctions, while patients would have to cope with the psychological damage and with the loss of confidence in the IVF process impacting on future cycles. For instance, in Italy, there was a recent high-profile mismatching error at a public hospital in Rome, in which incorrect embryos were transferred between two couples. After the embryo mix-up, the woman who got pregnant has decided to continue the pregnancy, while the other one that was not pregnant has decided to charge the medical and biological team, reclaiming her rights on the babies.

Critical points during the clinical and laboratory IVF procedures have been identified where mismatching of gametes and embryos is most likely to occur: initial gamete collection, mixing of gametes by either conventional IVF or IVF with intracytoplasmic sperm injection, gametes or embryos transfer between tubes or dishes, freezing and thawing of gametes or embryos, and embryo transfer into a patient [5].

Without an EWS, the main control measure used to reduce the risk of biological sample mix-up is a human double-checking approach. However, this mechanism of control has been shown to be vulnerable to human errors including: check omission, check incomplete, involuntary automaticity, and non-contemporaneous checking [6, 7]. For these reasons, several alternative options have been developed in order 1 to replace the majority of human manual witnessing steps in IVF: (i) systems based on barcode labels [8], (ii) systems based on silicon barcodes that are injected directly into eggs or embryos [9], and (iii) systems based on Radio Frequency Identification technology (RFID) [10, 11]. The latter has two major advantages: firstly, it prevents embryologists accidentally working on more than one patient's eggs or sperm at a time and, secondly, it marks each course step, preventing embryologists from omitting key tasks in the process. The use of these electronic systems is rapidly extending to fertility clinics worldwide [10, 12].

IVF Witness is an EWS (Research Instruments, UK) based on radio frequency identification (RFID) tags to track and record patients and samples during IVF. Using RFID tags, patient's identity is monitored at every stage of the treatment, and at the same time, the system captures information regarding the cycle progress and operator actions. The IVF witness system monitors every instance when gametes or embryos are transferred from one container to the next and ensures that only one patient can be worked on at one time. Monitoring is constant,

so an identity check can never be overlooked. Finally, to safeguard the beginning and end of the cycle, each patient is provided with an individual ID card, used in the treatment rooms, to verify that the identity of the patient matches that of the eggs, sperm, and embryos. From a technical perspective, the EWS works with low-level radio waves as for many other sources of electromagnetic and radio fields that are usually present in an IVF laboratory. Even though animal and cell lines studies showed reassuring data, [13–15] it still needs to be fully determined whether the systematic use of such electronic devices in the IVF laboratory might interfere somehow with the biology of gametes and embryos. However, other than using very moderate radio frequencies, the exposition time is limited to only few seconds that are required during some steps of cells manipulation outside the incubators. When in the incubator, the electronic tags are not receiving or emitting radio waves at all. Furthermore, efforts should still be made to improve the cost-effectiveness of the EWS devices in order to allow more clinics and patients to benefit from its routine application in IVF.

IVF Witness was recently introduced in our IVF laboratory, and the ID card is given to the patient that keeps it from oocyte retrieval to embryo transfer. This is the first study investigating the patient perspective about the implementation of such technology in the IVF practice. We have designed a prospective study with the purpose of measuring patient's awareness and concerns about a possible mismatch error and their satisfaction in response to the advantages of this electronic system and if this solution could reduce their worries about biological mix-up.

Furthermore, during the course of the study, there was a high-profile mismatching error at public hospital in Rome, Italy, in which incorrect embryos were transferred between two couples. The publication of this catastrophic event by the Italian mass media enabled us to measure patient prospective on the EWS before and after becoming aware of the significant mismatch event.

Materials and methods

This is a prospective study performed between September 2013 and December 2014 in a single private infertility center (GENERA Centre for Reproductive Medicine, Rome).

We recruited 408 consecutive infertility patients that were interviewed 1 on the day of embryo transfer by a psychological team. All patients were informed about the use of EWS on the day of oocyte retrieval and were given an individual electronic ID card by the embryological team. On the day of the embryo transfer, patients were introduced to the psychologist who gave them the questionnaire and explained the purpose of the study.

Because of the catastrophic embryo mix-up event that occurred in an Italian hospital during the study period, we were able to compare two patient groups; one group of patients

before the event and the other group after the event were made public. Each group consisted of 204 consecutive patients that received the same questionnaire. The main socio-demographic variables considered were the following: age of partners, gender, and number of previous IVF attempts (in other or in our reproductive center).

The institutional review board of the Valle Giulia Clinic approved the study, and signed informed consent was obtained from all patients recruited.

Questionnaire layout

A patient's prospective ad hoc questionnaire was developed with consideration of the possible ambiguities that the patients could have during an IVF treatment cycle with respect to the clinic practices and the patients concerns about a potential mismatch occurring in the laboratory. The target of the questionnaire was to identify different issues related to patient's awareness of a possible biological sample mix-up, their worries about this possibility, the degree of satisfaction towards the use of a new EWS (IVF Witness; Research instruments, UK) in clinical IVF procedures, and the satisfaction levels towards clinics using the technology.

The questionnaire was composed of seven questions, and each was linked to an answer on a Likert scale of values ranging from 1 to 6. The values corresponded to either categorical variables (1 = *No, never*; 2 = *Rarely*; 3 = *Sometimes*; 4 = *Frequently*; 5 = *Always*; 6 = *No viewpoint*) or to a nominal variable (1 = *No worries*; 2 = *Lack of information on its use*; 3 = *Loss of your personal electronic card*; 4 = *Because it is an electronic device*; 5 = *No viewpoint*) (Table 1).

Statistical analysis

Data are expressed as absolute counts and percentages and also as median \pm inter-quartile range. Continuous measurements are expressed as mean \pm standard deviation or as median \pm inter-quartile range as appropriate. Two sample comparisons were based on Mann-Whitney rank-sum test or Student's *t* test as appropriate. Relationship between 1 main predictors and question responses was evaluated by means of polytomous logistic regression with question-specific intercept. In comparing pre- and post alien mix-up event patients, we summarized two questions via principal component analysis (PCA). PCA was used to obtain the optimal summary between these two questions (as opposed to a simple score average which would have been sub-optimal). The resulting summary was treated as a continuous variable. All hypothesis tests were two-tailed. All *p* values reported are Bonferroni adjusted for multiplicity,

where an adjusted *p* value <0.05 was considered as statistically significant.

Results

A total of 408 patients were evaluated: 198 were male (48.52 %) with an average age of 39.64 years old (SD = 5.4) and 210 (51.47 %) were female with an average age of 36.39 (SD = 4.0) years old.

The female population was younger compared to males ($p < 0.01$). A mean number of 2.2 (SD = 1.8) previous IVF treatment cycles were performed in our clinic, while the average number of the attempts performed in other infertility clinics was 1.2 (SD = 1.7).

Detailed data obtained from the questionnaire per single question are reported in Tables 2. We observed that 369 (90.43 %) of patients being concerned of an error in the biological manipulation of samples with varying degree (question n.1). We also analyzed if the introduction of the EWS would be able to reduce patient's concern about a biological mix-up in IVF. 376/408 (92.15 %) of the patients confirmed that their concerns would be reduced if the new control device were available (question n.2). In analyzing the patient's approval of the EWS with respect to its ability to mark every step in the laboratory routine (question 3), we found that 396/408 (97.06 %) patients had some degree of approval.

The use of a sound alarm to alert the operators about an ongoing risk of mix-up or about procedural mistakes was appreciated by 97.55 % of patients interviewed (Table 2 question 4).

Among the possible issues related to the practical use of an EWS, most patients declared no worries at all (31.86 %, Table 2 question 5). Few patients expressed some concerns related to the electronic nature of the device (15.20 %), followed by the lack of information about its use (16.12 %), while most of them were concerned about the possibility of an occasional loss of the electronic card (29.90 %). Before starting the IVF treatment, patients received an EW card that was kept until the day of embryo transfer. The accidental loss of the card represented a noticeable source of concern. However, when informed about the possibility to 1 obtain a duplicate card and that losing the electronic card would not affect the procedure, they were much more comfortable and felt reassured (Table 2 question 6).

Finally, we assessed patient satisfaction towards centers that implemented the EWS (question n.7).

398/408 patients (97.1 %) were more satisfied if an EWS was used in their treating clinic. It was noted that patient age and gender was significantly associated with the responses to question 7 (Table 3). In particular, younger patients were more likely to prefer a clinic that had implemented an EWS system

Table 1 Questionnaire's questions to evaluate patient's perspective on different features of electronic witness systems

QUESTION 1	1	2	3	4	5	6
Supposing a mix-up due to human error during the manipulation of your biological samples occurs, even though the probability is extremely low, of, how much does it worry you?						
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint						
QUESTION 2	1	2	3	4	5	6
If you were aware of the implementation of a new device (electronic witness) able to minimize the possibility of human error during IVF procedures, would your concerns about a sample mix up be reduced?						
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint						
QUESTION 3	1	2	3	4	5	6
The electronic witness (described in Item. 3) is able to track and check every step of sample manipulation in the IVF laboratory. Therefore, each phase and procedure performed with your gametes and embryos is tracked and recorded. In relation to the sentence above, how much would you appreciate the use of this new device during your treatment?						
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint						
QUESTION 4	1	2	3	4	5	6
The electronic witness is programmed to go in alarm if there is a sample mix up or other identifying element or label discrepancy. Given this particular feature of the instrument, how much would you like to use the device during your treatment?						
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint						
QUESTION 5	1	2	3	4	5	6
If you were to benefit from the use of the electronic witness during your IVF treatment, reassured by the extra degree of control, what aspect would bother you most?						
1 = No worries at all 2 = Lack of information on its use 3 = Loss of the personal electronic card						
4 = The fact that it's an electronic device 5 = No viewpoint						
QUESTION 6	1	2	3	4	5	6
Would you feel more at ease in using the electronic witness if you knew in advance that in case of loss of your personal electronic card there wouldn't be any problem because a duplicate is available?						
1 = No 2 = Yes, a little 3 = Yes, moderately 4 = Yes, a lot 5 = Yes, extremely 6 = No viewpoint						
QUESTION 7	1	2	3	4	5	6
Now that you are aware of this technological innovation, how much does it increase your preference and trust in an IVF center that uses it?						
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint						

($p = 0.032$), and females were significantly more likely (one point in median on the Likert scale) than men ($p = 0.029$).

Comparison of patient's perspective in the pre- and post mix-up event period

In the next step, we compared patients' perspective before and after the mentioned embryo mix-up event that occurred in another clinic in the same city.

The first group (hereafter defined as pre-event) was made of 204 patients of which 99 were male (48.52 %) with a mean age of 39.12 (SD = 4.8) and 105 (51.47) were female, with a mean age of 36.4 (SD = 5.2). The mean previous IVF attempts

made in our clinic were 2.40 (SD = 1.7), and the mean previous IVF attempts made in other clinics was 0.60 (SD = 1.2).

The second group (hereafter defined as post-event) also consisted of 204 patients of which were 99 male (48.52 %) with a mean age of 40.16 (SD = 6.6) and 105 were female (51.47 %) with a mean age of 36.39 (SD = 4.1). The mean previous IVF attempts made in our clinic were 2.02 (SD = 1.9), and the mean previous IVF attempts made in other clinics was 1.79 (SD = 2.0).

There were no significant differences in gender, age, or number of IVF attempts at our clinic or in other clinics between the two groups. We decided to combine the replies to questions 3 and 7 of the questionnaire to obtain a single measure of the aptitude towards an EWS, which could also be sensitive to the advertisement of the mix-up event by the

Table 2 Descriptive analysis of questionnaire’s question inter-quartile range (IQR)

	Likert score	N. Patients (%)	MEDIAN ± IQR
QUESTION 1: Biological samples mix-up 1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint	1.00 2.00 3.00 4.00 5.00 6.00	36 (8.82) 132 (32.35) 71 (17.40) 69 (16.91) 97 (23.77) 3 (0.63)	3 ± 2
QUESTION 2: Laboratory device to avoid human errors 1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint	1.00 2.00 3.00 4.00 5.00 6.00	28 (6.86) 60 (14.71) 74 (18.14) 125 (30.64) 117 (28.68) 4 (0.98)	4 ± 2
QUESTION 3: Satisfaction toward the tracking property of the Electronic Witness 1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint	1.00 2.00 3.00 4.00 5.00 6.00	8 (1.96) 11 (2.70) 38 (9.31) 118 (28.92) 229 (56.13) 4 (0.98)	5 ± 1
QUESTION 4: Appreciation of EWS ability to signal in case of sample mix-up 1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint	1.00 2.00 3.00 4.00 5.00 6.00	4 (0.98) 4 (0.98) 39 (9.56) 119 (29.17) 240 (58.82) 2 (0.49)	5 ± 1
QUESTION 5: Possible concerns on the use of Electronic Witness 1 = No worries at all 2 = Lack of information on its use 3 = Loss of the personal electronic card 4 = the fact that it’s an electronic device 5 = No viewpoint	1.00 2.00 3.00 4.00 5.00	130 (31.86) 66 (16.18) 122 (29.90) 62 (15.20) 28 (6.86)	3 ± 2
QUESTION 6: Attitude toward EWS card loss 1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint	1.00 2.00 3.00 4.00 5.00 6.00	21 (5.15) 44 (10.78) 60 (14.71) 118 (28.92) 146 (35.78) 19 (4.66)	4 ± 2
QUESTION 7: Satisfaction toward the IVF clinic using EWS 1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint	1.00 2.00 3.00 4.00 5.00 6.00	2 (0.49) 7 (1.72) 58 (14.22) 130 (31.86) 203 (49.75)	5 ± 1

Italian media. The summary score was statistically different between the two groups ($p = 0.032$), showing an overall increase in attention of patients towards the implementation and use of an EWS in IVF clinical practice.

Finally, the distribution of scores obtained by comparing the responses of patients to the questions n. 1 and n. 7 was observed in a narrow time window around the mix-up event. In particular, questions 1 and 7 were observed at five different time points: between 30 and 15 days before (pre T0, $N = 32$), 15 days before (pre T1, $N = 29$), in the 15 days following the mix-up event (mix-up T2; $N = 34$), between 15 days and 1 month after (post T3, $N = 28$), and in the following 15 days (post T4; $N = 27$). As shown in Fig. 1, it was possible to observe a significant increase ($p < 0.01$) in the number of patients showing extreme concerns about the possibility of a human 1 error in the procedures, as well as in patients showing extreme

satisfaction toward an IVF clinic using EWS compared to patients receiving the interview in the immediate pre-event period. The effect of the mix-up event last for 1 month following the media reporting and then falls down to moderately higher levels (Fig. 1).

Discussion

When the EWS was introduced into our IVF setting, the attention was focused on reducing the possible errors, increase registration, standardization, and traceability, thus making IVF procedures safer and straightforward in our center. In this study, we focused on the patient perspective of the clinical utilization of EWS. We began by considering if patients were aware of the possibility of a sample mix-up error in the IVF

Table 3 Descriptive analysis of questionnaire's question 4 and 8 for the pre- and post-event groups

PRE - EVENT question 3 and question 7			POST - EVENT question 3 and question 7		
QUESTION 3	Frequency (%)	Median ± IQR	QUESTION 3	Frequency (%)	Median ± IQR
Satisfaction toward the tracking property of the Electronic Witness			Satisfaction toward the tracking property of the Electronic Witness		
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint			1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint		
1	2 (1.0)	5 ± 1	1	6 (2.9)	5 ± 1
2	5 (2.5)		2	6 (2.9)	
3	22 (10.8)		3	16 (7.8)	
4	61 (29.9)		4	57 (27.9)	
5	113 (55.4)		5	116 (56.9)	
6	1 (0.5)		6	3 (1.5)	
Total	204 (100.0)		Total	204 (100.0)	
QUESTION 7	Frequency (%)	Median ± IQR	QUESTION 7	Frequency (%)	Median ± IQR
Satisfaction toward the IVF clinic using EWS			Satisfaction toward the IVF clinic using EWS		
1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint			1 = Not at all 2 = A little 3 = Moderately 4 = A lot 5 = Extremely 6 = No viewpoint		
1	0 (0)	5 ± 1	1	2 (1.0)	4 ± 1
2	2 (1.0)		2	5 (2.5)	
3	28 (13.7)		3	30 (14.7)	
4	58 (28.4)		4	72 (35.3)	
5	113 (55.4)		5	90 (44.1)	
6	3 (1.5)		6	5 (2.5)	
Total	204 (100.0)		Total	204 (100.0)	

IQR inter-quartile range

laboratory and then set out to assess their concerns. We developed a questionnaire that could evaluate patient's perspective on different features of an EWS (Table 1). We investigated if the EWS reduced patient concerns about identification errors, how much patients appreciated the new device and if it could increase patient satisfaction with respect to our IVF clinic where we used this system.

Through the first phase of the questionnaire, we highlighted how most patients had significant concerns about a biological sample mix-up, but only when made aware about it as a possibility during their treatment. This data suggests that the idea of a possible errors in the laboratory might represents a significant source of stress when undergoing IVF, which properly meets the stress definition as a pattern of negative physiological states and psychological responses occurring in situations where individuals perceive threats to their well-being, which they may be unable to meet [16]. It is well known that IVF can be very stressful for the couples. In general, infertility and IVF treatment can be considered particularly stressful life events. According to the model of Lazarus, these events represent a major life change and involve a sense of frustration, because what was considered as a natural event lifecycle turns into a path medicalized by uncertain outcome [17]. Studies

highlighted how the most stressful events of an IVF cycle are: failure of the treatment, the oocytes retrieval, and most of all the waiting period between embryo transfer and pregnancy test [18–21]. In addition to these aspects, our study showed that the possibility of an error in the laboratory is an additional source of stress, as it would be an event beyond the control of patients and 1 therefore could lead to negative emotional reactions such as frustration, worry, and anxiety.

In this study, we have also established the capacity of an EWS to reduce the patient concerns relating to identification errors. We note that the implementation of this new device was able to reassure patients and alleviate their concerns. This showed that the EWS is an instrument capable of reducing stress and represents a protective tool that could be beneficial for patient well-being, especially for those patients that are more sensitive to developing emotional distress.

When considering the general satisfaction with respect to the EWS, we note that most patients appreciated the use of the new control device, and they felt highly comfortable with an IVF center equipped with EWS. In this context, an EWS can be seen as a tool to improve patient satisfaction during an IVF cycle in addition to increasing procedural safety in the laboratory.

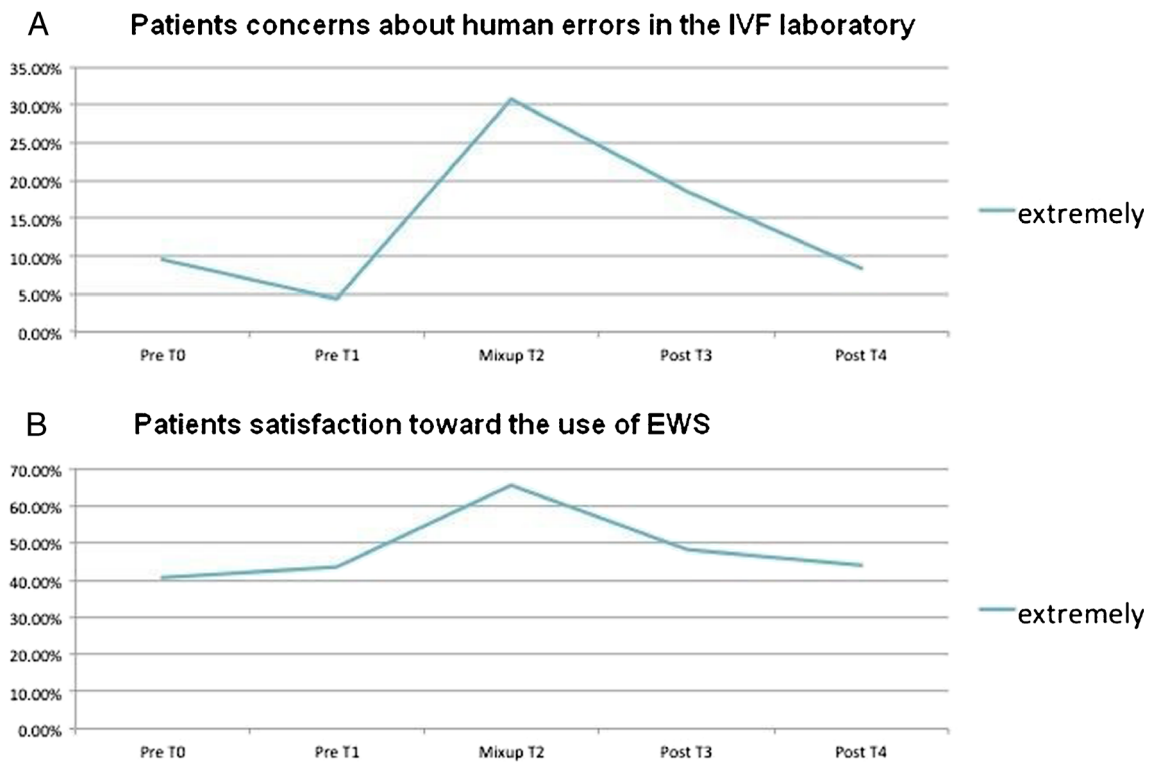


Fig. 1 Descriptive timeline analysis of patients showing extremely high concerns in the timeframe around the reporting of mix-up event happened in a public hospital in Rome (a). Descriptive timeline analysis of patients showing extremely high satisfaction in the timeframe around the reporting of mix-up event happened in a public hospital (b). *Pre T0*

between 30 and 15 days before, *Pre T1* 15 days before, *mix-up T3* 15 days after the mix-up event was publicly reported by the mass media, *Post T3* 15 days after, *Post T4* between 15 and 30 days after, *EWS* electronic witness system

Another interesting point that our data showed was that women had a greater appreciation of the EWS and the clinic in which it was used when compared to men. This is compatible with numerous studies that have documented that men and women use different strategies to cope with IVF treatment. It has been observed that women are more inclined to talk about IVF difficulties and their emotional burden, while men are more distancing and emotionally self controlling [22]. Women could therefore be considered to be more inclined to give consideration to some IVF issues, as in this case. We also note that the older women in the study tended towards a lower EWS satisfaction. We hypothesize that they could be less familiar with the technology or due to the lower enthusiasm related to a lower pregnancy chance.

When we compared the two patient groups (pre- and post mix-up event), we observed how the satisfaction towards the EWS significantly increased in the post-event group and how these patients felt significantly more comfortable with an IVF center equipped with an EWS. This high-profile mismatching error that was made public during the course of the study is likely to have had an emotional impact on patients who became aware of it, making these patients more interested in the technical aspects of

IVF procedures and possible risk associated with biological sample manipulation.

Moreover, the analysis of patient’s concerns about human errors in IVF laboratory and on their satisfaction toward a clinic using EWS performed within a narrow time intervals close to the mix-up event revealed that the media influence on patient perspective was particularly effective in the 15 days after the reporting of the event. In this period, patients were extremely worried about the possibility of human error in IVF laboratories and felt extremely satisfy to perform their treatment in an IVF clinic using EWS. However, the magnitude of this extreme 1 effect last for about 1 month, with patient feeling coming back to slightly normal values afterwards. This observation is consistent with the general impact of mass media on people view.

In conclusion, our data have highlighted that an EWS is a valid instrument in an IVF clinic.

Not only it does safeguard all the step of IVF procedures, decreasing the error risk, but it also has an important role in IVF patient’s point of view. From a psychological perspective, an EWS can increase patient well-being during IVF treatment and can minimize an additional source of stress that could overload a patient’s emotional balance.

Acknowledgments We are very thankful to the patients who completed the questionnaire and consented to this analysis.

Compliance with ethical standards The institutional review board of the Valle Giulia Clinic approved the study, and signed informed consent was obtained from all patients recruited.

Conflict of interest The authors declare that they have no conflicts of interest.

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