Electronic witnessing in the medically assisted reproduction laboratory

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Electronic witnessing in the medically assisted reproduction laboratory: insights and considerations after 10 years of use

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Abstract

Study question: What did we learn after 10 years of electronic witnessing?

Summary answer: When applied correctly, an electronic witnessing system can replace manual witnessing in the MAR lab to prevent sample mix-up.

What is known already: Electronic witnessing systems have been implemented to improve the correct identification, processing and traceability of biological materials. When non-matching samples are simultaneously present in a single workstation, a mismatch event is generated to prevent sample mix-up.

Study design, size, duration: This evaluation investigates the mismatch and administrator assign rate over a 10-year period (March 2011 - December 2021) with the use of an electronic witnessing system. Radio frequency identification tags and barcodes were used for patient and sample identification. Since 2011 IVF and ICSI cycles and frozen embryo transfer cycles (FET) were included, intrauterine inseminations (IUI) cycles since 2013.

Participants/materials, setting, methods: The total number of tags and witnessing points were recorded. Witnessing points in the electronic witnessing system RI Witness™ represent all the actions that have been performed from gamete collection through embryo production, transfer and cryopreservation. Mismatches and administrator assigns were collected and stratified per procedure (sperm preparation, oocyte retrieval, IVF/ICSI, cleavage stage embryo and blastocyst embryo biopsy, vitrification/warming, embryo transfer, medium changeover and IUI). Critical mismatches (such as mislabeling or non-matching samples within one work area) and critical administrator assigns (such as non-RI Witness™-identified samples and unconfirmed witnessing points) were selected.

Main results and the role of chance: A total of 109,655 cycles were included: 53,023 IVF/ICSI, 36,347 FET, and 20,285 IUI cycles. The 724,096 used tags, led to a total of 849,650 witnessing points. The overall mismatch rate was 0.251% (2,132/849,650) per witnessing point and 1.944% per cycle. In total, 144 critical mismatches occurred over the different procedures. The yearly mean critical mismatch rate was 0.017% ± 0.007% per witnessing point and 0.129% ± 0.052% per cycle. The overall administrator assign rate was 0.111% (940/849,650) per witnessing point and 0.857% per cycle, including 320 critical administrator assigns. Average critical yearly administrator assign rate was 0.039% ± 0.010% per witnessing point and 0.301 ± 0.069% per cycle.
Overall mismatch and administrator assign rates remained stable during the evaluated time period. Sperm preparation and IVF/ICSI were most prone to critical mismatch and administrator assign.

Limitations, reasons for caution: The procedures and methods of integration of an electronic witnessing system may vary from one laboratory to another and result in differences in the potential risks related to sample identification. Individual embryos cannot (yet) be identified by such a system, this makes extra manual witnessing indispensable at certain critical steps where potential errors are not recorded. RI Witness™ still needs to be used in combination with manual labelling of both bottom and lid of dishes and tubes to guarantee correct assignment in case of radio frequency identification tags malfunction or incorrect use.

Wider implications of the findings : Electronic witnessing is considered to be the ultimate tool to safeguard correct identification of gametes and embryos. But this is only possible when used correctly and requires proper training and attention of the staff. It may also induce new risks, i.e. blind witnessing of samples by the operator.

Study funding/competing interest(s): No funding was either sought or obtained for this study. JS is presenting webinars on RIW for CooperSurgical.

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Keywords: electronic witnessing, manual witnessing, mismatch, administrator assign, error, mix-up

Introduction

Every embryologist is aware of the complexity of the workflow in a medically assisted reproduction (MAR) laboratory. A multitude of procedures are being performed simultaneously at any given time at different dedicated work stations. These procedures require a high level of technical expertise with no room for any error, as these errors may directly impact the treatment of the patient. This creates a certain level of stress in an already complex environment that may lead to human errors (*Turner et al., 2003*). Moreover, it is a true fact that humans inevitably are prone to making errors (*Myhre et al., 2000*). During MAR, the crucial steps susceptible to human error are patient identification and the traceability of gametes and embryos (*Kennedy et al., 2007)*.

In any laboratory where a quality management system is installed, non-conformances, i.e. failure to conform to the standard requirement or protocol during treatment, should be registered. Monitoring the occurrence, grade of severity and impact of these non-conformances on patient outcome allows for measures and appropriate procedures to be installed to prevent their re-occurrence (*Sakkas et al., 2018*). A mix-up of gametes and/or embryos has the highest grade of severity. It is therefore the responsibility of any MAR laboratory to avoid this event at any time (*Mark et al., 2020*).

As recommended by international guidelines and directives (*Commission Directive, 2006; ESHRE Guideline Group on Good Practise in IVF labs, 2016; Human Fertilisation and Embryology Authority, 2021; EDQM Tissues and cells, 2022*), specific protocols concerning correct identification, processing and traceability of biological materials must be in place. The combination of clearly and permanently labelled devices containing biological material, the separate processing of biological materials from different patients in time and space, and the witnessing of critical steps are some of the key elements to avoid mix-up errors.

For a very long time, witnessing via a double-checking approach was the only possible solution. This involves a verbal double check and extra pair of eyes of a second operator before the executing colleague can start or continue with a specific procedure. A handwritten signature of the witness is required to guarantee the traceability of this check. This approach, however, has some limitations: (i) it can become rather tedious to be applied in a complex and busy environment as it takes two persons to perform the witnessing, (ii) independent redundancy, (iii) unintentional blindness and (iv) ambiguous accountability (*De los Santos et al., 2013*). The need to interrupt a second operator and the automaticity in the constant repetitive task of manual witnessing, is a recipe for making double witnessing prone to human errors (*Toft et al., 2005, 2009*) and difficult to perform for each procedure (*Rienzi et al., 2017*). To tackle these issues, electronic witnessing systems (EWS) have been developed and introduced in MAR laboratories.

EWS systems are mainly based on radio-frequency identification (RFID) and/or barcode labelling of all tubes and dishes. With barcode labelling, the operator needs to scan all barcodes manually, whereas systems with RFID automatically detect all RFID labelled consumables by a reader integrated in the workstation. Thanks to this automation, procedural electronic witnessing steps are less likely to be circumvented by the operator (*De los Santos et al., 2013*). RFID readers integrated into the workstation have the additional advantage that the biological material of only one patient can be present in a given workstation, which will help to ensure that a mismatch is prevented. In addition, EWS have the advantage over double witnessing in improving risk reduction and decreasing time needed to witness (*Rienzi et al., 2015, Holmes et al., 2021*). Since the introduction of EWS systems, error rates are being presented as mismatch rates. However, administrator assigns, i.e. when the administrator needs to assign a previously untagged or incorrectly assigned tag, have not previously been presented as an error rate when using EWS.

The aim of the current study was to evaluate our EWS after 10 years of use and to analyse how this system impacted our mismatch rates and admin assigns over time.

Materials and Methods

Study design

This is a single centre retrospective analysis of all conventional IVF/ICSI, intrauterine inseminations (IUI) and frozen embryo transfer (FET) cycles performed with the use of EWS RI Witness™ (CooperSurgical), between March 2011 and December 2021. Cycles with IVF/ICSI and FET were included since the start in 2011, while IUI cycles were only included since 2013. Implementation of the barcode labels for labelling of cryopreserved samples started in 2014. For this study, no approval from the Local Ethical Committee was required.

MAR procedures subject to witnessing

The following eight procedures were followed over time: (i) sperm preparation including sperm preparation for IVF/ICSI/IUI and cryopreservation, (ii) oocyte retrieval (OR), (iii) IVF/ICSI including denudation of oocytes before ICSI or cryopreservation and after IVF insemination, (iv) cleavage stage embryo and blastocyst biopsy excluding the tubing of the biopsied samples, (v) embryo transfer, (vi) medium changeover (vii) cryopreservation of oocytes and embryos and (viii) IUI. The number of witnessing points were collected and stratified per procedure.

Electronic witnessing system

RI Witness™ (RIW) is an electronic witnessing system based on RFID cards and RFID tags which are automatically detected by an RFID reader once they are in the detectable range (Supplementary Figure S1 A+B). RIW uses printed labels with barcodes to identify cryopreserved gametes and embryos. As these are not automatically detected by the reader, the operator needs to scan them manually. Every sample needs to be labelled with an RFID tag (on the bottom of dishes or the side of tubes) or barcode and assigned by the operator into the EWS through a witnessing point (WP). Based on the lab procedures, the lab representatives have to set up an EWS-WP diagram. Whenever new laboratory procedures are introduced, new WPs and items can be added in the EWS-WP diagram. Every step in a lab procedure, where it is necessary to have a witnessing step, is hereby defined as a WP. By selecting a WP, not only the identity of that specific patient will be transmitted to the RFID tag, the tag will also be marked as a specific item (e.g. sperm pot, ICSI dish). The date, hour, working station and operator who marked the item will be recorded as well. Only when a specific combination of items is presented in the working area, the system will pop-up the possible WP (Supplementary Figure S1 C). By selecting the corresponding WP, the action will be recorded in the EWS. A WP can also be used to confirm a specified action without the necessity of a new RFID tag. The number of WP may vary from one procedure to another: OR, biopsy, embryo transfer, medium changeover, cryopreservation of oocytes and embryos and IUI only require one or two WPs. Sperm preparation and IVF/ICSI are a consecutive sequence of multiple WP (Supplementary Figure S2).

In our setting, the EWS is used in combination with the manual writing of patient's name and a unique patient cycle identifier on lid and bottom of all dishes and on tubes. In our current setting, labelling is only performed at the time a dish or tube will be used. To keep this logistically as simple as possible and while moving to a completely paperless lab, it was deliberately chosen not to use the pre-printed labels provided by the EWS. A double manual check remains in place for all entry points in the EWS (for instance receiving a sperm sample), when assigning donor samples to an acceptor, when embryo or cryopreserved straw numbers need to be verified and when the lab file is assigned. The paper lab

file is RFID labelled and is required to confirm a WP when starting sperm preparation, denudation of oocytes and for IVF insemination. An RFID patient card is created, with mandatory double check, and will be used to confirm the patient's identity at the start of oocyte retrieval, surgical retrieval of sperm and embryo transfer.

Each operator has a unique login into the system. Only the basic elements of using the EWS are part of the introduction training. Once the operator is trained for a specific procedure (for instance sperm preparation or OR), the relevant parts of the RIW system are explained. As operators are trained for all procedures, they will gradually know the complete RIW flow.

Mismatch

A mismatch (MM) event is referring to a situation where two or more non-matching samples are simultaneously present in a single workstation on a RFID reader. A visual and audible signal will appear to stop the operator's actions. A real mismatch error, e.g. a mix-up of two non-matching gamete or embryo sources, will hereby be prevented. Even when there is no intention to do any manipulation (false mismatch), a mismatch event may also occur once multiple samples of different non-matching individuals are on or too close to an RFID reader. Continuing the impeded process is only possible by entering an explanation on what went wrong, this information can be used to distinguish true from false mismatches. True mismatches were selected and defined as critical (i) when non-matching samples were present within one working area prior to the manipulation and (ii) when mislabeling during cryopreservation procedures occurred: in this case straws are prepared for a patient that do not correspond to the patient's identity. Critical MM (CMM) were collected and stratified for the above-described eight procedures. MM are expressed as total numbers, percentages (%) and average ± standard deviation.

Administrator assign

An administrator assign (AA) is used when a tube or dish is labelled via an incorrect WP, when the tag was not assigned, when no tag was present or when a previously assigned tag cannot be read anymore. Only a specific group of administrators is able to perform AA after thorough checking of previous steps of the process. In the EWS-WP diagram, all WP are outlined for the different procedures by drawing different combinations that can be selected when different items are present in the reader. In this way, when an operator wants to assign a new RFID tag, only the most possible applicable WP will be presented to the operator. Although the operator is shown only this selection of WP, it may happen that the allocation was not done properly by choosing an incorrect WP. In this case the patient's identity will be transferred correctly, but a wrong item's name will be given to that specific tag. This in turn will cause that a next WP cannot be performed and an administrative correction will be required. Much more dangerous is that an operator has forgotten to make the EWS assignment or has forgotten to label the sample at all. In those cases, an electronic or manual witness is missing. These AA were selected and defined as critical. Critical AA (CAA) were collected and stratified for the eight above-mentioned procedures. AA are expressed as total numbers, percentages (%) and average ± standard deviation.

Statistical analysis

Every MAR laboratory should decide whether the increase or decrease of a single (C)MM or (C)AA may have a significant impact on traceability or not. This is a descriptive study, no statistical analysis was performed.

Results

During this study period 53,023 oocyte retrievals (OR), 36,347 FET cycles and 20,285 IUIs were performed with the use of EWS. To cover this total of 109,655 cycles, a total of 724,096 RFID tags and 58,720 barcodes were used resulting in 849,650 registered WP (Table I). An overall average of 7.701 ± 0.443 WP per cycle was obtained.

Total number of WP per procedure were: (i) sperm preparation: 255,134, (ii) oocyte retrieval: 69,585, (iii) IVF/ICSI: 195,949, (iv) cleavage stage embryo and blastocyst biopsy: 17,978, (v) embryo transfer: 65,650, (vi) medium changeover: 30,669, (vii) cryopreservation of oocytes and embryos: 75,556 and (viii) IUI: 40,513. Sperm preparation and IVF/ICSI involve a sequence of multiple steps that are controlled through the EWS, these therefore include the largest proportion of WP (Figure 1).

Mismatch

The overall MM rate was 0.251% (2,132/849,650) per WP and 1.944% (2132/109,655) per cycle with an average of 0.268%±0.078 and 2.047%±0.597 per year, respectively. When selecting only CMM, the rate was 0.017% (144/849,650) per WP and 0.131% (144/109,655) per cycle with an average rate of 0.017% ± 0.007 and 0.129% ± 0.052 per year, respectively. With an average of only 13.1 CMM/year, a reduction or increase of 1 CMM/year can influence this average. The overall MM rate per WP decreased slowly over time, the CMM per WP remained stable (Figure 2A). However, within the MM, the proportion of CMM increased over time (Figure 2C).

Out of the 2,132 MM, 144 CMM occurred in the eight different procedures: (i) sperm preparation: 61, (ii) oocyte retrieval: 3, (iii) IVF/ICSI: 37, (iv) cleavage stage embryo and blastocyst biopsy: 1, (v) embryo transfer: 11, (vi) medium changeover: 3, (vii) cryopreservation of oocytes and embryos: 25, and (viii) IUI: 3 (Table II). The proportion of CMM per procedure on the total number of CMM is outlined in Figure 3. Procedures with the highest CMM rate were sperm preparation, with a steep increase since 2014, and IVF/ICSI with a steep decline in CMM since 2015. All other procedures remained stable with a very low incidence over time. Most common errors observed in both procedures were: starting the sperm processing with a wrong sample; wrong labelling at cryopreservation of sperm and having a non-matching sperm sample and oocytes together when preparing an ICSI insemination dish. The non-critical MM mainly occurred in the administrative preparation of the RFID cards and paper lab files, the manipulation of donor and the assigned acceptor samples and when taking samples intended for training.

Administrator assign

The overall AA rate was 0.111% (940/849,650) per WP and 0.857% (940/109,655) per cycle with an average of 0.113 % ± 0.027 and 0.866 % ± 0.212 per year, respectively. When selecting only CAA, the rate was 0.037% (320/849,650) per WP and 0.292% (320/109,655) per cycle with an average rate of 0.039% ± 0.010 and 0.301% ± 0.069 per year, respectively. The AA rate and CAA rate per WP remained stable over the years (Figure 2B), however, the proportion of CAA/AA is much higher compared to the CMM/MM (Figure 2C).

Occurrence of the CAA per procedure was: (i) sperm preparation: 83, (ii) oocyte retrieval: 34, (iii) IVF/ICSI: 173, (iv) cleavage stage embryo and blastocyst biopsy: 3, (v) embryo transfer: 0, (vi) medium changeover: 21, (vii) cryopreservation of oocytes and embryos: 6, (viii) IUI: 0 (Table II). The proportion of CAA per procedure on the total number of CAA is outlined in Figure 3.

Re-emerging procedures with high levels of CAA were sperm preparation with an increase in CAA since 2019 and IVF/ICSI which remained stable, but high over time. Most common observed errors in both procedures were the failure to assign the final sperm tube during sperm processing (Supplementary

Figure S2: WP Sperm wash) and not assigning the culture dish before culturing the injected oocytes (Supplementary Figure S2: WP Post ICSI). Both are the final WP of a procedure, before the samples are released from the working station.

The AA rate due to network system failure was 2.2% (21/940). Such system failure only occurred in one weekend in 2015, where laboratory staff resorted to witnessing by a second operator for all lab processes. RFID tag failure occurred in 14.7% (138/940) of all the AA. RFID tags were assigned correctly but were found to be no longer working in a next step. Correct identification of samples was possible due to double labelling of tubes and dishes.

Discussion

This is the first study reporting on a long-time experience with electronic witnessing in a busy lab in a single centre with high level of activity. With close to one million of WP analysed during the study period, only 0.251% lead to a MM and 0.111% to an AA. When only considering critical actions, where a potential mix-up is prevented, only 0.017% CMM and 0.037% CAA were recorded. Sperm preparation and IVF/ICSI were most prone to (C)MM and (C)AA.

The potentially prevented true mismatch rate in this study, presented as CMM rate (0.017%) is lower than previously published data which are based on a small number of WP (803 to 17,435) evaluated during a short period: 0.12%, 0.05%, 0.46% and 0.05% (*Brunetti et al. 2012, Rienzi et al. 2015, Gupta et al. 2020, Holmes et al. 2021*). This discrepancy may be explained by a different interpretation and classification of critical or true mismatches between publications.

Highest (C)MM rates were observed during sperm preparation and IVF/ICSI, as these procedures have a more extensive WP diagram. An average sperm preparation or ICSI procedure takes a longer processing time and contain a sequence of three WP, while OR and biopsy contain one and two WP, respectively. This makes these procedures more prone to MM in general. The semen samples are also brought in and out of the working area several times for centrifugation, hence increasing the risk of potential errors during sperm preparation. For IVF/ICSI, gametes of matching maternal and paternal origin are brought together for insemination, a procedure that requires utmost attention.

Unlike the other procedures where CMM dropped or remained low over time, a significant increase occurred only during the sperm preparation procedures (Figure 3 (i)). Incorrect verification of identity on sperm pots, tubes and barcodes are the main cause of this increase. A certain laxity to properly read labels may occur, as operators believe the EWS will catch potential errors. The gradual increase in workload has probably reached a threshold in 2015 for many operators above which they are more prone to errors. In an initial stage, the workflow for sperm sample preparation was revised to allow an improved spreading of samples. In a second phase, alternative sperm preparation techniques are being explored that are less labor intensive. Sperm preparation, together with warming of gametes and embryos, have also previously been reported to be the procedures with the highest risk of MM *(Rienzi et al. 2015, Holmes et al. 2021).*

It is noteworthy that only 6.75% (144/2,132, corresponding to one CMM every four months) of the total mismatch events were considered critical.

The EWS will prevent any mix-up error, but prevention can only be assured when the operator is using it correctly. The standard operating procedure is to move gametes and embryos from one recipient to another on the reader only and to confirm every WP before any manipulation to assure that the EWS can prevent a potential error. If the operator forgets to select a WP, the action will not be registered, despite the audible signal that is generated when removing an unassigned tag from the reader, hence

a CAA is generated and a correction by an administrator is required. An AA is only allowed after thorough verification: patient's history in the EWS, other simultaneously conducted procedures, strictly separating the cycles that have already been processed from the ones to be processed. Inability to trace back the history of a sample forces the operator to ask for a second sperm sample, to discard oocytes or to perform a genetic test on embryos to confirm their parental origin. It is clear that the number of CAA should be reduced to the absolute minimum.

Although, working with an EWS seems to be very intuitive, workload for the operator may influence the correct use of it. An increase of CAA can be noticed during medium changeover (figure 3 (vi)). Together with data-input, medium changeover was a task for the operator performing the ORs until 2018. Redistribution of this task, has led to a decrease in CAA since 2019 (figure 3 (vi)). This in contrast with sperm preparation, where workload increased over time whilst task allocation and number of working stations remained stable. This may explain that just as with CMM, sperm preparation also scored highest for CAA. After sperm preparation, the final sperm tube is moved from the andrology to the embryology laboratory. It occurred that at start of the IVF/ICSI the sperm tube was found not to be correctly RFID labelled. Operators where then returning to the andrology lab to assign the tube, while the correct procedure here would have been an AA to maintain full traceability. The awareness of applying the correct registration in 2019 (AA instead of assigning) explains the low occurrence of CAA in the period 2014-2018 followed by a steep increase in CAA from 2019 onwards (Figure 3 (i)).

An RFID tag is not an error-free substitute for the classic handwritten or printed labelling of samples with names and/or unique cycle identifiers. Hardware and software, requiring a highly reliable network, are always needed to read the RFID tag, but there is also a risk of its malfunctioning. It remains unclear why a RFID tag initially works but can become undetectable in time. These AA can only be resolved if the tagging is combined with manual labelling of names and unique cycle numbers. As lids of dishes can easily be transferred from one dish to the other, manual labelling on the bottom or side of dishes is a minimal requirement.

Implementing an EWS is a way to standardize all sample identification witnessing procedures. It eliminates, with some exceptions, the need for the second human witness, it allows operators to start and complete a procedure independently with full traceability of all (crucial) steps. Even when performing IUI, the use of an EWS can assure the use of the correct gametes without the need for a second witness. This helps in gaining efficiency in staff deployment which is important at any level when managing a fertility clinic. By using an EWS, not only interruptions of operators performing delicate procedures are reduced, it may also save time (*Holmes et al. 2021)*. Replacing the manual double witnessing by an EWS is part of the automation that is already ongoing in the modern MAR lab (*Bori et al., 2021)*. As full traceability (operator, time, steps, working station) is now automatically recorded, EWS also reduce the administrative registration of double-witnessing steps.

When starting a procedure in the lab, it is important for each embryologist to be confident that all previous steps were performed correctly. When proper entry and exit points are generated for all samples it is, according to our experience, safe to solely rely on the EWS upon gamete insemination, which is in contrast to the double manual witnessing recommendation by HFEA (*Human Fertilisation and Embryology Authority, 2021)*. In our perception, the use of EWS increases the trust not only within the lab, but also from the patient's point of view as already confirmed by previous publications (*Forte et al., 2016; Holmes et al., 2021)*.

The integrated RFID reader into the workstation obliges the operator to work with only one patient at a time. This implies that manipulation of non-matching samples is excluded for procedures where gametes and embryos stay within one working area with a strict control of entry. In our experience,

sperm preparation procedures, where the RFID reader is only occupying 10% of the working area (Supplementary Figure S1C), is the most sensitive procedure in the EWS. Workload (necessity of multiple sperm samples to be processed in limited time span), involuntary automaticity and multiple WP combined with multiple centrifugation steps outside the reader may lead to the blind/wrong witnessing. An EWS-cage comprising the complete working area and centrifuge would reduce the number of errors in sperm preparation tremendously.

It can be questioned if such an EWS-cage has any toxic effect on embryo development. These safety questions were already raised since the introduction of RFID based EWS. The RFID tag, which is tested for toxicity per batch, is a passive item and is not expressing radio waves. The readers in the lab are using only low level (13.56 MHZ) frequencies emitted in a short range unlike the ubiquitous presence of the high levels used for WIFI and other mobile technologies. It is difficult to prove whether or not EWS may have any impact on embryo development, considering the overall presence of radio technology out of our control. Gupta and colleagues *(2020)* evaluated 128 cycles with and 59 IVF cycles without exposure to the RFID readers and found the EWS was not adversely affecting gametes and embryos.

One of the most dangerous disadvantages of the EWS is the unavoidable involuntary laxity of operators. Operators rely 100% on the system and they read names with a 'single' eye, as EWS will read it anyway. Even though patient information is displayed on the tablets attached to the EWS, they are often positioned outside the laminar flows, in an ergonomically bad position for reading. Integrating this system in the working area is thus beneficial when not interfering with the workspace. An intensive training, increasing awareness and indicating consequences concerning laxity of all operators is the start of any good laboratory practice. Reporting on performance indicators related to identification and traceability per operator including CMM/CAA will help to improve the EWS flow of each laboratory and will also alert operators when repetitive errors are being reported (*Fabozzi et al., 2020)*. In the current setting, most MM and AA were sporadic events by different operators: good communication of the type and consequence of MM and AA and follow-up of possible recurring events were implemented here.

Identifying individual embryos in an EWS is not (yet) available. This makes double manual witnessing indispensable at certain critical steps, for instance when moving embryos for biopsy and vitrification, as potential 'numbering' errors cannot be recognized by RFID witnessing. A tracking system, where the operator needs to indicate which embryo is moved, within RIW is recently introduced and needs further validation to assure its safety as a replacement for the manual witnessing at those steps.

To conclude, EWS is a good addition to the manual witnessing for sample identification, but only when applied in a correct way. Our results indicate that potential errors may still occur even though the EWS is already in use for a long period of time. Real mix-up of samples is prevented by the EWS, although it can never be proven whether or not these errors would have been intercepted by a manual check too. At least, prevented mix-ups are now recorded, which was very time-consuming to quantify with manual witnessing. Any intervention by an operator in any EWS remains a possible source for errors, and these should be reduced to an absolute minimum. Therefore, an EWS should always be used in combination with the manual/printed labelling of bottom and top of dishes and tubes to guarantee correct assignment in case of RFID/network failure or administrator assign. Like this, not only the best embryo will be transferred, but also the correct one.

Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author.

Authors' roles

J.S.: conception and design, acquisition of data, analysis and interpretation of data, writing the article and critical review and acceptance of the article. K.W., I.M., I.S., A.D.V., L.V.L and H.T.: critical review and acceptance of the article. N.D.M.: conception, design and critical review and acceptance of the article.

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Conflict of interest

J.S. is presenting webinars on RIW for CooperSurgical.

Figure legends

Figure 1: Proportion of witnessing points per procedure

Figure 2: A: Yearly overview of percentage of mismatches per witnessing point and critical mismatches per witnessing point B: Yearly overview of percentage of administrator assigns per witnessing point and critical administrator assigns per witnessing point; C: Proportion of percentages of critical mismatches per total mismatches and percentage of critical administrator assigns per total administrator assigns; WP: witnessing point; MM: mismatches; CMM: critical mismatches; AA: administrator assign; CAA: critical administrator assign

Figure 3: Proportion of critical mismatches per procedure on the total of critical mismatches and proportion of critical administrator assigns per procedure on the total of critical administrator assigns; CMM: critical mismatches; CAA: critical administrator assign

Supplementary Figure S1: A: Integrated RFID reader with the detectable range marked within the red lines; B: RFID sperm reader with the detectable range marked within the red square; C: View of the possible next witnessing points when a sperm sample and an empty, unassigned tube is on the reader; RFID: radio-frequency identification

Supplementary Figure S2: witnessing points overview of procedures sperm preparation and oocyte retrieval to ICSI; RFID: radio-frequency identification

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Figure 1: Proportion of witnessing points per procedure

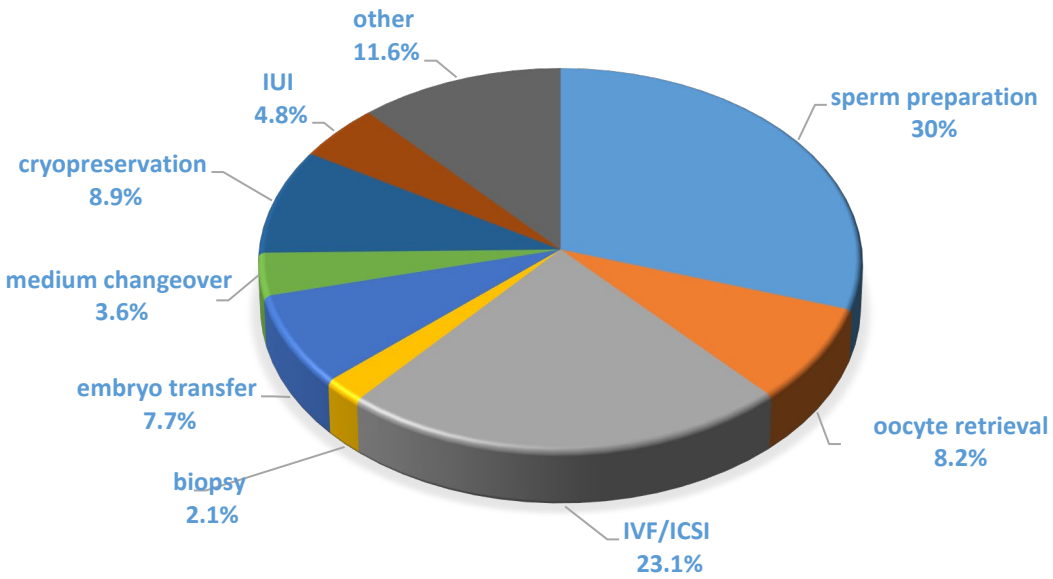
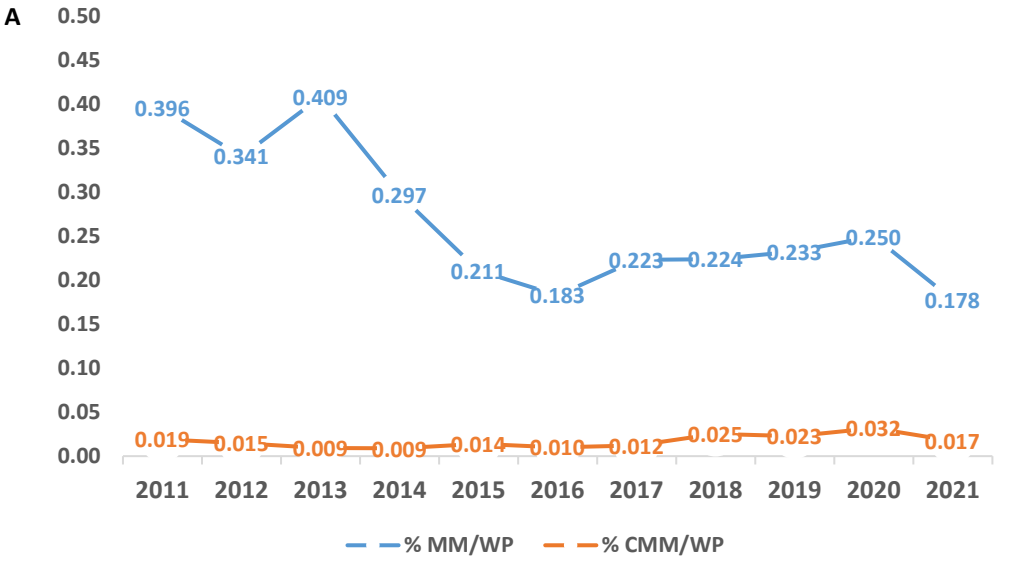
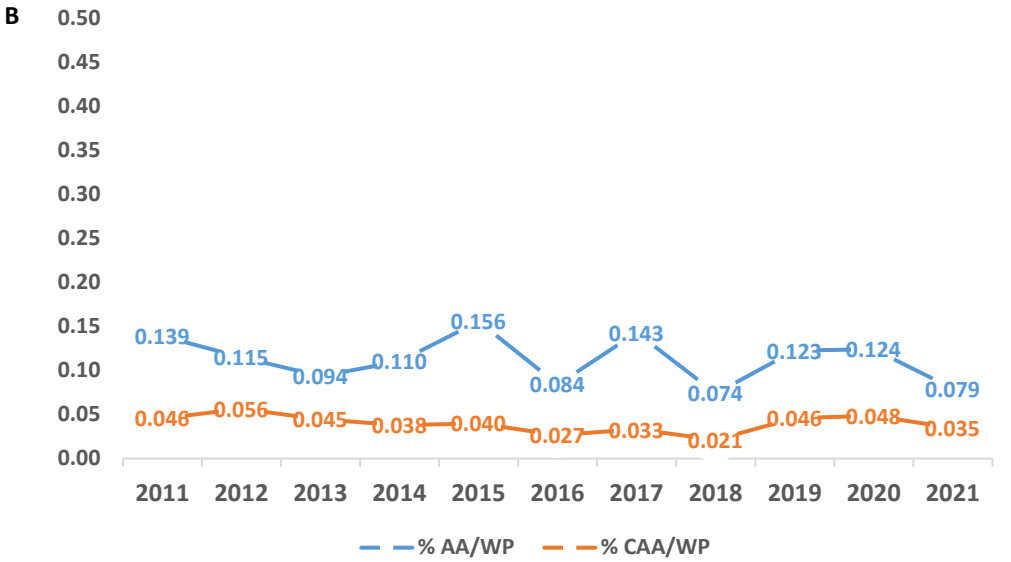


Figure 2: Mismatches and administrator assigns over the years of using the electronic witnessing system. A: Yearly overview of the percentage of mismatches (blue) and critical mismatches (orange) per witnessing point B: Yearly overview of percentage of administrator assigns (blue) and critical administrator assigns (orange) per witnessing point; C: Proportion of critical mismatches per total mismatches (blue)and proportion of critical administrator assigns per total administrator assigns (orange). WP: witnessing point; MM: mismatches; CMM: critical mismatches; AA: administrator assign; CAA: critical administrator assign.





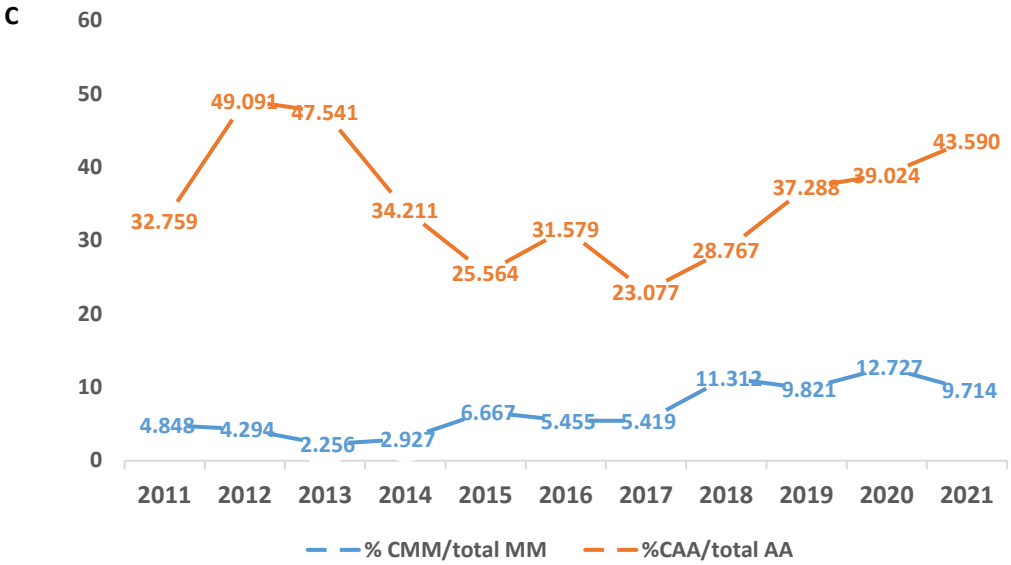
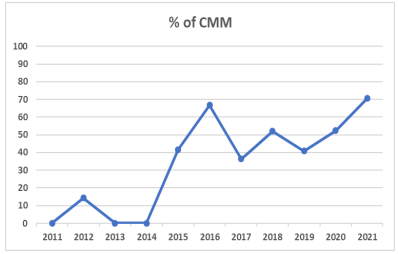
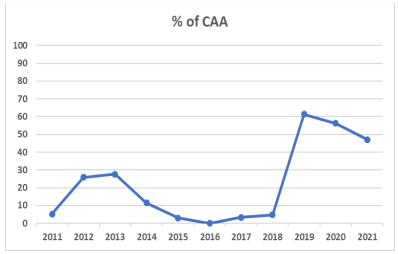


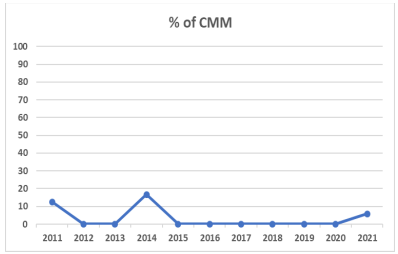
Figure 3: Proportion of critical mismatches per procedure on the total of critical mismatches and proportion of critical administrator assigns per procedure on the total of critical administrator assigns; CMM: critical mismatches; CAA: critical administrator assign

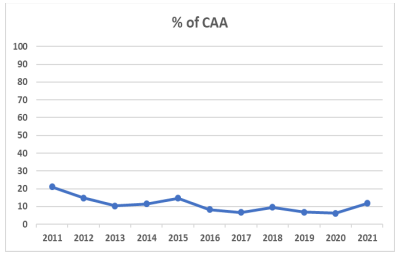
(i) sperm preparation



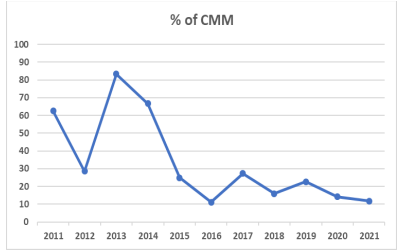


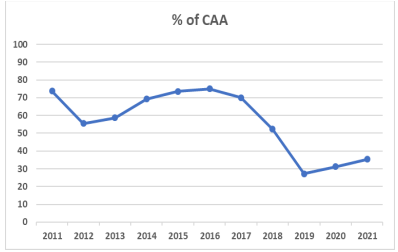
(ii) oocyte retrieval



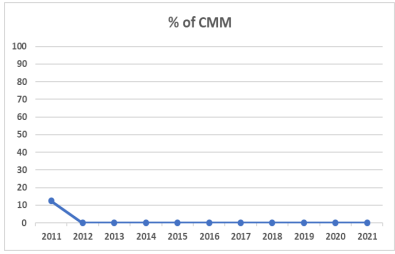


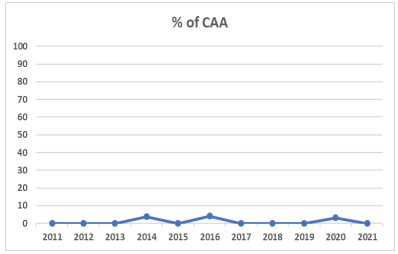
(iii) IVF/ICSI



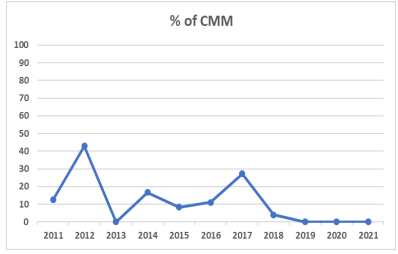


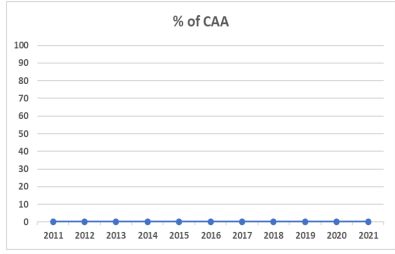
(iv) cleavage stage and blastocyst biopsy



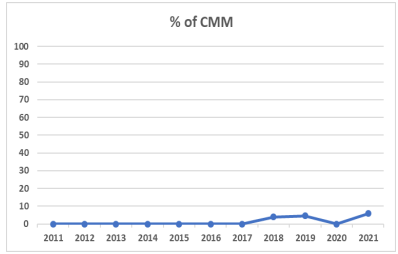


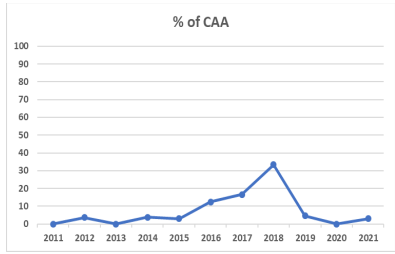
(v) embryo transfer



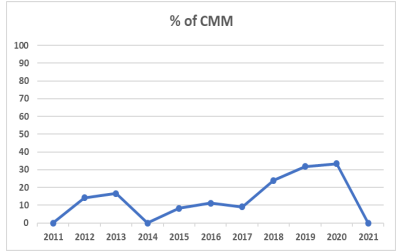


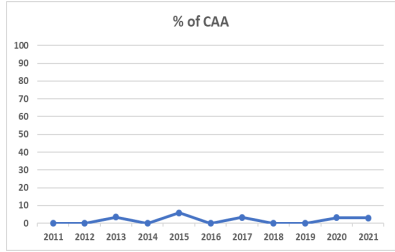
(vi) medium changeover



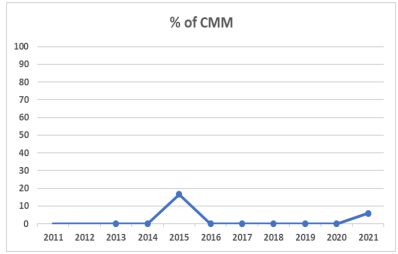


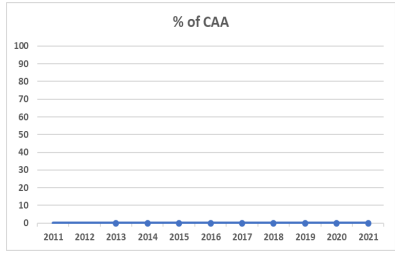
(vii) cryopreservation of oocytes and embryos





(viii) IUI



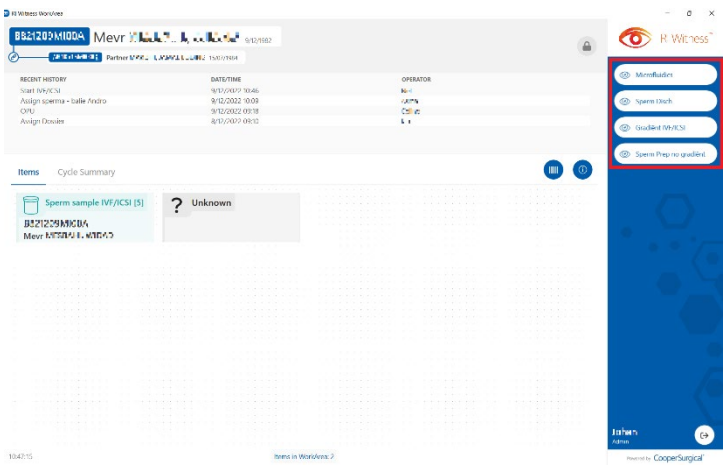


Supplementary Figure 1: A: Integrated RFID reader with the detectable range marked within the red lines; B: RFID sperm reader with the detectable range marked within the red square; C: View of the possible next witnessing points within the red lines when a sperm sample and an empty, unassigned tube is on the reader; RFID: radio-frequency identification

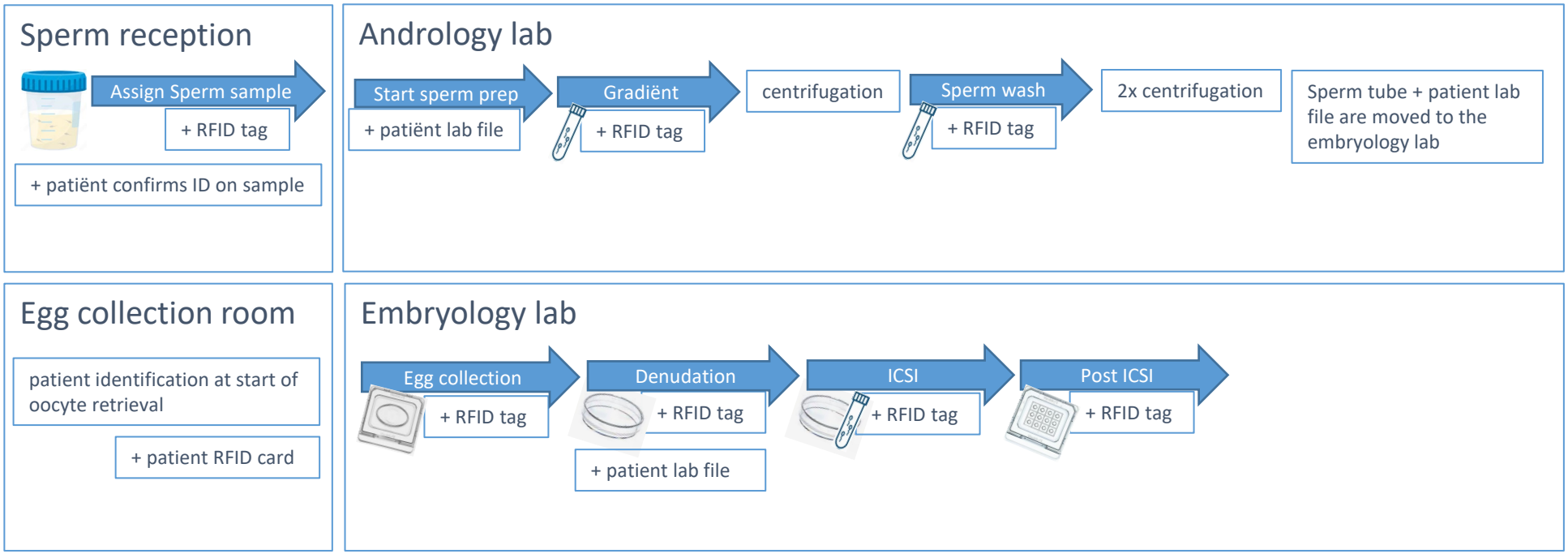
A

B

C



Supplementary Figure S2: witnessing points overview of procedures sperm preparation and oocyte retrieval to ICSI; RFID: radio-frequency identification



+ patient lab file	a paper lab file with RFID label is prepared on day -1 with double manual check
+ patient RFID card	a RFID card is prepared on day -1 with double manual check
+ RFID tag	a RFID tag is placed on the recipient
→	referring to the corresponding witnessing point

Table I: Overview of the total number of cycles, witnessing points, tags and barcodes used per year

Year	N of OR	N of FET	N of IUI	Total N of cycles	N of WP	N of RFID tags	N of barcodes	Average WP/cycle
2011	3,829	2,040		5,869	41,695	36,130		7.104
2012	4,378	2,317		6,695	47,815	42,639		7.142
2013	4,635	2,267	1,029	7,931	65,105	61,577		8.209
2014	4,445	2,374	2,743	9,562	68,912	61,484	621	7.207
2015	5,049	2,900	2,487	10,436	85,353	70,876	2,671	8.179
2016	5,198	3,484	2,404	11,086	90,296	74,051	3,709	8.145
2017	5,121	3,899	2,315	11,335	90,959	74,279	8,276	8.025
2018	5,550	4,330	2,488	12,368	98,742	81,333	10,954	7.984
2019	5,619	4,792	2,551	12,962	96,301	82,300	11,848	7.429
2020	3,587	3,484	1,840	8,911	66,078	55,957	8,067	7.415
2021	5,612	4,460	2,428	12,500	98,394	83,470	12,574	7.872
Total	**53,023**	**36,347**	**20,285**	**109,655**	**849,650**	**724,096**	**58,720**	**7.701±0.443**

N: number, OR: oocyte retrieval, FET: frozen embryo transfer, IUI: intrauterine insemination, RFID: radio-frequency identification, WP: witnessing point; average ± SD.

Table II: Overview of the total number of witnessing points, critical mismatches and critical administrator assigns per procedure

Procedure	N of WP	N of CMM	N of CAA
(i) sperm preparation	255,134	61	83
(ii) oocyte retrieval	69,585	3	34
(iii) IVF/ICSI	195,949	37	173
(iv) cleavage stage embryo and blastocyst biopsy	17,978	1	3
(v) embryo transfer	65,650	11	0
(vi) medium changeover	30,669	3	21
(vii) cryopreservation of oocytes and embryos	75,556	25	6
(viii) intrauterine insemination	40,513	3	0

N= number, WP: witnessing point, CMM: critical mismatch, CAA: critical administrator assign