The Importance of Witnessing and the Benefits of Electronic Witnessing in the Laboratory

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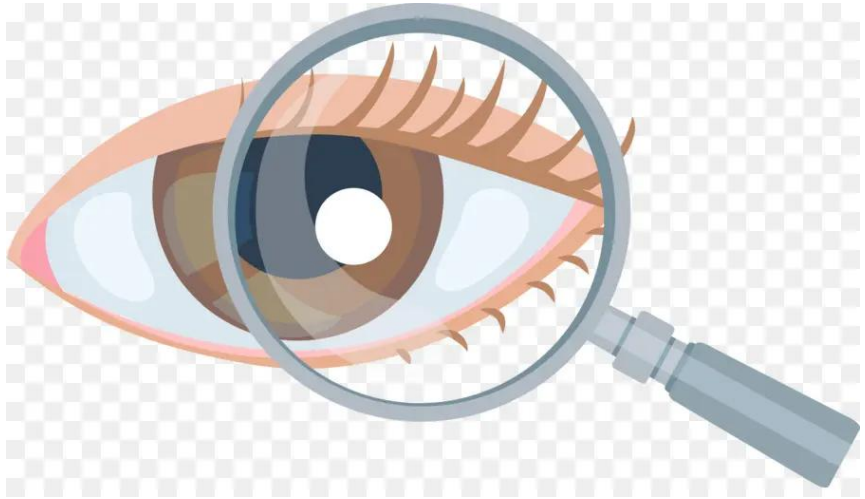
Vice President, Network Lab Compliance

Objectives

- Why do laboratory errors happen?
- Witnessing in the laboratory
- Benefits of electronic witnessing (EWS)
- Selecting a system to fit your laboratory
- Tips for implementation



Why do Errors Happen?

Conscious Automaticity

- Occurs when **the environment becomes too familiar** and the **cognitive system**, instead of processing information and analyzing it with the degree of awareness required, **actually reduces working memory to be able to do something else** (e.g., focusing attention on the next task or even an anticipated after-work activity).

Involuntary Automaticity

- A situation which occurs when someone **inadvertently reduces the working memory demand** required for a procedure, which becomes too predictable and tedious.

Toft, B., Gooderham, P., Qual Safe Health Care, 2009, 18, 69-73; 2. Kennedy, CR., Mortimer D., Clin Obstet Gynaecol, 2007, 21, 691-712.

Ambiguous Accountability

- Happens when **two people are responsible for the same task**. In this case, **rather than reinforcing safety and diminishing risk**, the procured **attention is rendered insufficient**.

Independent Redundancy

- Double checkers do **not behave independently** as predicted and **failures are not identified**

Toft, B., Gooderham, P., Qual Safe Health Care, 2009, 18, 69-73; 2. Kennedy, CR., Mortimer D., Clin Obstet Gynaecol, 2007, 21, 691-712.

Inattentional Blindness

- Discrepant information not perceived because of limited cognitive resources[1].

Stress

- Is a factor that **increases the chance of an error occurring**. Normally stress goes hand in hand with other situations, such as *heavy clinical workload, distraction, and fatigue*[1,2].

1. Toft, B., Gooderham, P., Qual Safe Health Care, 2009, 18, 69-73; 2. Kennedy, CR., Mortimer D., Clin Obstet Gynaecol, 2007, 21, 691-712.

2. Forbrig, M., et al. Risk factors for mismatch in the ART laboratory: an analysis of 73719 electronic witnessing points, 2024, https://doi.org/10.1016/j.rbmo.2024.104500.

When errors do happen, they can be devastating and costly

Los Angeles Times
https://www.latimes.com › california › story › couple-gi...

Couple gives birth to wrong baby in 'nightmare' IVF mix-up

Nov 8, 2021 — The mix-up, described in court documents as a “non-stop nightmare,” began after the couple contacted the clinic for help getting pregnant with ...

The Guardian
https://www.theguardian.com › us-news › nov › califor...

California women gave birth to each other's babies after ...

Nov 9, 2021 — In 2019, a couple from Glendale, California, sued a separate **fertility** clinic, claiming their **embryo** was mistakenly implanted in a New York ...

USA Today
https://www.usatoday.com › news › nation › 2021/11/08

California fertility clinic implanted wrong embryos on couples

Nov 8, 2021 — In 2019 a couple from Glendale, California, sued a separate **fertility** clinic, claiming their **embryo** was mistakenly implanted in a New York woman ...

Washington Post
https://www.washingtonpost.com › ... › Morning Mix

Couple sues New York fertility clinic, alleging it implanted ...

Apr 6, 2022 — Now, the couple is suing the New York **Fertility** Institute, embryologist Michael Femi Obasaju, and **fertility** specialists Khalid Sultan and Majid ...

TODAY.com
https://www.today.com › parents › ivf-mix-discovered-...

IVF mix-up discovered after DNA test for 12-year-old son

Nov 12, 2021 — **IVF** mix-up: Donna and Vanner Johnson realized their **son**, an **IVF baby**, wasn't conceived using his father's sperm.

NBC Los Angeles
https://www.nbclosangeles.com › news › local › la-cou...

LA Couple, Given the Wrong Baby, Settle Lawsuit ...

9, 2022 — "Genetic testing revealed that the **baby** Alexander and Daphna delivered and r months was not genetically related to them," according to ...

People should recognize common IVF mistakes

Jun 12, 2023 — The disappointment of a failed **IVF** treatment or **health** challenges related can be made worse if it is found to have been due to medical ...
Missing: ~~human~~ | Show results with: human

Texas Fertility Center
https://txfertility.com › Fertility Blog

IVF Lab Mix-ups: Could It Happen to You? - Texas Fertility ...

Although it may not make the news, the reality is that the odds of a **mistake** in a certified **IVF** laboratory in the United States are extremely low. Save. Leave ...

People
https://people.com › ... › Real People Pregnancy

Inside Couple's Shocking IVF Embryo Swap: What Went ...

Nov 24, 2021 — "There's really numerous safeguards that are put in place to keep the **human error** to an absolute minimum," says Alper, an Associate Clinical ...

Fertility and Sterility
https://www.fertstert.org › do-content › ivf-errors-only-ti...

IVF errors: Is this only the tip of the iceberg?

Jan 25, 2020 — While **human error** is a constant variable in any facet of medicine, recent reports involving misplaced embryos; the failure of cryopreservation ...

The Telegraph
https://www.telegraph.co.uk › family › life › ivf-baby-f...

How Britain avoids IVF mix-ups – and why America gets it ...

Jan 3, 2024 — In his findings, Toft was critical of the **IVF** watchdog, the **Human Fertility** and Embryology Authority (HFEA). Set up in 1990, as more and more ...

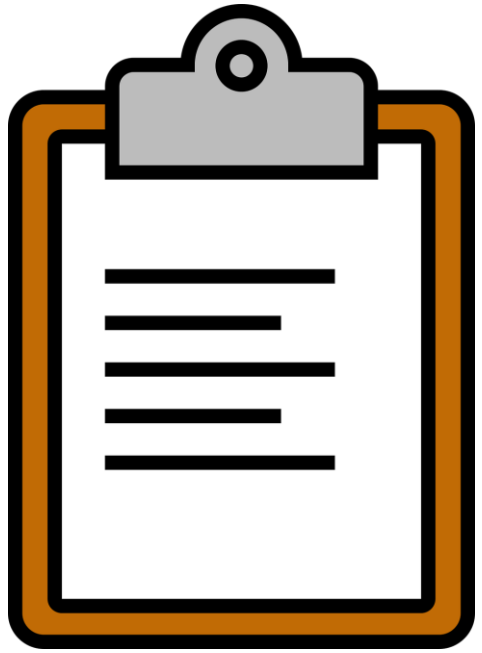
CNN
https://www.cnn.com › 2021/11/09 › ivf-mix-up-califo...

California couple sues fertility clinic after IVF mix-up

Nov 9, 2021 — A lawsuit filed by a Southern California couple says a Los Angeles-based **fertility** clinic implanted the **wrong** embryos into two women during ...
ing: ~~human~~ | Show results with: human

Witnessing in the Laboratory

PATIENT PERSPECTIVE



Patient survey of 408 patients

- 90% expressed concerns about mix-up
- e-Witnessing reduced concerns in 92%
- 97% were particularly satisfied with the electronic traceability
- 97% felt highly comfortable with center equipped with e-Witnessing

Enable transparency for patients on lab procedures

Forte et al. Assist Reprod Genet 2016 33:1215-1222

Error Reduction Guidelines

“Traceability”
(2006/86/EC)

The ability to **locate and identify** the tissue/cell **during any step** from procurement, through processing, testing and storage to distribution to the recipient and disposal. Traceability also covers the ability to **locate and identify** all relevant data relating to **products and materials** coming into contact with those cells [1]

eshre
SCIENCE MOVING PEOPLE MOVING SCIENCE

During **critical steps** (such as first identification of cells and tissues, each time biological material is moved from one container to another and at final destination, e.g. embryo transfer, **cryocontainer**), double-checks by a second person **(witness)** and/or an **electronic identification system** is strongly advised [2]

Human Fertilisation & Embryology Authority

Witnessing protocols should ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process to **prevent any mismatches** of gametes or embryos.

Electronic systems such as **barcoding** and **radio frequency identification (RFID)** for assisted conception are appropriate, subject to a risk assessment [3]

asrm
American Society for Reproductive Medicine

Positive identification of the patient and/or specimen **should be verified by at least 2 qualified witnesses**. Depending on the staffing level in the laboratory and the established workflow, an **electronic witnessing system may be appropriate** for serving the purpose of witnessing key manipulation events[4]

1. European Commission directive 2006/86/EC; 2. ESHRE revised guidelines for good practice in IVF laboratories (2015). 3. HFEA Code of Practice, 9th edition, revised January 2019.
4. ASRM Comprehensive guidance for human embryology, andrology, and endocrinology laboratories: management and operations: a committee opinion (2022)

Error Reduction Actions

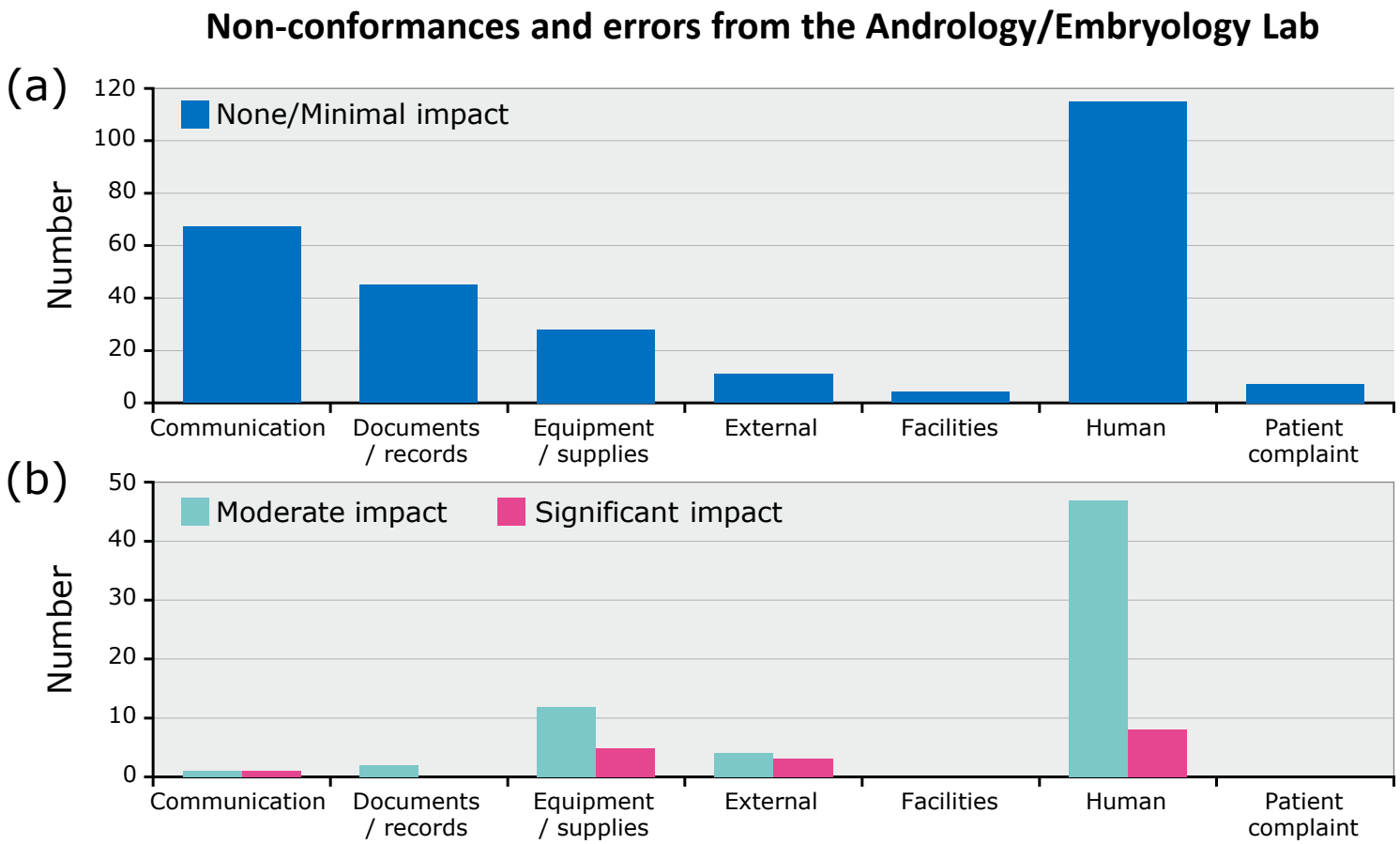
- Human Fertilisation and Embryology Act 1990 mandated witnessing in the UK
  - To minimize human errors during critical steps in IVF procedures by requiring a witness to verify actions
  - EWS systems meet this requirement

- Human Fertilisation and Embryo Authority recommended the use of EWS (2014)

- Several countries have legislation that mandates use of EWS

Types and frequency of non-conformances in an IVF lab

Majority of IVF cycles - no significant mishaps



Human Errors

- Overlooking assessment
- Dropping/misplacing a dish
- Mislabelling
- Poor embryo outcome

Sakkas et al. Hum Reprod 2018; 33 (12), 2196-2204

Identify Critical Witnessing Steps in Your Phase Process

Protocols for tracking and witnessing samples and patients in assisted reproductive technology

Maria José de los Santos, Ph.D.,[a] and Amparo Ruiz, M.D.[b]

[a] IVF Laboratory, and [b] IVI Valencia, Valencia, Spain

In view of the increasing emphasis being placed on patient safety and quality health care, it is extremely important to develop fail-safe mechanisms to prevent assisted reproductive technology (ART) mix-ups. Sample mismatch is the most undesirable event that can occur in an IVF laboratory as it may have catastrophic consequences for both patients and health care professionals. Many strategies can be adopted to reduce laboratory errors, such as improved quality control and quality assessment, certification, educational programs, and external quality assessment. Nevertheless, none suffices to absolutely prevent this error. Therefore, the implementation of specific policies, such as double-checking safety protocols, is receiving more and more interest. After some adverse events involving sample misidentification occurred in some countries, double-checking every step of the IVF clinical and laboratory procedure has become mandatory. However, double-checking protocols can also prove difficult to implement and a new generation of errors may occur. Other approaches, including electronic strategies for tracking, and even microlabeling embryos, are currently being evaluated. (Fertil Steril® 2013;100:1499–502. ©2013 by American Society for Reproductive Medicine.)

Key Words: Risk management, human errors, sample tracking, sample mismatching, mix-ups

Discuss: You can discuss this article with its authors and with other ASRM members at http://fertstertforum.com/delossantosmj-witnessing-art-risk-safety/

Use your smartphone to scan this QR code and connect to the discussion forum for this article now.*

*Download a free QR code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

One of the requirements for Quality Management Systems (ISO 9001:2008) and EU Directives followed by many IVF laboratories is to implement, whenever necessary, mechanisms to identify and keep track of the "product" throughout the process. In the assisted reproductive technology (ART) context, products are the female and male gametes, as well as the resulting embryos generated after insemination procedures, which all have to be identified and tracked until the embryo transfer.

At present, IVF laboratories are very complex in terms of not only the technology and equipment being used, but also of the type and number of tasks being done simultaneously in the laboratory—a hazard that is greatly magnified in large, busy facilities. Gametes and embryos belonging to a particular case may be manipulated at different times by various embryologists. If to this we add a very heavy clinical workload, time pressure, and other risk factors, collectively they might form an error chain that leads to sample misidentification, whereas any one individual factor might not (1).

Risk is always present and is directly correlated to the size of the IVF program. As the number of staff members in the laboratory increases, the chances of introducing unexpected errors also augments.

Some key safety aspects need to be taken into account in large programs: [1] excellent communication skills among team members; [2] daily organization, distribution, and easy visualization of laboratory tasks; and [3] the role of the clinical supervisor figure, who will act as a link among physicians, embryologists, and nurses.

To ensure patient safety, risks must be continuously identified, analyzed, and minimized (2). Evidently, mismatching incidents constitute a major threat that need to be managed and eliminated as much as possible.

The goal should be to completely eliminate mismatching. From a risk management perspective (3), a way to help avoid mismatches should be to answer the following three questions:

1. What can go wrong? Mismatching the wrong patient's eggs to the wrong sperm; mismatching the wrong embryos to the wrong patient; contaminating one semen sample with another; patients who deliberately bring a different third party sperm sample claiming semen mix-ups.
2. How can we prevent harm? By identifying the critical steps during the

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M.J.d.l.S. has nothing to disclose. A.R. has nothing to disclose.

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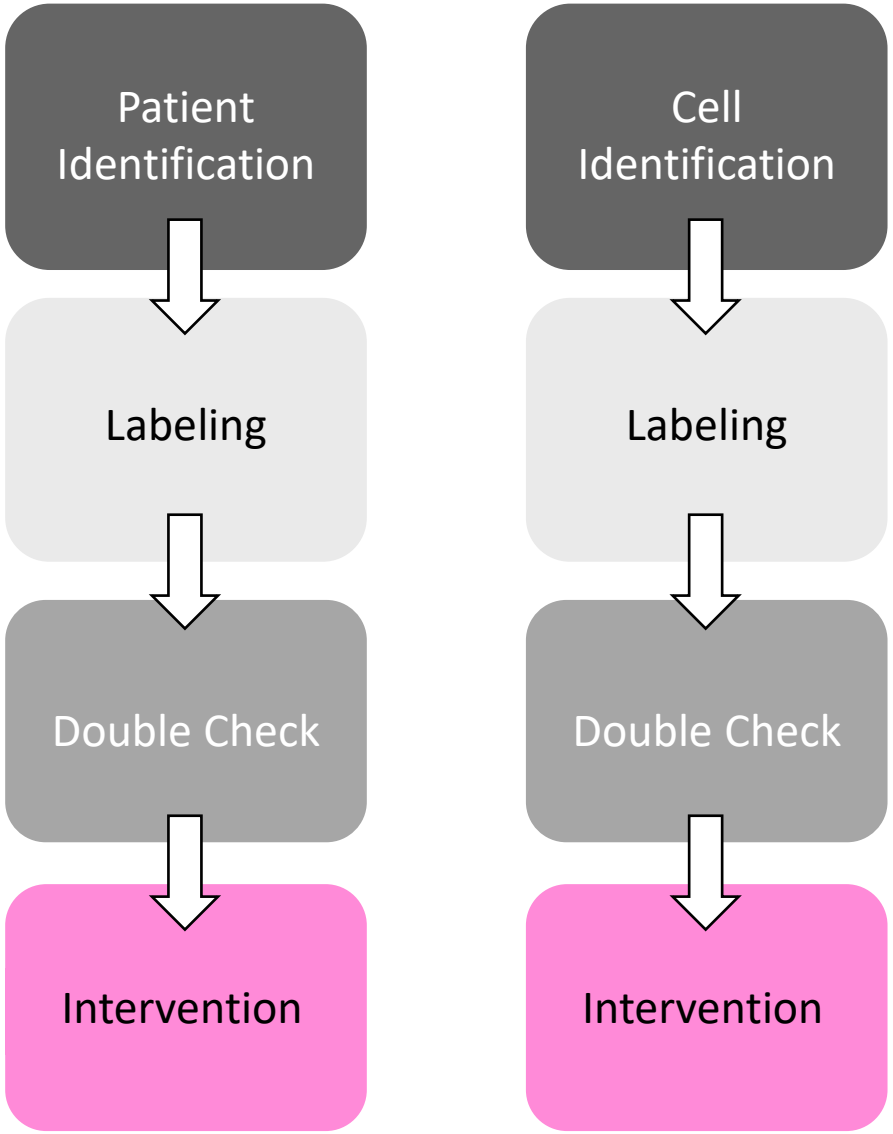
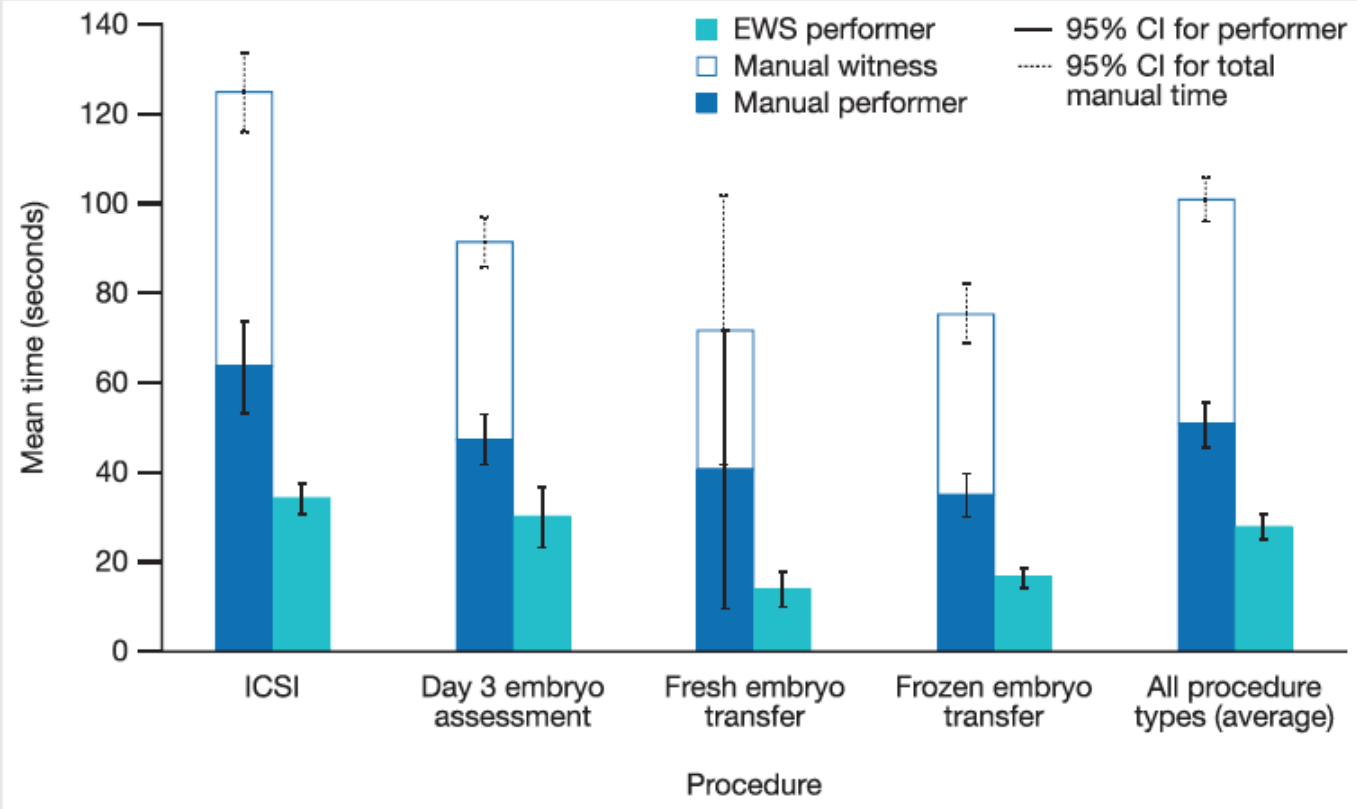
http://dx.doi.org/10.1016/j.fertnstert.2013.09.029



Benefits of E-Witnessing

INCREASED EFFICIENCY



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.

STANDARDIZATION

- Ensure witnessing is performed according to laboratory standards for best practices

Correct ID & Witnessing: [1]

- Oocyte collection
- Sperm preparation
- Adding sperm to oocytes
- Embryo Changeovers
- Embryo Transfer
- Embryo ID and vitrification/warming
- Disposal of embryos
- Transporting gametes or embryos

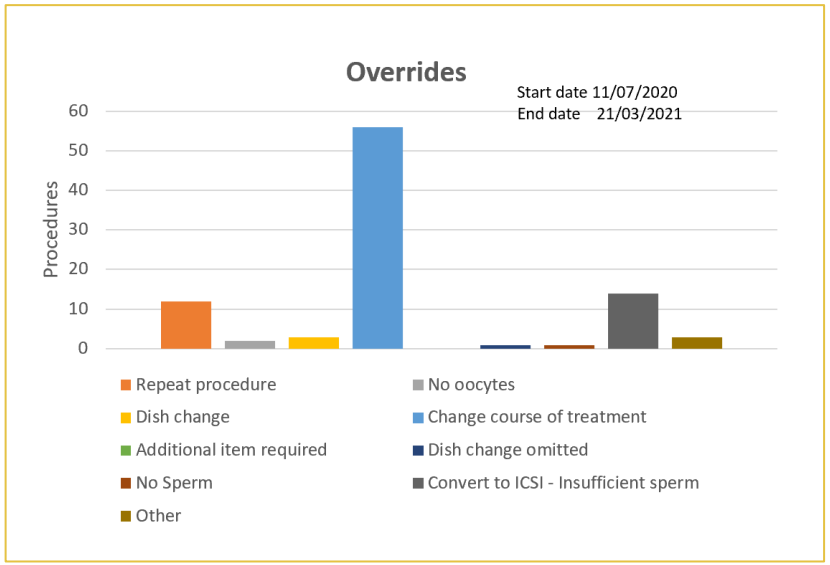
1. Human Fertilisation and Embryology Authority (HFEA) Code of Practice, 9th edition, revised January 2019. E-Witnessing: Electronic witnessing

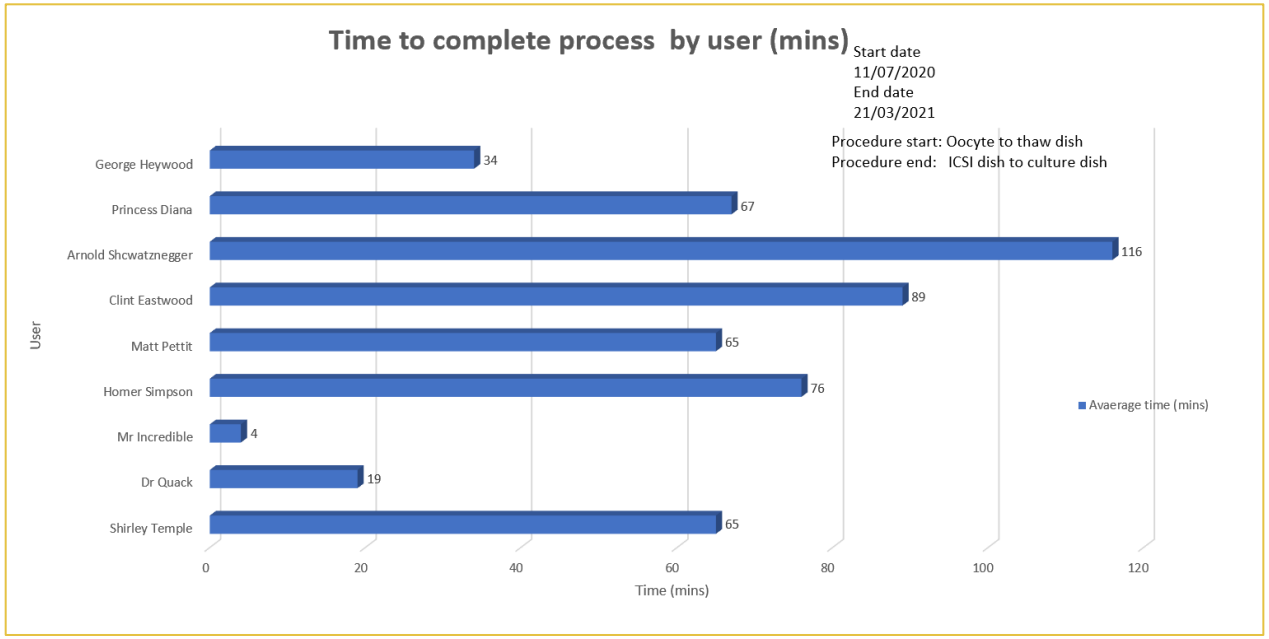
STANDARDIZATION

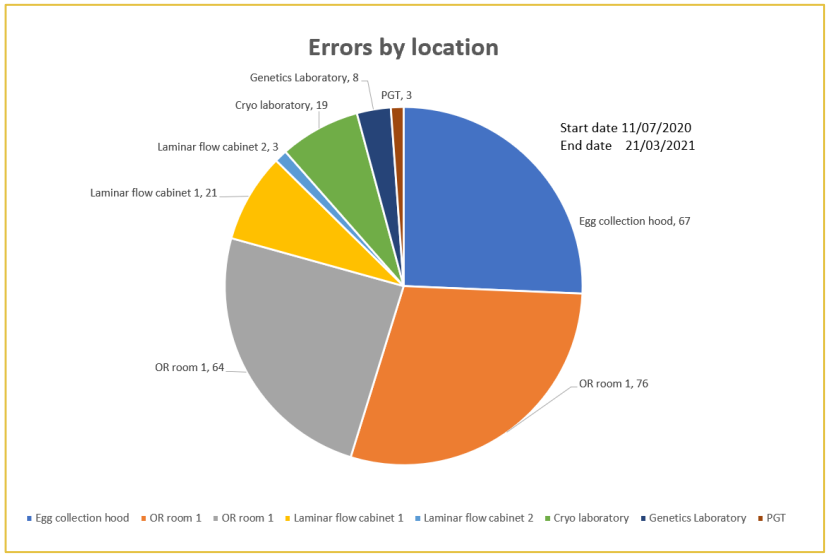
- Minimize variances = enhanced outcomes

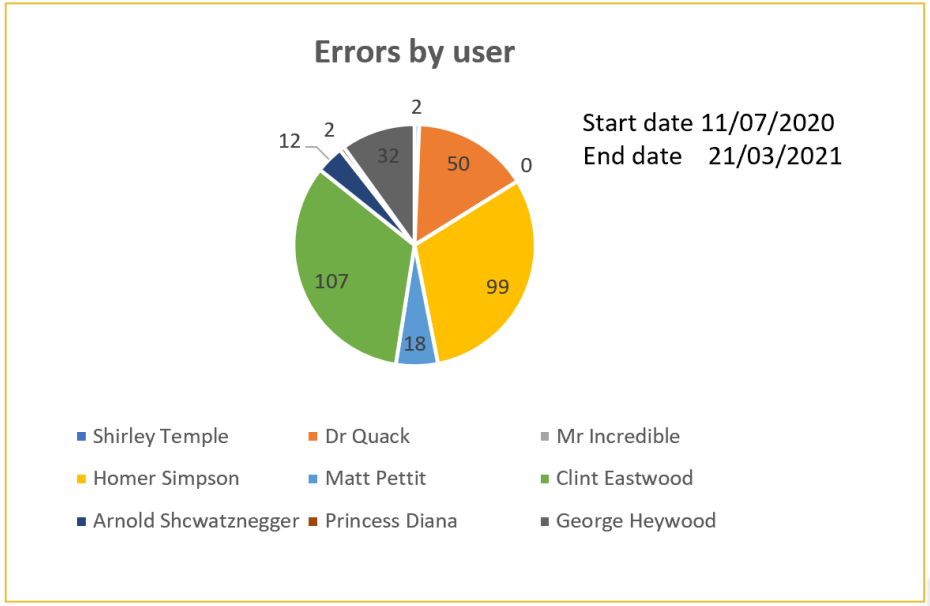
- Poor outcome patient → any procedures take too long or completed at incorrect time?
  - Strip, ICSI, biopsy, vit procedure length?
  - Fert check completed at correct time?

DATA/INFORMATION









SAFETY

Human Reproduction, Vol.33, No.12 pp. 2196–2204, 2018
Advanced Access publication on November 2, 2018 doi:10.1093/humrep/dey320

human reproduction ORIGINAL ARTICLE *Embryology*

Types and frequency of non-conformances in an IVF laboratory

Denny Sakkas*,†, C. Brent Barrett†, and Michael M. Alper
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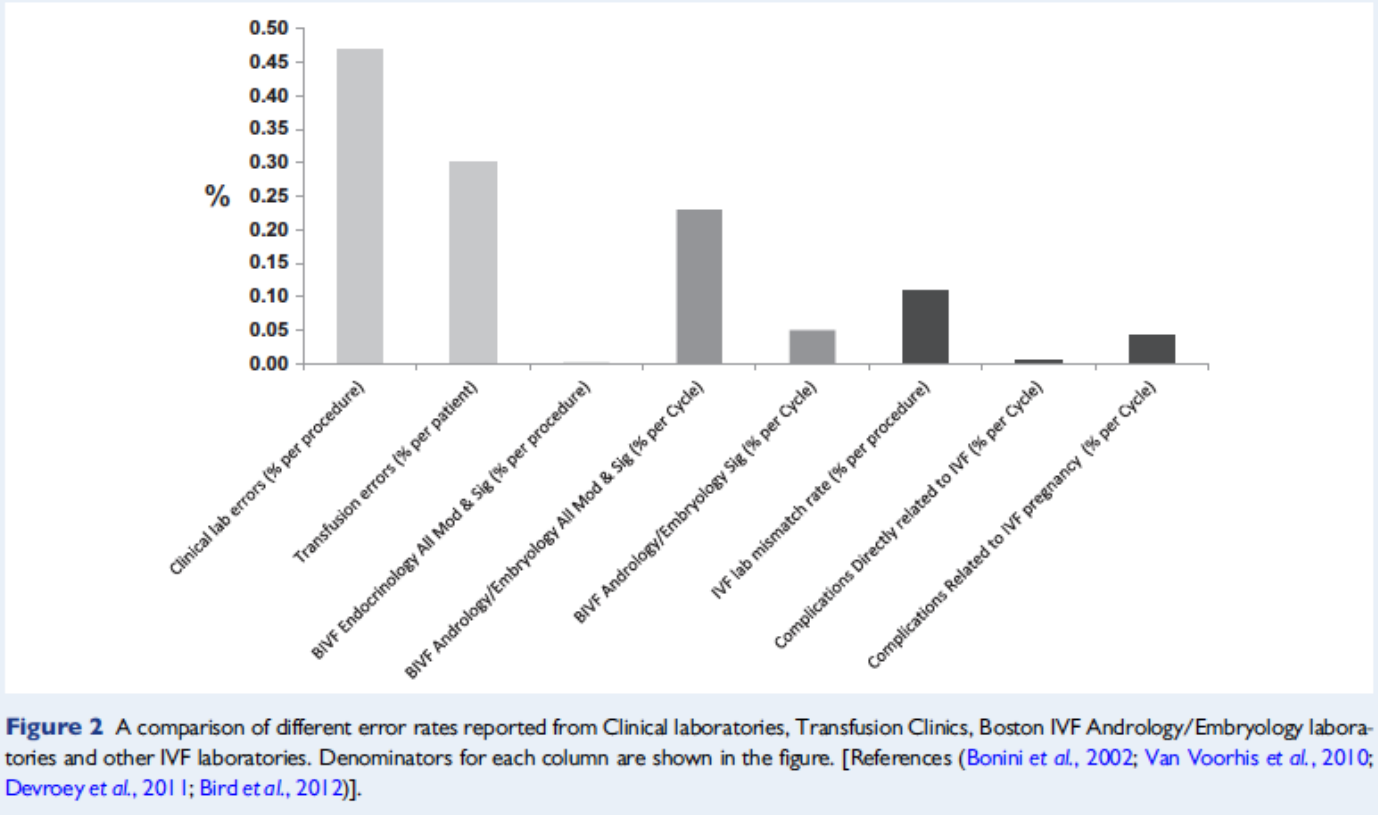


Figure 2 A comparison of different error rates reported from Clinical laboratories, Transfusion Clinics, Boston IVF Andrology/Embryology laboratories and other IVF laboratories. Denominators for each column are shown in the figure. [References (Bonini *et al.*, 2002; Van Voorhis *et al.*, 2010; Devroey *et al.*, 2011; Bird *et al.*, 2012)].

Abstract citation ID: deac107.699
P-758 Evaluating mismatch categories and true errors using an electronic witnessing system

C. Leisinger[1], M. VerMilyea[2]

[1]Ovation Fertility, Laboratory, Baton Rouge, U.S.A.
[2]Ovation Fertility, Laboratory, Austin- TX, U.S.A

Study question: What are the types and frequency of errors occurring in the laboratory identified by an electronic witnessing system (EWS)?

Summary answer: Several types of mismatch categories were identified, and the rate of a potentially catastrophic true mismatch error was < 1%.

What is known already: Mix-ups in the IVF laboratory have been recently highlighted in the media. These errors can have devastating long-term consequences for the fertility clinics and families involved. Prevention of these errors should be paramount in the laboratory.

Measuring human error in the IVF laboratory using an electronic witnessing system

A.R. Thornhill[1,2], X. Orriols Brunetti[1], S. Bird[1]
[1]The Bridge Centre, London, United Kingdom; [2]Department of Biosciences, University of Kent, Canterbury, United Kingdom

SAFETY

EWS information creates a safe

and transparent patient experience

Match Confirmed

Procedure Patient ID to frozen sperm **User** Toups, Danya

Location IMT-020839 **Procedure date** 9/16/2020 2:38 P

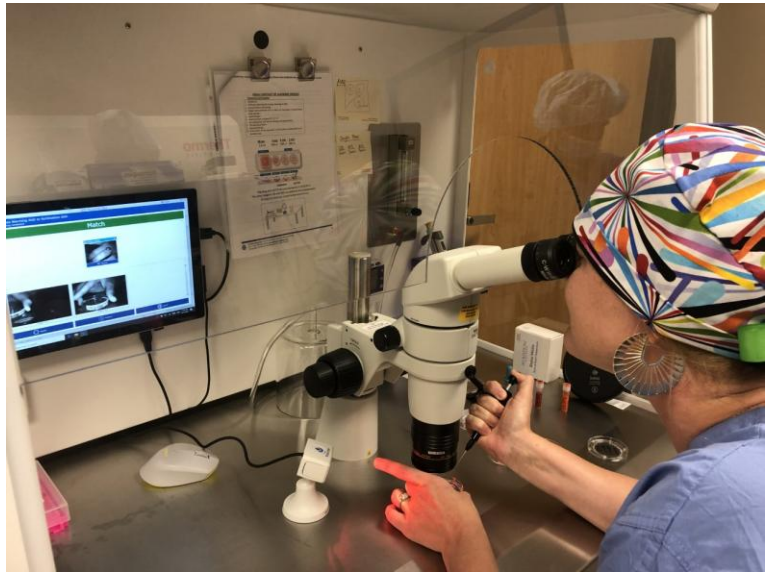
TEST000005
TEST PATIENT 2, Test Patient 2
7/23/1985
Capture date 9/16/2020 2:38 PM

TEST000005
TEST PATIENT 2, Test Patient 2
7/23/1985
Capture date 9/16/2020 2:38 PM

28 February 2022 13:23 2/3 Leisinger, Chelsey

STAFF BENCHMARKS

- Training
- Staff growth
- Evaluate efficiency of lab



P-206 6:30 AM Tuesday, October 19, 2021

NOVEL APPROACH TO DEVELOPING TECHNICIAN BENCHMARKS IN THE CONTEMPORARY EMBRYOLOGY LABORATORY.

Tricia Leigh Adams, MS,[1] Chelsey Audra Leisinger, PhD,[1] Matthew David VerMilyea, PhD[2] [1]Ovation Fertility, Baton Rouge, LA; [2]Ovation Fertility.

OBJECTIVE: Objective analysis of timestamped electronic witnessing procedures provides benchmarks which can be used to estimate staffing requirements and measure staff progression. Training and annual competencies are objectively defined, and realistic goals provided and documented. Objective benchmarks serve as standards for unbiased technician review in the assisted reproductive laboratory [1].

MATERIALS AND METHODS: A retrospective analysis was conducted to evaluate mean procedure time of four embryologists in one location each with varying levels of experience (> 10 years, 5-10 years, and < 5 years). A total of 284 procedures were analyzed for mean procedure time (minutes per oocyte/embryo) and evaluated by level of experience. Elapsed time to procedure completion was obtained by an electronic witnessing system (Matcher, IMT International). Mean time in minutes per oocyte or embryo was analyzed for the following procedures: oocyte denudation, intracytoplasmic sperm injection (ICSI), embryo biopsy, vitrification of biopsied and non-biopsied embryos. Data was analyzed with ANOVA and significance was set at $p < 0.05$.

RESULTS: All experience levels yielded a difference in the following procedures: ICSI, embryo biopsy, and oocyte denudation. Embryo vitrification of biopsied embryos noted a significant difference >10 years versus 5-10 and < 5. Non-biopsied embryo vitrification displayed the same statistical difference according to varying levels of experience > 10 years versus 5-10 and <5.

Procedure	Mean time (min)	> 10 years	5-10 years	< 5 years
Oocyte denudation	0.48 ± 0.25	0.39 ± 0.16[a]	0.52 ± 0.26[b]	0.58 ± 0.34[c]
ICSI	1.84 ± 0.95	0.97± 0.29[a]	1.81 ± 0.80[b]	2.78± 0.99[c]
Embryo biopsy	3.57 ± 2.20	2.50± 1.05[a]	4.05± 1.42[b]	5.83± 4.08[c]
Vitrification biopsied embryo	6.31 ± 1.77	5.48 ± 0.68[a]	6.98 ± 2.38[b]	7.12± 1.02[b]
Vitrification non-biopsied embryo	3.96 ± 1.51	2.75± 0.48[a]	4.48± 1.38[b]	7.00 ± 7.00[b]

EMBRYOLOGIST CONFIDENCE

Survey of 50 embryologists

- 78% felt that EWS improves sample ID and traceability
- 80% agreed it reduced labelling errors
- 61% felt it reduced risk of errors by minimizing disruptions
- EWS reduced concerns and increased confidence in 85%

90% would recommend EWS to a colleague

Holmes et al. Fertil Steril Rep 2021 2:2666-3341

CCRM

Selecting Witness System

Hazard	Applicable to:			Comments for Matcher
	Manual witnessing	RFID	Matcher	
Users				
Involuntary automaticity	Yes	No	No	Removes human verification
Distractions from requesting and waiting for a witness	Yes	No	No	Removes human verification
Confusion due to excessive paperwork	Yes	No	No	Reduces paperwork, and ability to go paperless
Interrupting and returning to a task	Yes	No	No	Removes human verification
Staff shortage at weekends	Yes	No	No	Removes human verification
Staff shortage due to holiday/sickness/maternity leave	Yes	No	No	Removes human verification
Labels				
No manual/legible label	?	Yes	Yes	Labelling system
Microscopy obscured	?	Yes	No	Barcode label on side of dishes
Separate label for unique identifier and other identifying information	?	Yes	No	Single integrated label contains all information including machine readable identifier
Cryolabels/tags unable to withstand long term liquid nitrogen	?	Yes	No	Tested to industry standards, and in use at IVF clinics since 2005
Adhesives	?	Yes	Yes	Independent mouse embryo assay and sperm assay batch tests
Plastics	?	Yes	Yes	Independent mouse embryo assay and sperm assay batch tests
Ink or toner	?	Yes	Yes	Independent mouse embryo assay and sperm assay batch tests
Identity Verification				
Verification of patients, donors and users identities	Yes	Yes	Yes	Barcode ID system with unique user logon IDs
Patients, donors and users with impaired sight	Yes	Yes	Yes	Barcode ID system with audible confirmations and alarms
Patients, donors and users with impaired hearing	Yes	Yes	Yes	Barcode ID system with colour coded visual confirmations and alerts. Photo ID cards
Patients, donors and users who do not understand English	Yes	Yes	Yes	Barcode ID system with colour coded visual confirmations and alerts. Photo ID cards
False positive matches	Yes	No	No	Barcodes cannot be mismatched even with similar ID numbers and names
False negative matches	Yes	No	Yes	If a barcode cannot be read, or an item has no barcode, system pro-actively alerts users
Forcing functions not present	Yes	No	No	Process Mapping functionality

Tips for EWS Implementation

TRAINING

Name

Matcher Training for Clinical Lab

User has demonstrated understanding of the following Matcher processes/procedures:		Date & Initial
Cycle set up	Entering patient demographics	
	Entering a sperm donor	
	Linking partners and donors	
	Creating cycles	
	Print labels	
Scheduler Navigation	Understands white/orange/green/red banners	
	Resize days in order to see all patients	
Handheld Scanner	Scanner use	
	Repeat procedure on handheld	
	Alternate procedure	
	Review a procedure	
	Log a non-Matcher label (sperm vial)	
Cryopreservation	Entering into the cryo store	
	Editing Straw #	
	Understands editing straw number after printing means re-labeling ALL devices in that days freeze	

Name:

Matcher Training for IVF Lab

User has demonstrated understanding of the following Matcher processes/procedures:		Date & Initial
Cycle set up	Entering patient demographics	
	Entering a sperm donor	
	Entering an egg donor	
	Entering a GC	
	Linking partners and donors	
	Creating cycles	
	Edit cycle type to add/remove procedures (2nd day ICSI, TBR)	
	Print labels	
	Unitrack assignment at FET	
Scheduler Navigation	Understands white/orange/green/red banners	
	Resize days in order to see all patients	
	Understands all patients must be green before EOD	
	Delete procedures if not done (e.g. no biopsy freeze on day 5)	
	Scanner use	
	Repeat procedure on handheld	

ROBUST SOPs

CCRM FERTILITY	Title **ELECTRONIC WITNESSING FOR IUI AND SPERM CRYOPRESERVATION PROCEDURE**

I. POLICY

Matcher is the electronic witnessing system in the laboratory. Each cycle is set up using the Matcher application. All dishes and tubes are labeled with a Matcher sticker containing and barcode, patient name, DOB and MRN. During procedures, dishes and tubes are scanned to ensure that the correct patient sample is being used. As well as a barcoded match, each scan is recorded photographically. Please refer to the user manual for complete instructions, below are some procedures that relate specifically to CCRM workflow.

II. PROCEDURE

1. Access:
   a. Individuals are assigned a log-in by the lab director.
   b. The lab director determines the level of use that individuals are assigned.
   c. Each user has an individual log-in and PIN is not to be shared with anyone
   d. Only the lab director for each site is assigned admin access to the system.

CCRM FERTILITY	Title **ELECTRONIC WITNESSING FOR IVF LABORATORY PROCEDURE**

I. PRINCIPLE

Matcher is the electronic witnessing system in the IVF lab. Each cycle is set up using the Matcher application. All dishes and tubes are labeled with a Matcher sticker containing and barcode, patient name, DOB and MRN. During procedures, dishes and tubes are scanned to ensure that the correct patient sample is being used. As well as a barcoded match, each scan is recorded photographically. Please refer to the user manual for complete instructions, below are some procedures that relate specifically to CCRM workflow.

II. ACCESS:

1. Individuals are assigned a log-in by the lab director.
   hat individuals are assigned.

CCRM FERTILITY	Title **MATCHER AUDITS**

I. PURPOSE

This document defines the process and intervals for audits of the electronic witnessing system required by all laboratories at monthly intervals.

II. SCOPE / PERSONNEL RESPONSIBILITIES

The laboratory director or designee is responsible for ensuring that audits are conducted monthly for sperm vials thawed and correct Matcher use in the IVF and clinical laboratory.

III. PROCEDURE

Matcher reports can be generated for specific date ranges, specific cycle types, and specific procedures within cycle types as described below to allow for various queries to be performed depending on what is needed for audit purposes.

1. To pull a matcher report

CCRM

AUDITS → Implementation Audits

Installation Audit of Matcher Cycle Scans

Audit all cycles for completeness of scans. At each step ensure all labels are included in the scans and records. Use Appendix I in the SOP for a complete list of expected scans. Complete audit until all scans are completed correctly on a routine basis. after this time, move to a monthly audit
If items are missing or not clear, complete corrective action and address with staff

Fresh IUI cycle				
	Patient ID	Sperm Prep	IUI procedure	Corrective action
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				

…s are missing or not clear, complete corrective action and address with staff

Sperm Cryopreservation			
	Patient ID	Sperm Cryo	Corrective action
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

Reviewed by:

Installation Audit of Matcher Cycle Scans

First weeks of Matcher installtion, check cycles for completeness of scans. At each step ensure all labels are included in the scans and records. Use Appendix I in the SOP for a complete list of expected scans. Conintue auditing until all scans are being completed correctly and then move to monthly spot audit
If items are missing or not clear, complete corrective action and address with staff

ICSI CCS cycle										
	Date of Procedure	Patient ID	TVOR	Stripping	ICSI	Sperm Prep *	Fert Check	Biopsy	Blast vit	Corrective action
1										
2										
3										
4										
5										
6										
7										
8										

FET					
	Patient ID	Date of Procedure	Thaw **	Transfer	Corrective action
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					

** ensure straw label is visible on paperwork

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AUDITS → Routine

Monthly Audit of Matcher Cycle Scans

Each month spot check completed cycles for completeness of scans. At each step ensure all labels are included in the scans and records. Use Appendix I in the SOP for a complete list of expected scans
If items are missing or not clear, complete corrective action and address with staff

	Patient ID	TVOR	Stripping	ICSI	Sperm Prep *	Fert Check	Biopsy	Blast vit	Straws Scanned	Corrective action
1										
2										
3										
4										
5										

Egg Vit Cycle

	Patient ID	TVOR	Stripping	Egg vit	Straws scanned	Corrective action
1						
2						
3						

Egg Thaw Cycle

	Patient ID	Egg thaw**	ICSI	Sperm Prep *	Fert Check	Biopsy	Blast vit	Corrective action
1								
2								

FET

	Patient ID	Thaw **	Transfer	Corrective action
1				
2				
3				
4				
5				

CRYOVIAL INVENTORY RECONCILED WITH ARTISAN		MISMATCHES REVIEWED	

* ensure vial ID is entered into system if frozen sperm used
** ensure straw label is visible on paperwork

Reviewed by

Monthly Audit of Matcher Cycle Scans

Year:

Each month spot check completed cycles for completeness of scans. At each step ensure all labels are included in the scans and records. Use Appendix I in the SOP for a complete list of expected scans
If items are missing or not clear, complete corrective action and address with staff

Fresh IUI cycle

	Patient ID	Sperm Prep	IUI procedure	Corrective action
1				
2				
3				
4				
5				

Frozen IUI

	Patient ID	Sperm Prep*	IUI procedure	Vials Removed from Artisan inventory	Corrective action
1					
2					
3					
4					
5					

* ensure vial label is visible in photo of the vial scan AND ID is entered into system

Sperm Cryopreservation

	Patient ID	Sperm Cryo	Corrective action
1			
2			
3			
4			
5			

CRYOVIAL INVENTORY RECONCILED WITH ARTISAN		MISMATCHES REVIEWED	

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QUESTIONS?