Electronic Witnessing Platforms

Has the time come for ART Programs to Abandon Human Independent Double Check?

Carli W Chapman

Reproductive Medicine Institute Oak Brook, IL CChapman@TeamRMI.com

Disclosures

- KOL Speaker Irvine Scientific
- Advisory Board Good Start Genetics
- Long time user of electronic witnessing

Objectives:

- Why we make mistakes
- Review current 'witnessing' procedures in ART
- Introduce various electronic witnessing devices
- Pros and Cons of the various systems
- Encourage an open dialog

Know your audience

- How many programs represented here have just one or two persons in the ART laboratory?
- How many programs represented here utilize a 'witnessing' process?
- How many programs represented here have a written SOP for their witnessing procedure?
- How many programs represented here utilize an electronic witnessing platform?

Safety Critical Work

 Airline Pilots Air Traffic Controllers Train Engineers Transfusion Therapists Nurses • ART Laboratory Staff



To err is human





The Error Chain



- In aviation "error chain" is a term referring to the concept that many contributing factors typically lead to an accident (mishap)
- Should any of the links be "broken," then the mishap probably will not occur
- It is up to each crewmember to recognize a link and break the error chain.

Error Chain

Operational Clues

- Failure to meet targets
- Use of an undocumented procedure
- Departure from SOP
- Violating minimumsNo pilot

Human Clues

- Incomplete communications
- Ambiguity
- Unresolved discrepancies
- Preoccupation/Distraction
- Confusion or anxiety

Introducing the SHELL Model



Errors Lead To

- Complex Litigation
- Financial expense
- Reputational damage
- Emotional consequences
- Ethical consequences



Why do we make mistakes?



- Human Automaticity
- Subconscious
- Enhanced by trust and comfort
- Our brains are susceptible to read what we *EXPECT* to see, not what is actually in front of our eyes!

Ambiguous Accountability

am•big•u•ous

doubtful, uncertain, unclear in meaning



Stress



- Our jobs are stressful
- Staffing issues
- Pressure to succeed
- Lack of or limited control
- Funding

Culture of Safety

- Environmental tools
- Individual performance parameters
- Multiple strategies
 Clearly defined SOPs
 Proper staffing



An IVF cycle can have multiple points of contact



 Oocyte retrieval Sperm collection/processing Oocyte stripping ICSI or insemination Fertilization check Cleavage checks **Embryo Transfer Embryo Vitrification Biopsy**

How can we minimize risks?

- Written procedures that have safe guards built in
- Written procedures that are followed
- Cultivate a culture that understands humans can make mistakes so that the impact of errors can be minimized by early reporting
- Proper staffing
- Proper training

Independent Double Checks (IDC)

- Risk avoidance strategy widely promoted in healthcare to detect potentially harmful errors before they reach patients
- For maximum effectiveness double checks must be conducted independently
- Should be used only for selective high-risk tasks
- IDCs are a poor substitute for system improvements

Independent Double Checks (IDC)

- Inconsistent conceptualization of double checking
- Costly and time-consuming procedure
- Paucity of evidence to justify the practice
- Interruptions are challenging
- Processes to support double-checking

IDCs in the ART Laboratory

- Do not have a defined process
- Poor documentation or no documentation
- Interruptions and distractions contribute to poor patient care
- High work loads and poor staffing contribute to superficial routine performance of IDC

Number of full time embryologist(s) excluding laboratory director:



Adapted from SRBT salary survey data

Witnessing Employee

| | Low Wage | Medium Wage | Reasonable Wage |
|---------------|-------------|---------------|-----------------|
| | \$7.25 | \$12.00 | \$18.00 |
| | 77.25 | ΥΙΖ.00 | J10.00 |
| Annual Salary | \$15,080 | \$24,960 | \$37,440 |
| Onboarding | \$2600 | \$2600 | \$2600 |
| Benefits | \$3317 | \$5491 | \$8236 |
| Coverage | 40 hrs/week | 40 hrs/week | 40 hrs/week |
| Total | 20,997 | 33,051 | 42,876 |

How can we minimize risks?

Utilize available technology to protect your practice









Electronic Systems Provide

- Insurance against patient mis-match
- Not subject to automaticity
- Provides traceability of who what when and where
- Documentation of error resolution
- Can replace human independent double checking

Electronic Systems Provide

- Limits the number of persons required to confidently perform all steps in a process
- Reduces laboratory traffic which has the added benefit of decreasing VOCs and dirt in the laboratory
- Reduces necessary manpower costs

Types of IDC Systems

BAR CODE BASED

- Matcher
- Gidget
- Fertiproof



Types of IDC Systems



RFID BASEDRI Witness

Gidget

- Hand held bar code scanning
- QR code scanning enables multidirectional scanning
- EMR connectivity
- Workflow management
- Electronic witnessing
- Process mapping
- Batch/lot tracking
- Cryo management
- Reporting
- Training, Service, Support



Fertiproof

- Intuitive Barcode Tracking System
- Modular, compact and flexible set-up
- One-step instant individual labelling
- Tablet, barcode readers and label printer
- **Traceability and Audits**



Matcher

- Uses digital photo images to read the barcoded labels
- No lasers, radio frequency radiation, supplementary heating
- No equipment modifications
- Electronic witnessing
- Process mapping
- Batch/lot tracking
- Reporting



Bar Code Based Systems

Pros

- Provide IDC
- Do not require equipment modifications
- Provide additional management/QA information
- Less expensive



Cons

- Bar code readers require direct line of site to read
- Process change required to incorporate scanning bar code
- Bar codes are ubiquitous
- Bar codes have no read/write capabilities
- Can be circumvented

WITNESS



- Automatically reads tags any time a sample is out
- Constant monitor of all activity in the work areas
- Labels are linked for male and female patients
- Identity checks can
 NEVER be overlooked

RFID Based Systems

Pros

- Provide IDC
- Cannot be circumvented
- No process change required for use
- Each label is unique
- Labels have read/write capabilities
- Multiple labels can be read at once
- Provide additional management/QA information

Cons

Cost

- Readers have to be installed on all working microscopes
- RFID frequency theoretically can be damaging to embryos (?)



Electronic Witnessing

PROS

- Provides independent double check
- Not subject to automaticity
- Electronic record of who, what, when
- Provides audible alerts if samples are mis-matched
- Improves patient satisfaction
- Provides additional management/QA information

CONS

- Perception of complicated usage?
- Perception that processes must be changed to accommodate system?
- Bulky equipment?
- Cost?
- Not necessary?

Thanks so much

- Manny Magno
- Ian Oravek
- Siby Varghese
- Ghada Istanbouli
- Marianna Pantos
- Yuri Wagner



Questions

