Minimizing Errors in an ART Lab

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Disclosure

- Consultant and lab director for ReproSource Fertility Diagnostics

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To Err Is Human:

Building a Safer Health System

"The title of this report encapsulates its purpose. Human beings, in all lines of work, make errors. "

Institute of Medicine Report, 1999

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“My lab never makes mistakes…”

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What is the big picture in health care?

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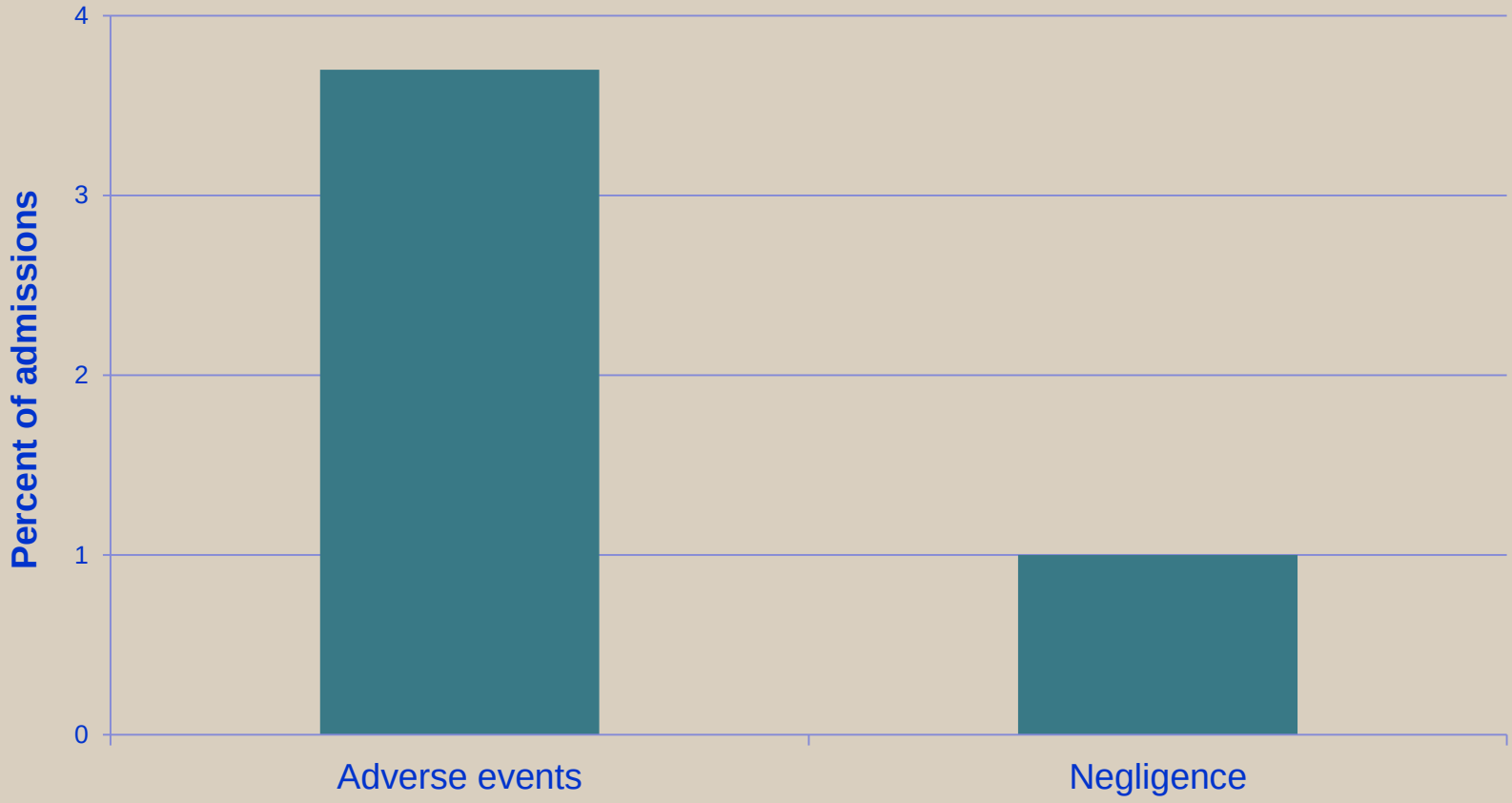
Adverse events per hospitalization



Adverse event: injury caused by medical management that prolonged the hospitalization, produced a disability at the time of discharge or both.

NEJM 324:370, 1991

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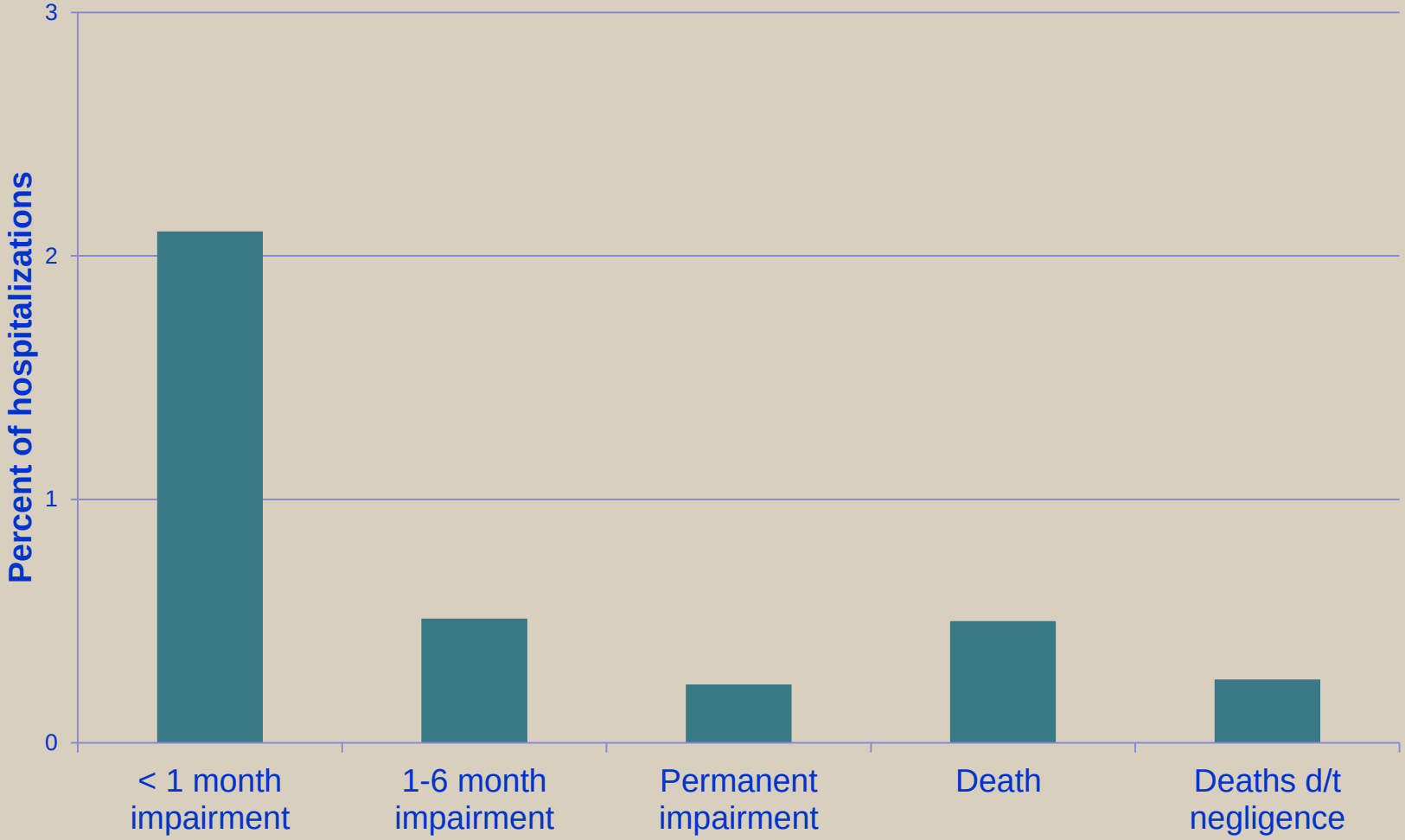
Disability and deaths per hospitalization



NEJM 324:370, 1991

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"…deaths due to medical errors exceed the number attributable to the 8th-leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516)."

Institute of Medicine Report, 1999

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"U.S. health care organizations still have a ways to go to achieve a culture in which all errors are openly identified and investigated."

NEJM 369:1677, 2013

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What about ART??

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"As health care and the system that delivers it become more complex, the opportunities for errors abound."

Institute of Medicine Report, 1999

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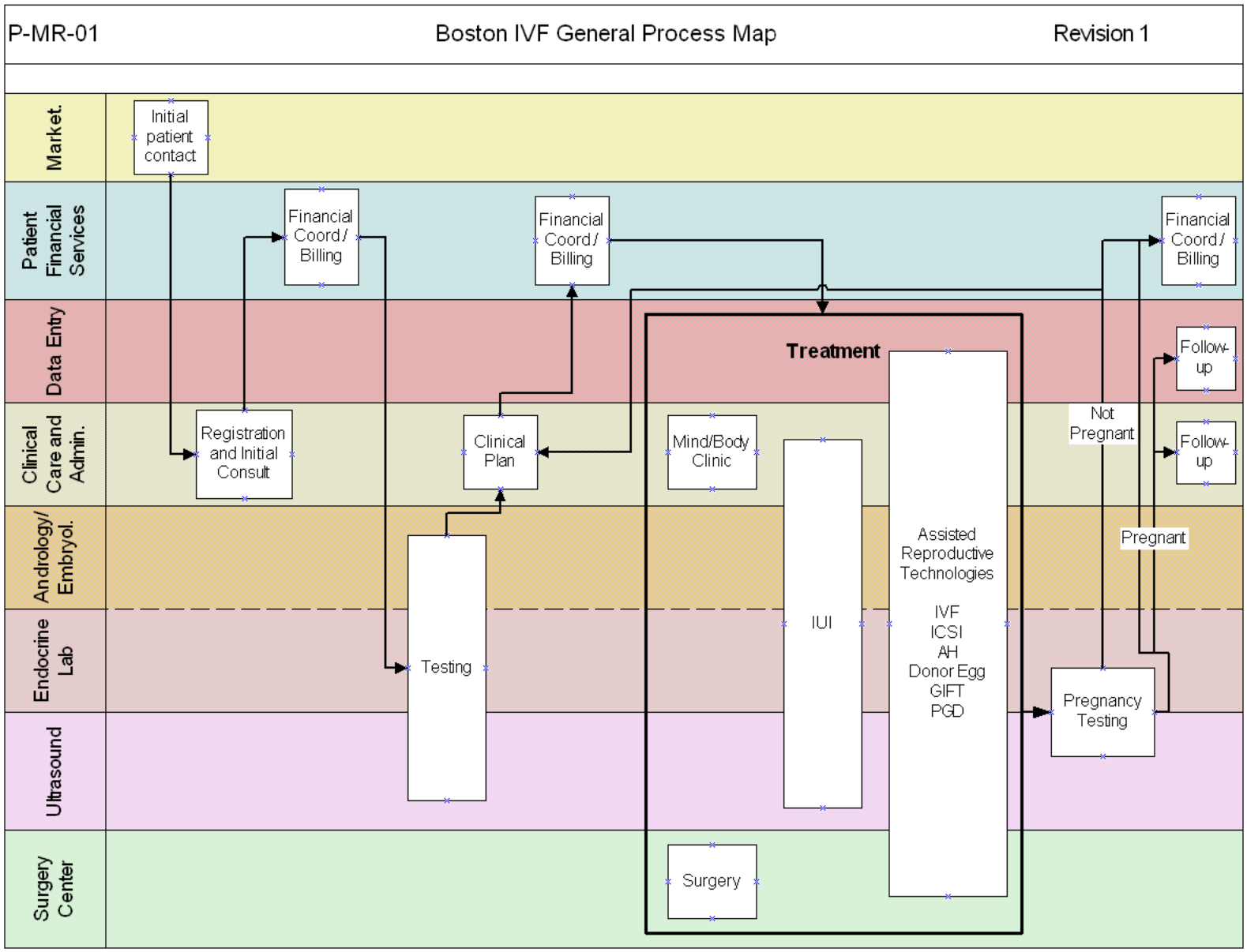

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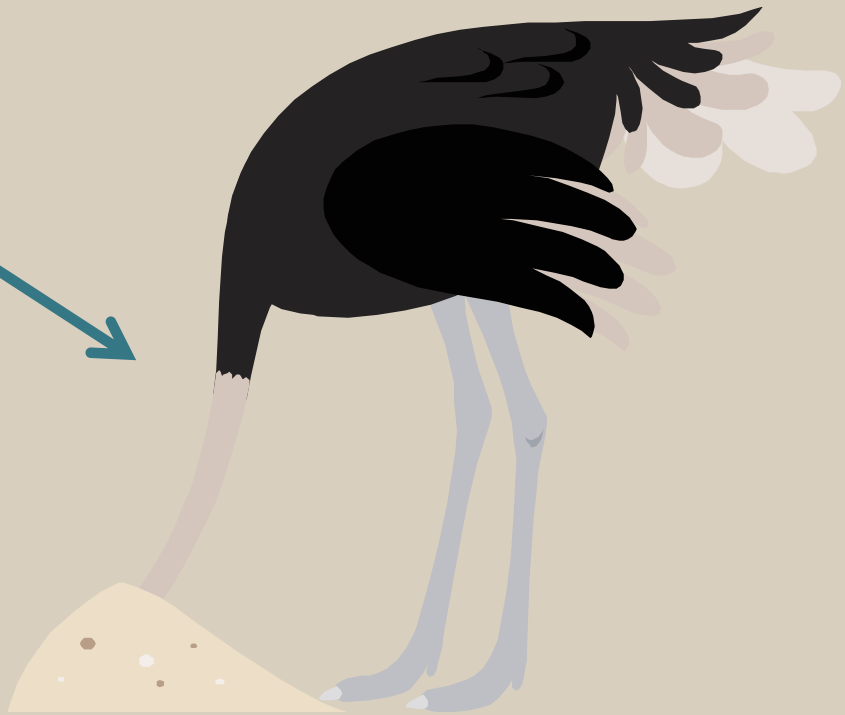
Errors in ART

- How do we know how we are doing?
- No data!
- Perpetuates



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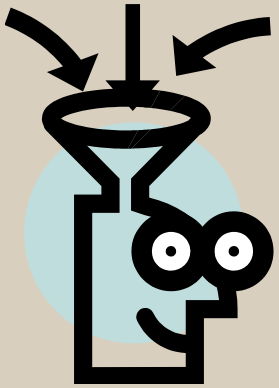
"Much can be learned from the analysis of errors. All adverse events … should be evaluated to assess whether improvements … can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events."



Institute of Medicine Report, 1999

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Nonconformance database

- In March, 2003, BIVF became certified to the ISO 9001:2000 quality standard
- Standard requires documentation of errors – created and currently maintain electronic database
- “non-fulfillment of a requirement,” i.e. any problem, error or deviation from protocol.
- Database audited annually to ensure that all records are complete

ART lab errors

- Reviewed our nonconformance database between March, 2003 and November, 2013
  - What errors are made?
  - How many errors?
  - How significant were the errors?
  - What was the cause?

Departments and procedures

- Phlebotomy/pre-analytic procedures
- Endocrine
- Andrology
  - SA; IUI and IVF sperm preparation; sperm freezing and storage; associated ID
- Embryology
  - All procedures including frozen embryo and egg storage; PGS/D; Pt ID

Study period

- March, 2003 - November, 2013
- Total number of cycles = 31,715
  - 25,764 egg retrievals
  - 5,951 thaw cycles
- 25,205 IUI sperm preparations
- 20,994 Semen Analyses

Average number per year

- 2,417 retrievals
- 558 thaw cycles
- 2,364 IUI cycles
- 1,969 SA

Procedure totals

- Included:
  - Egg retrievals; SA; semen prep for IUI/IVF/ICSI; embryo, egg and sperm cryopreservation; ICSI and insemination; embryo biopsy; embryo transfers.
- Average of 14,660 laboratory procedures per year
- Total of 156,276 procedures

Report ID # 1958

Type of nonconformance Document problem

Date of occurence 09/09/2013

NOTE: For an Internal Audit finding, a CAR must be completed.

Supervisor Brent Barrett

Department Andrology/Embryology

Department Head

Employee description of nonconformance (supervisor copy)

Patient SB had a thaw and transfer on 09/09/2013. Her embryos were not logged out of the database.

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Employee correction of nonconformance (supervisor copy)

I updated the FMP record to reflect the thaw.

Employee name

Date of entry 11/14/2013

Time of entry 10:00:02 AM

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Supervisor Correction Report

Please describe your correction below. Be specific.

Other staff or departments involved in correction None

Please indicate if other supervisors, physicians or managers participated in the correction and identify them in the description of the correction below. If more than one supervisor, physician or manager was involved in the correction, please record the highest level person involved above and identify others in the description.

Description of correction

If the employee completed all necessary corrections, write "no further correction is required".

As of 11/26, we changed the thaw form to include a box for the thaw person to check that they had recorded the thaw in the database.

Corrective action required? No

If Corrective Action is required, complete the Corrective Action layout.

Supervisor name Brent Barrett

Date 11/26/2013

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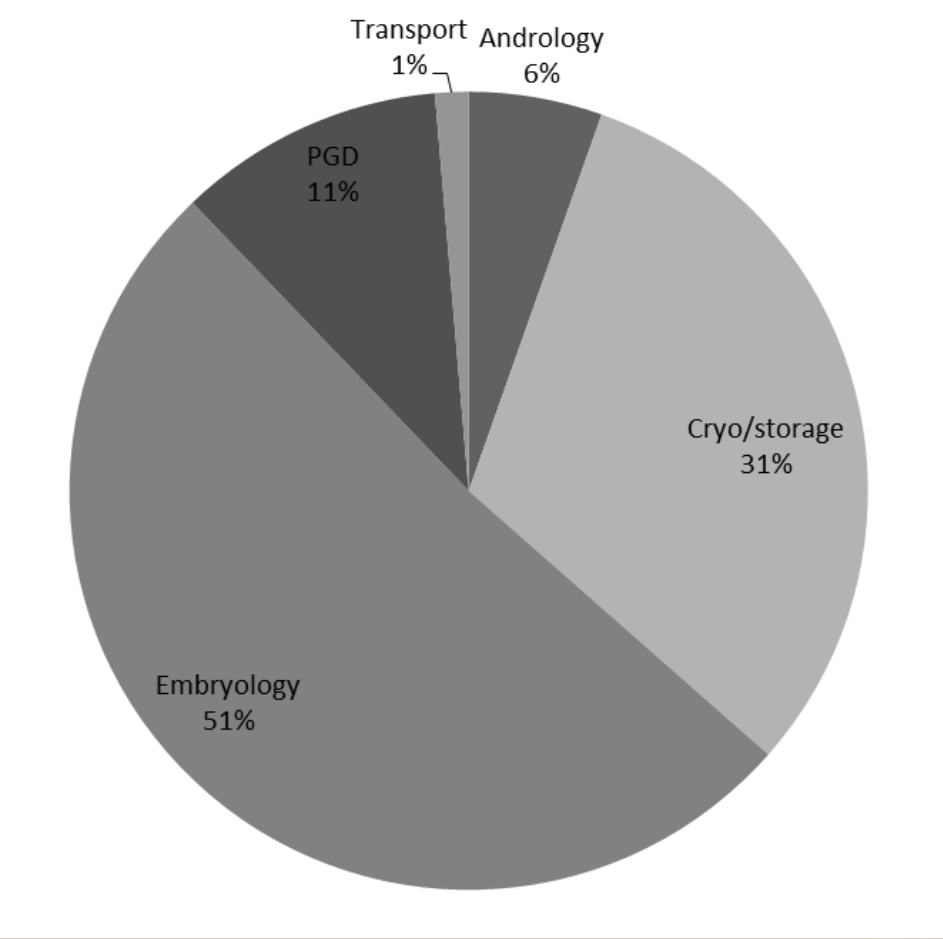
Where are the errors made?



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Category	
Communication	Inter-departmental communication problems
Documents/records	Incorrect or incomplete documentation
Equipment and supplies	Failure of a piece of equipment, including computers, or supply item.
External	A problem which occurred outside of Boston IVF (e.g. transport)
Facilities	A problem with infra-structure such as HVAC.

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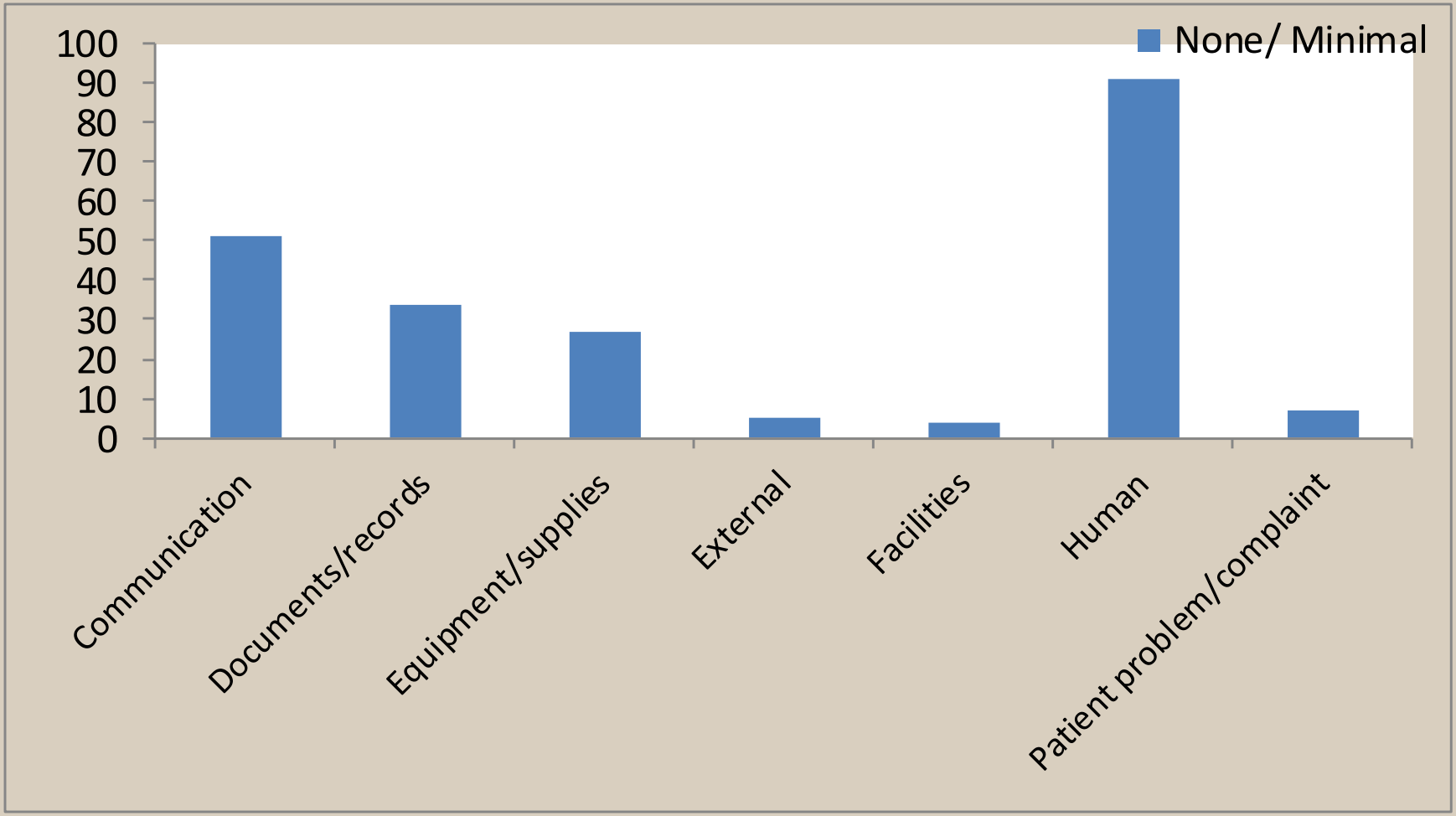
Category	
Human	An error such as performing a task outside of a documented protocol or a mistake or oversight which was most likely the direct result of a human action.
Patient problem/complaint	A problem with a specific patient or a complaint from a patient.
QA/QC/PT/Statistical out-of-range values	A problem not directly attributable to a specific cause such as a transient drop in fertilization or pregnancy rates.

Grading

- None/Minimal
  - Error or problem occurred, but fully correctable or no measurable effect



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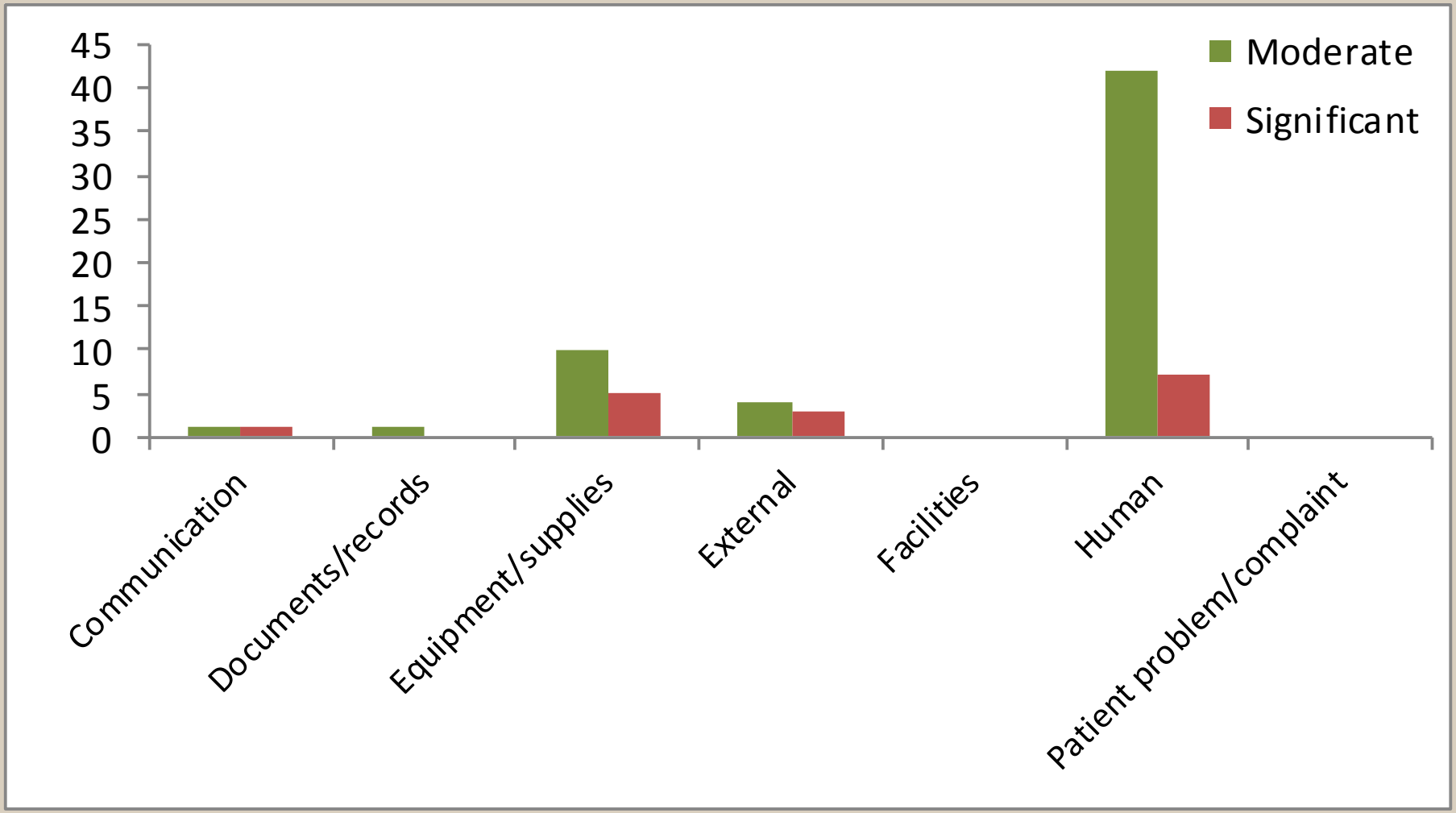
Grading

- Moderate
  - Serious error which affects a cycle, but cycle not lost
- Significant
  - Significant compromise or loss of cycle



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Grading

- Major
  - A pregnancy or birth confirmed to have arisen from a misidentification of gametes or embryos
  - Systemic or repeated problems which significantly affect multiple patients over a period of time
  - Serious and repeated deficiencies during FDA, CLIA, CAP or State inspections

Documentation errors

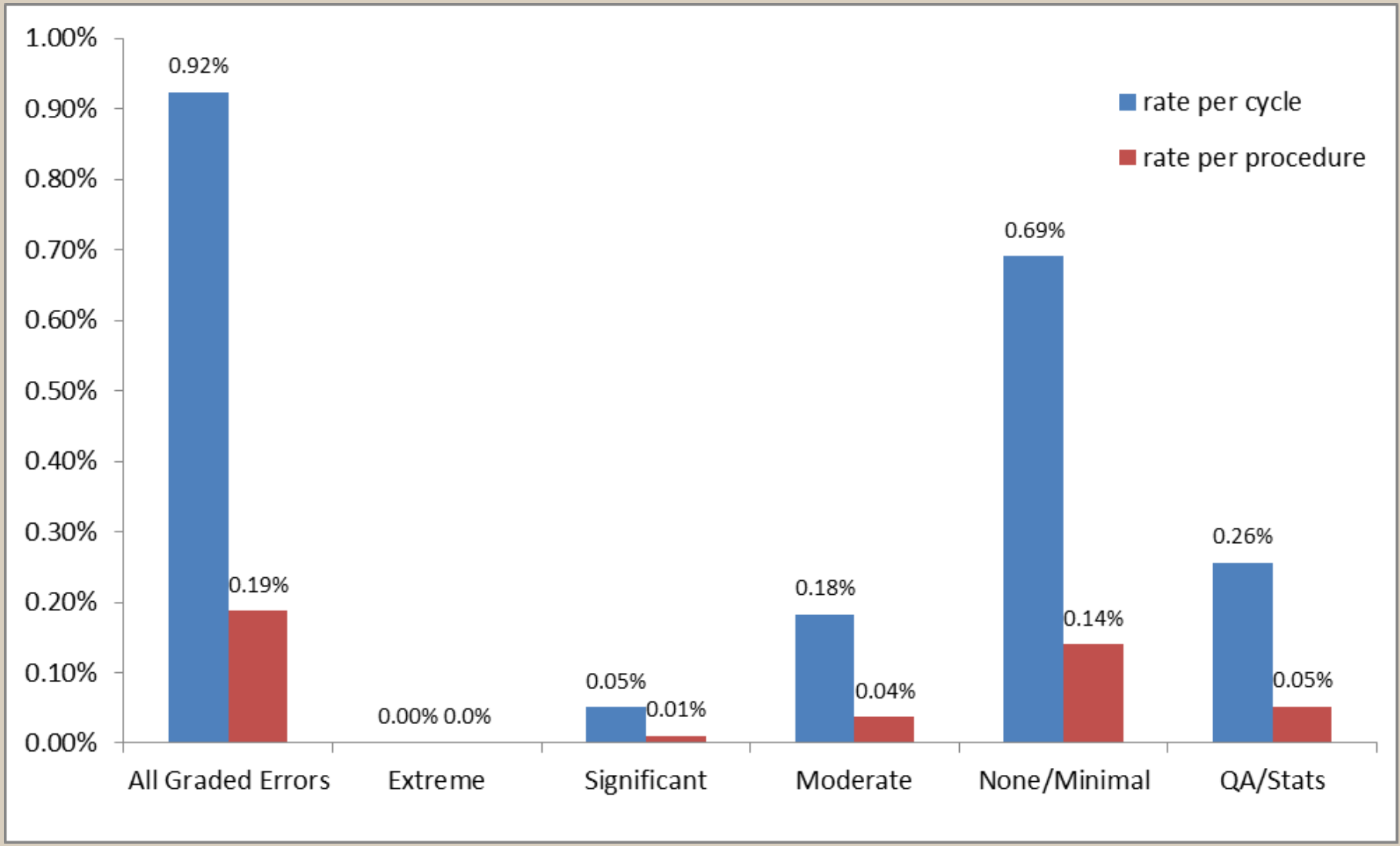
- Expert review at lab “X” (since closed)
  - Reviewed all embryology and cryo records
  - 9.5% of cycles with significant documentation errors with 1.9% without embryologist “A”
  - Another 16.7% with minor errors
  - Many lawsuits and these are the only records!!

TYPE	SEVERITY	DESCRIPTION
Communication	None/Minimal	I had to remind the nurse regarding the official time out on pt SJ. She initially told me that she was bringing down “Jones." I confirmed with her that the full name was “Susie Jones."
Human	None/Minimal	When preparing to do an embryo transfer I saw that the culture dish was properly labeled, but the transfer dish was mislabeled with an incorrect first name. This dish had the proper number of embryos in it at the proper stages of development and the correct last name and date of birth.

TYPE	SEVERITY	DESCRIPTION
Human	Moderate	"John" *(a new embryologist)* was handling the dishes of pt P during fertilization assessment. There were 14 oocytes in the dish, 9 ICSIed and 5 inseminated. The 8 ICSI ferts were moved to the culture dish, but, before the remaining 5 eggs were assessed for fertilization, the original dish was accidently flipped over. 1 of the remaining oocytes was found, but 4 were not recovered.
Equipment	Moderate	During a cryo run, the power to the computer running cryologic controller shut down and the alarm went off. "Sam" and "Bob" were in the lab and heard the alarm. The temperature on the controller was -27 but rising rapidly. After quickly determining that the computer had, for an unknown reason, shut down, and there was no hope of continuing the run, the embryos were immediately plunged.

TYPE	SEVERITY	DESCRIPTION
Human	Significant	A patient was scheduled for a thaw and on the day of the thaw her cryo paperwork could not be found in the usual place. The record in the electronic database was checked and it indicated that her embryos had been discarded and the paperwork was located in the 'discarded' filing cabinet. The patient had filled out a 'consent to thaw embryos' designed for a thaw cycle, rather than consent to thaw and discard embryos'.
Equipment	Significant	I was using a 150um stripper tip to strip the eggs of pt R. I individually picked up each egg from their original drops and moved them through a wash drop and then to a culture drop. When I expelled the media into the culture drop, no eggs emerged. I examined the pipet under the microscope and could see no eggs in it, but could see a particle of plastic lodged in the tip. I flushed the pipet using a needle and syringe but still found no eggs. The drop I had expelled the media into was then re-examined and 7 ruptured zonas could be seen.

	Number	1 error per X cycles	1 error per X procedures
All Nonconformances Andrology/Embryology	374	-	-
Statistical/QA	81	-	-
All Graded Errors	293	108	533
None/Minimal	219	145	714
Moderate	58	547	2694
Significant	16	1982	9767
Major	0	-	-



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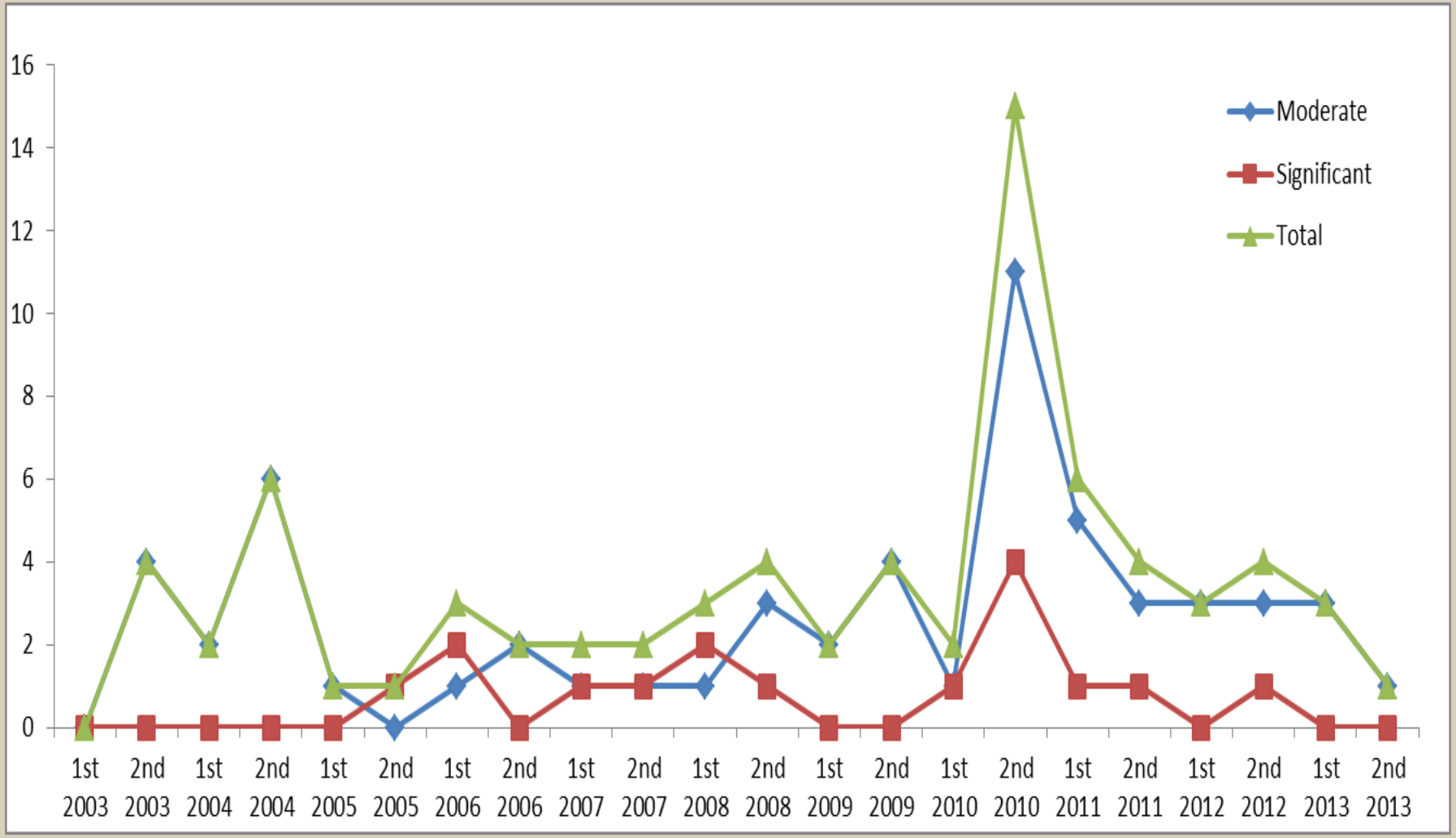

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Human Error

	Number	None / Minimal (%)	Moderate (%)	Significant (%)
Andrology	31	29 (93.5)	2 (6.5)	0 (0.0)
Cryo. / Storage	39	24 (61.5)	12 (30.8)	3 (7.7)
Embryology	67	38 (56.7)	25 (37.3)	4 (6.0)
PGD	3	0 (0.0)	3 (100.0)	0 (0.0)
TOTAL	140	91	42	7

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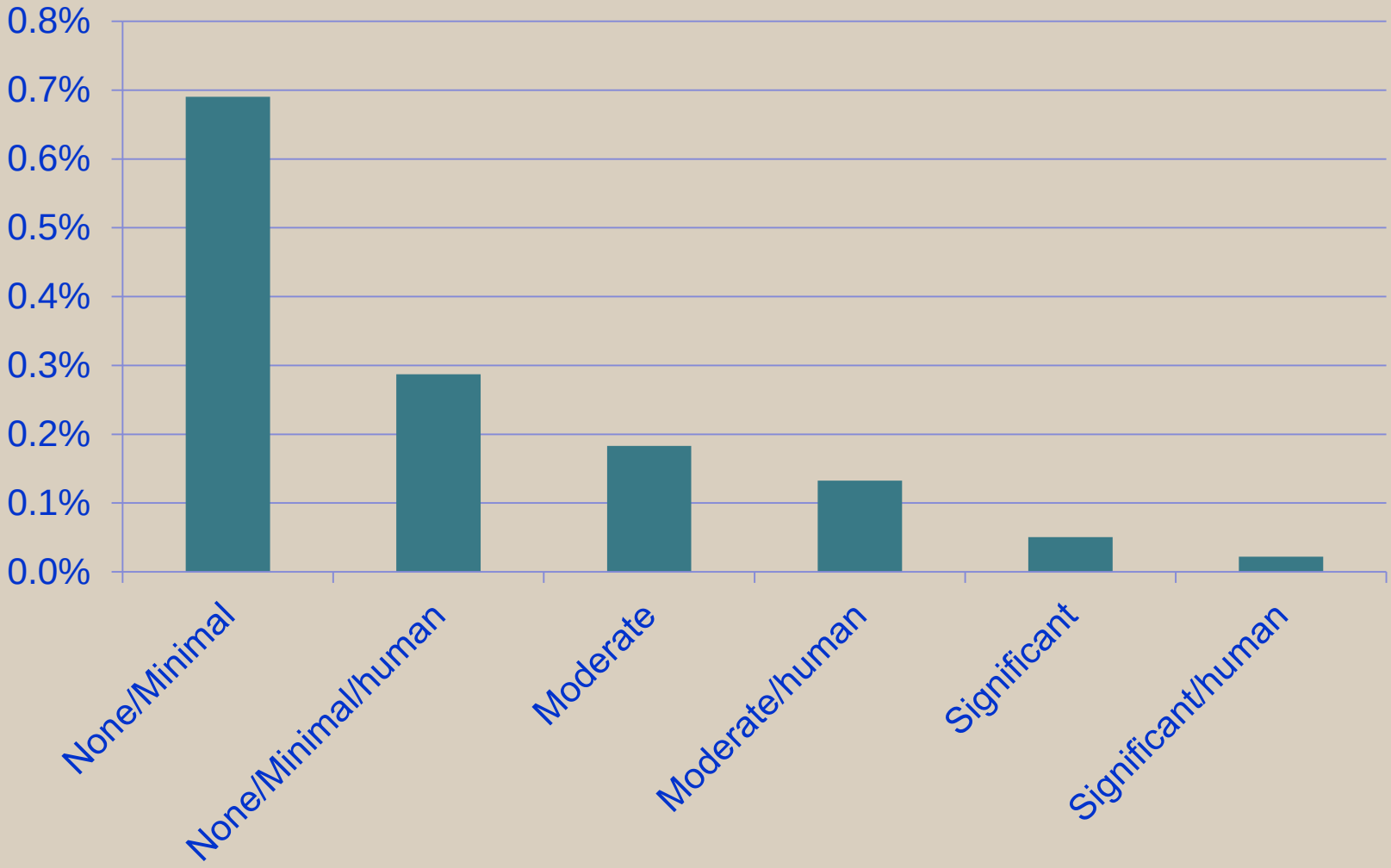
Error rate per cycle



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How do our error rates compare?

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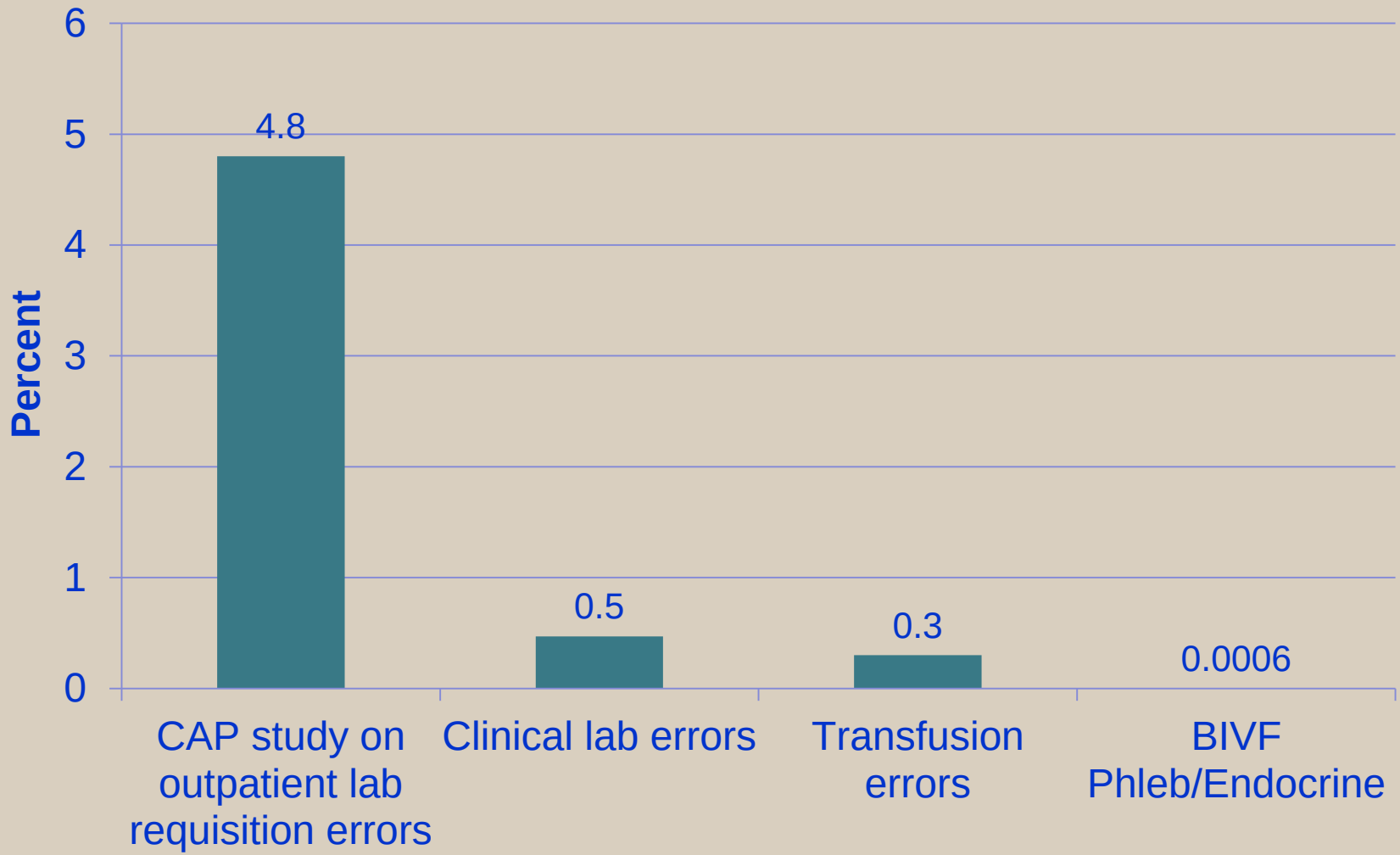
Rate of errors in clinical labs and transfusions



Clin Chem 48:691, 2002

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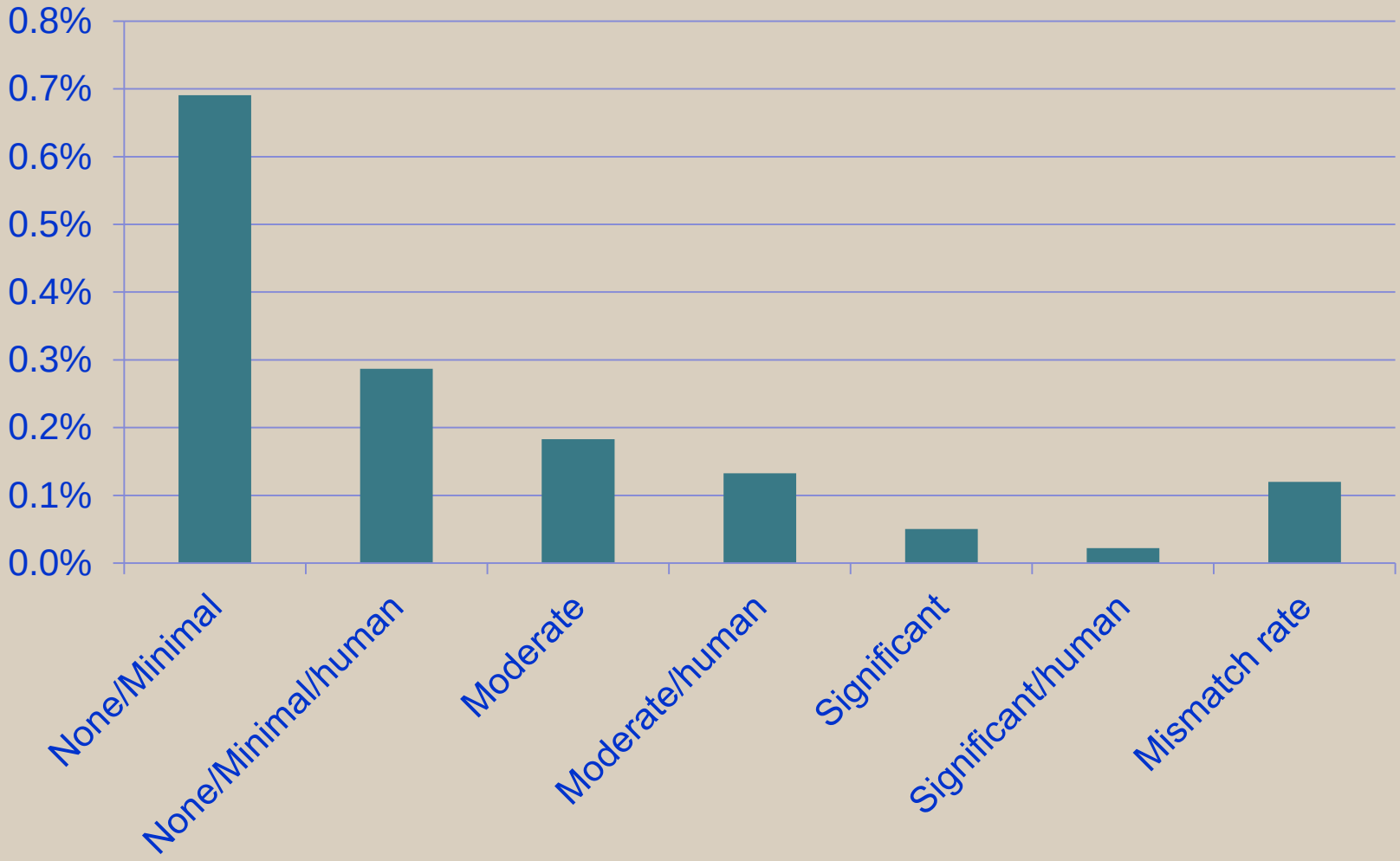
Error rate per cycle



Brunetti et al., RBM Online 24 (suppl 1): S1, 2012
Bird et al., P-001, Assoc of Clinical Embryologists, Leeds, UK, 2012

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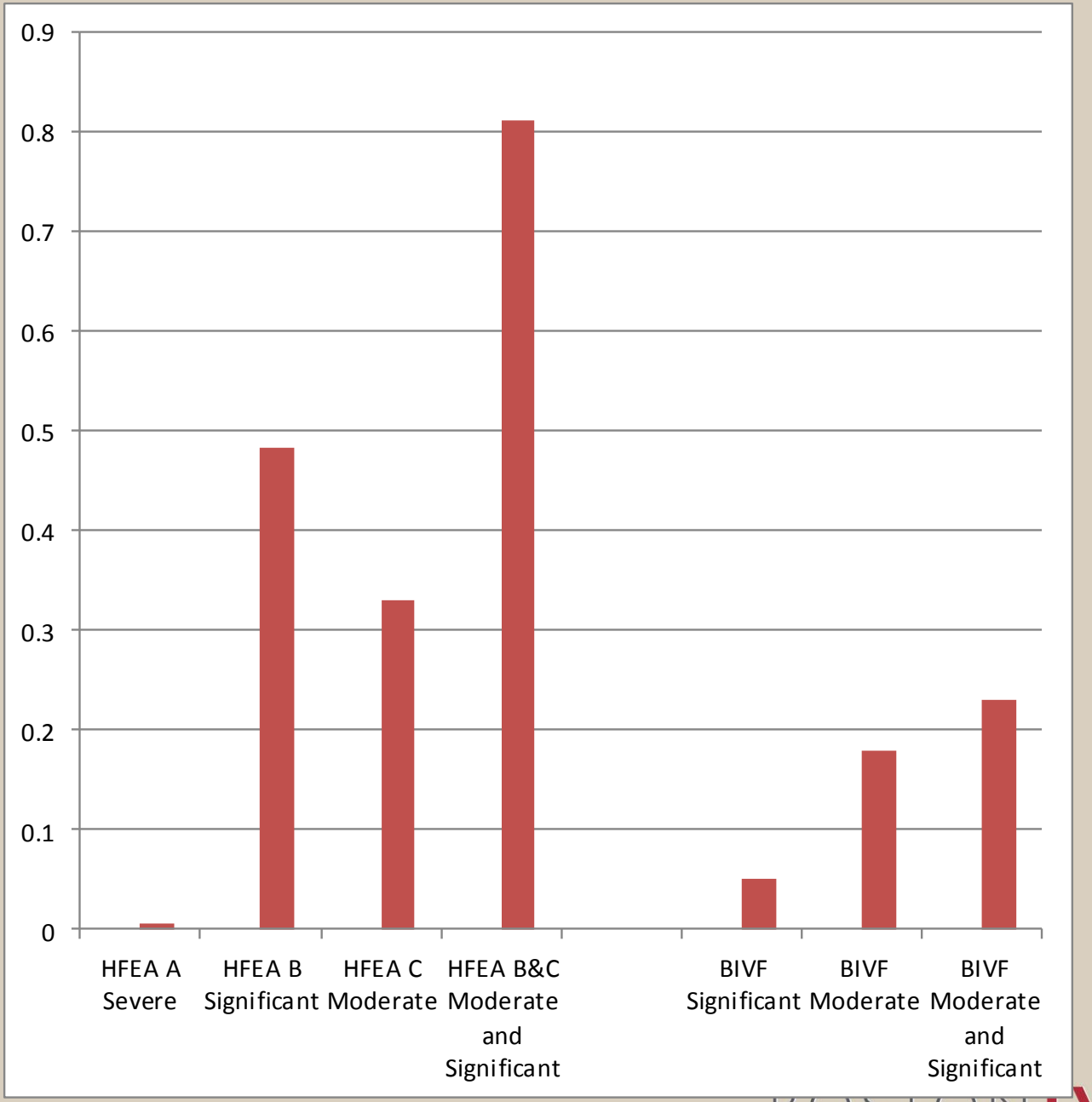

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Comparison

	Number	1 error per X cycles	Number of years for clinic with 400 cycles/yr
Moderate	58	547	1.4
Moderate/Human	42	755	1.9
Significant	16	1982	5.0
Significant/Human	7	4530	11.3

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"This report describes a serious concern in health care that, if discussed at all, is discussed only behind closed doors."

Institute of Medicine Report, 1999

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Disclosure: 2011 ASRM Ethics Committee Report

- Ethical obligation
- Errors that affect the number of quality of embryos should be disclosed
- Obligatory to disclose errors where gametes or embryos are switched
- Promote culture of truth-telling
- Write procedures for disclosure
- Rigorous procedures for proper ID and prevention of loss

Disclosure

- Difficult
  - Hard to admit mistake has been made
  - Reputation
  - Legal fears
  - Blame focused on individual, not system

Disclosure to patients

- Every situation unique
- Do we disclose every error or near-miss?
- Disclosure, Apology and Offer

“Culture of truth-telling”

- Within lab
  - Be upfront with embryologists about how errors are handled and possible consequences
  - Foster a culture of openness and honesty
  - Discuss in meetings
- Talk with physicians about errors and how to handle them

Corrective Action

- Accountability
  - Must have fair and just procedure
  - No blame where the problem stems from the system
  - Proportionate blame where procedures were violated

Procedures for identification

- HFEA – witnessing requirement
- Electronic witnessing
  - Matcher – bar codes
  - RI Witness – RFID chips

Procedures for ID

- BIVF - Witnesses for every step
  - All SA and IUI specimens witnessed
  - Wristband checks for all egg retrievals and transfers
  - Time out prior to egg retrieval
  - At time of transfer, TV monitor displays pt. name and DOB on bottom of dish to pt., nurses and physician

Minimizing errors

- Many moving parts
- Excellent Quality Management System
- ISO 9001:2008 talk tomorrow!

Final thoughts

- Errors are inevitable!
- We can ignore them or
- Use them to improve
  - Acknowledge them
  - Understand why they happened - get to the source of the problem
  - Opportunities to improve processes

Thank you!

- Dr. Denny Sakkas, Scientific Director
- Dr. Michael Alper, Medical Director
- Entire lab team at Boston IVF