ISO and Quality Management in the IVF Lab

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Disclosure

- Consultant and lab director for ReproSource Fertility Diagnostics

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

…most importantly, we must systematically design safety into processes of care.

Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. Cars are designed so that drivers cannot start them while in reverse because that prevents accidents."

Institute of Medicine Report, 1999

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ISO

- International Organization for Standardization
- Derived from the Greek word isos–equal or standard
- NGO
  - 150 countries (including the USA)
  - established in 1947 to promote the development of standardization to facilitate the international exchange of goods and services
- ISO 9001:2008 is an international quality management system

ISO Pros

- Gold standard quality management system
  - Certified to highest level
  - Will greatly increase efficiency and organization
- Reduce the chance for errors!

ISO cons

- But, it takes human and some financial resources…
  - Boston IVF experience
- If too much –
  - Look for low hanging fruit at your clinic
- ISO 15189 for lab

How do we define Quality in ART?

- SART/CDC statistics (and marketing)
- Research
- Latest Technology
- PT and inspections
- Internally
  - QC and QM, errors
  - FR, PR etc.

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ISO definition of Quality

- Degree to which a set of inherent characteristics fulfills requirements
- Characteristics
  - All that goes into making our clinics
  - Lab, physicians, nursing, billing, documents, etc.

Requirements

- Whose requirements?
  - Patients
  - Physicians
- What requirements?
  - Pregnancy
  - No mistakes
  - Respectful, efficient, etc.

Testing lab

Phase	Percent of errors
Pre-analytic	14%
Analytic	0.2%
Post-analytic	7.2%

Plebani, Clin Chim Acta 404:16, 2009

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Questions

- How is quality defined at your clinic?
- Do you think it is working well?
- What improvements would you like to make?

Overview of constituents of Quality System

- “50,000 foot view”
- Management
- Documents and records
- Service delivery
- Measurements of quality
- Audits (internal and external)
- Problems, corrective action, improvement

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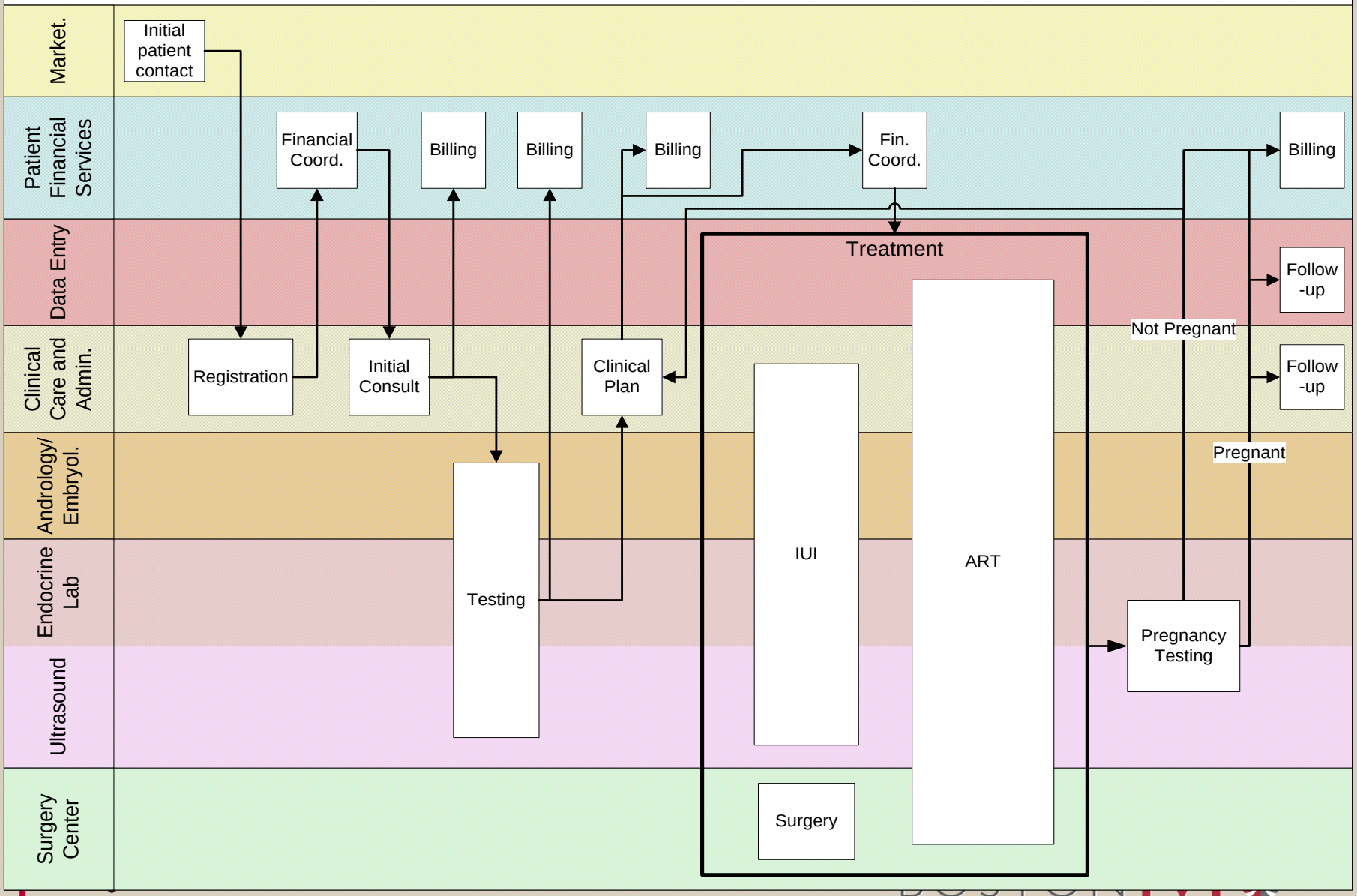
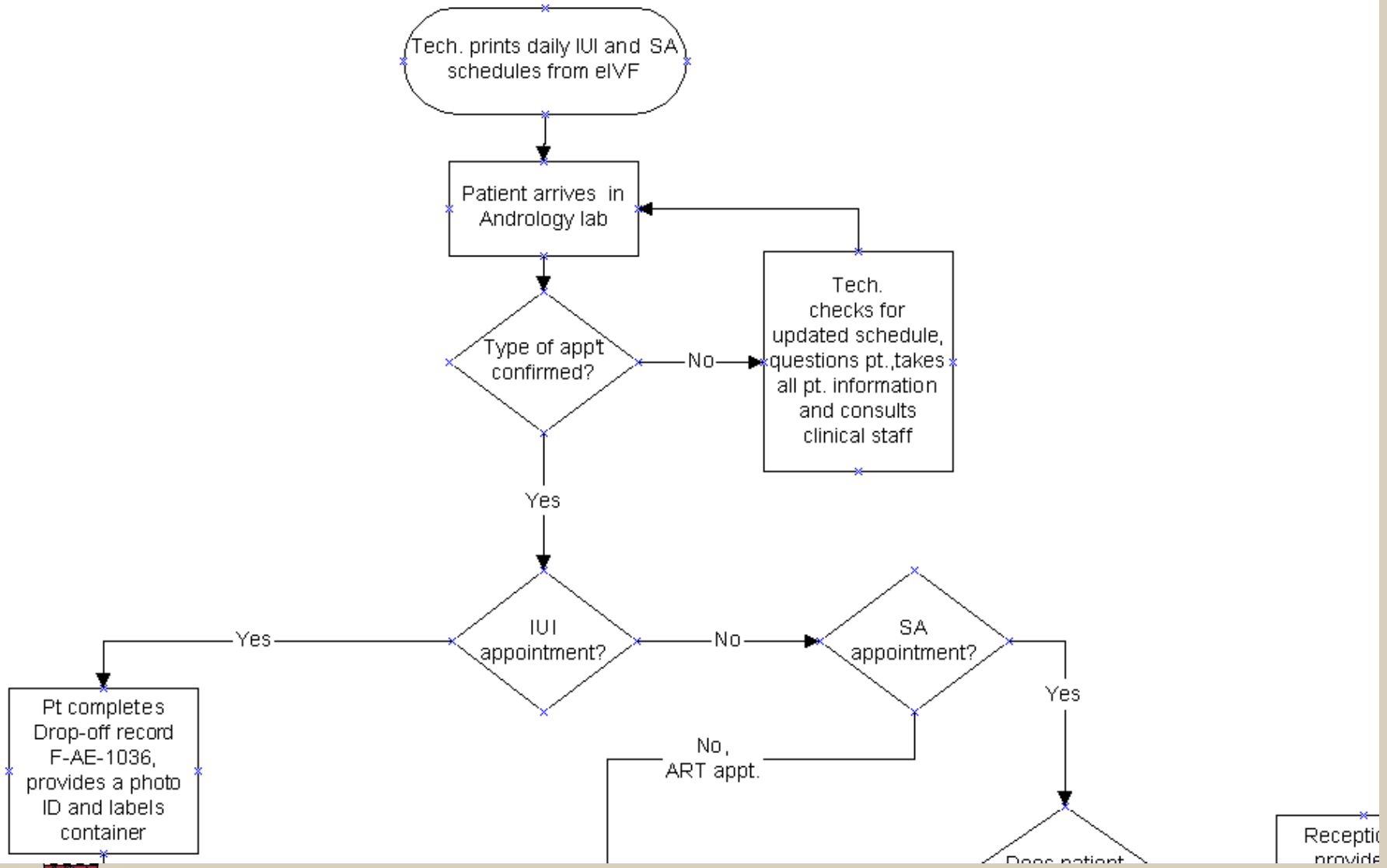
Boston IVF Workflow



Boston IVF	PROCEDURE Andrology processing	*Approved by:* *Gen.Lab.Sup*	PM-AE-A1 Revision: 2



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Management

- Before ISO: No one designated as being responsible for quality
  - Different doctors and supervisors would launch a project to fix one part of the problem, but effort was often diffuse and temporary
- After ISO:
  - Upper management ultimately responsible for implementation
  - One person (management representative) in charge of entire system which leads to greater organization, consistency and follow-through
  - Annual Management Review

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Documents

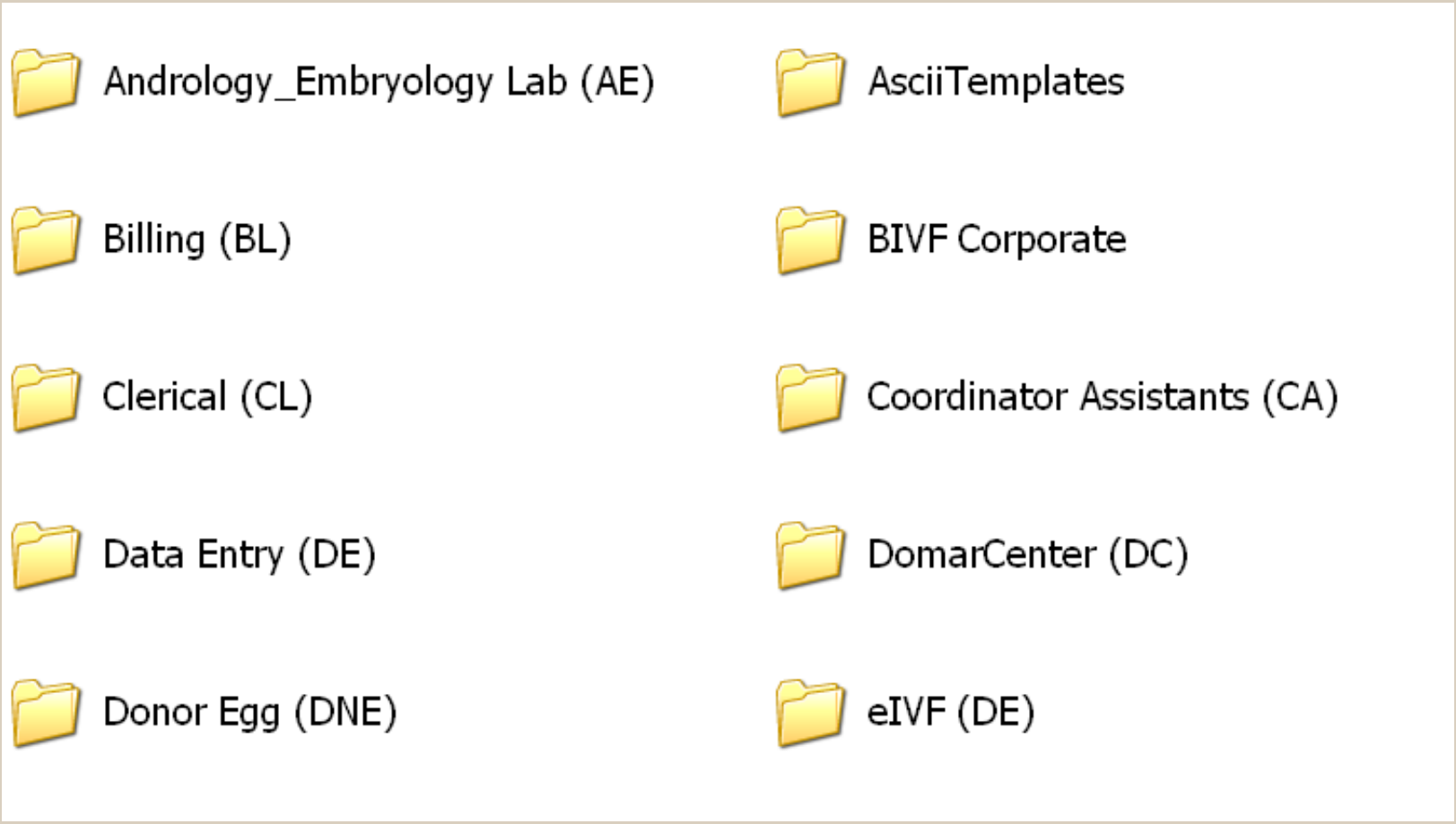
- >3000 documents
- Before ISO:
  - Multiple versions
  - Which is current revision?
  - Example: OR/PACU: some documents had 3 or 4 different versions of the same procedure on paper, different computers and floppy disks
  - Control
  - Who can revise documents?
  - Example: Nursing: physicians e-mail new instructions

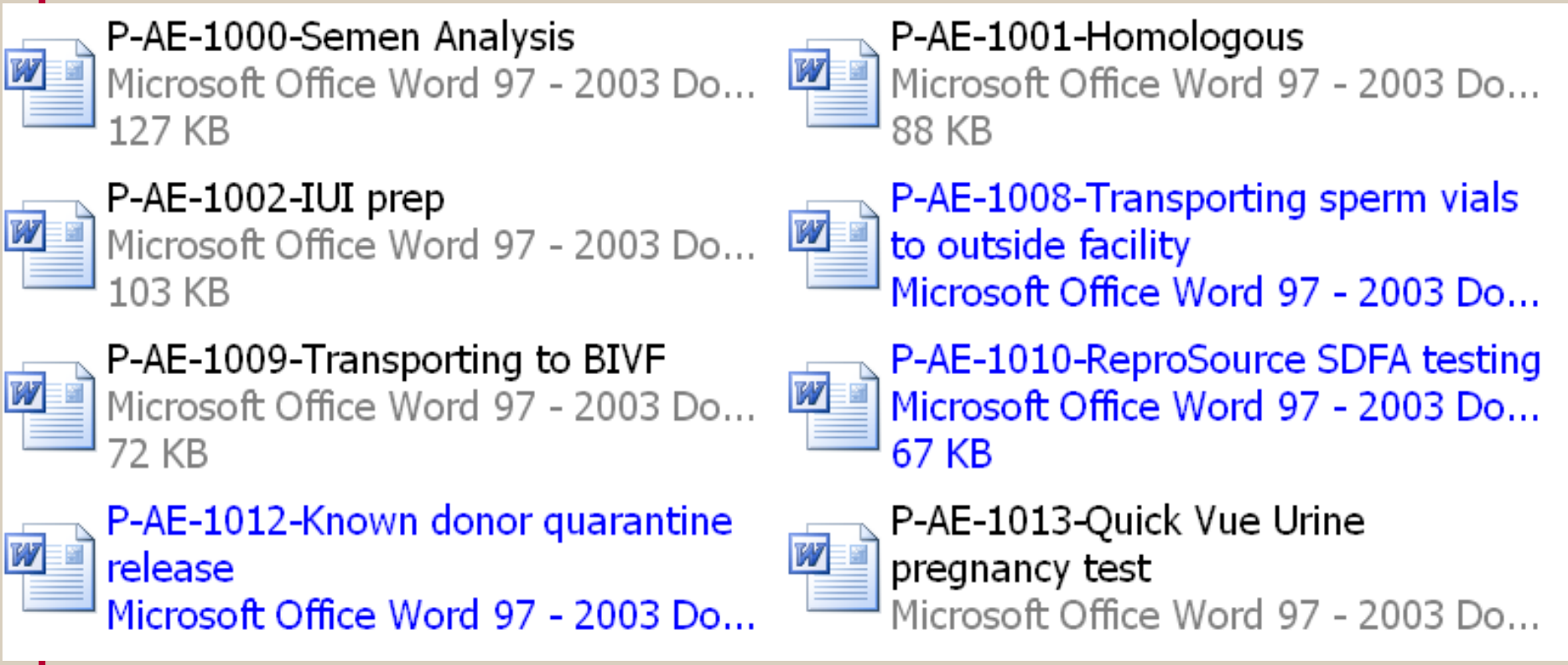
Documentation errors

- 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!!
- BIVF
  - Every record reviewed by embryologist

Types of documents

- Quality manual
- System procedures
- Procedures and Process maps
- Work instructions
- Forms
- Job descriptions


Andrology_Embryology Lab (AE)
AsciiTemplates
Billing (BL)
BIVF Corporate
Clerical (CL)
Coordinator Assistants (CA)
Data Entry (DE)
DomarCenter (DC)
Donor Egg (DNE)
eIVF (DE)



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Boston IVF	PROCEDURE *Semen Analysis*	*Approved by: And. Gen. Sup.*	P-AE-1000 Revision : 16 Page 1 of 19

Policy/Principle

A Semen Analysis is a laboratory test designed to aid physicians in diagnosing male factor infertility. The sperm are analyzed using a Makler counting chamber for count, total count, motility and rate of progression. Sperm morphology is assessed using a semen smear examination.

Responsibility

Andrologist

Procedure

EQUIPMENT AND REAGENTS

Review and Revision History

Revision Number	Authorized Signature(s)	Date	Description of change (If no changes, write N/A)
0	MCristello	11/29/06	Initial draft
1	M Ferraro	2/22/12	Updated documentation of out of protocol drop off
2	Mcristello	5/22/12	Added discrepancies and male ID
	Mcristello	2/18/13	reviewed
	Mcristello	2/13/14	Reviewed

Procedure ID	Authorized by:	Current revision
P-AE-1000-Semen Analysis	Gen.Lab.Sup.	17
P-AE-1001-Homologous freeze	Gen.Lab.Sup.	5
P-AE-1002-IUI prep	Gen.Lab.Sup.	12
P-AE-1008-Transport of sperm vials to outside facility	Gen.Lab.Sup.	3
P-AE-1009-Transport to BIVF	Gen.Lab.Sup.	2
P-AE-1010-SDFA with Reprosource	Gen.Lab.Sup.	6
P-AE-1012-Known donor vial release	Gen.Lab.Sup.	1
P-AE-1013-Quick Vue pregnancy kit	Gen.Lab.Sup.	0
P-AE-1014-Multistix urinalysis	Gen.Lab.Sup.	6
P-AE-2003-GIFT	Gen.Lab.Sup.	3
P-AE-2004-ART sperm prep	Gen.Lab.Sup.	17
P-AE-2005-TB processing	Gen.Lab.Sup.	0
P-AE-2008-ICSI	Gen.Lab.Sup.	8

Resources and Product (service) realization

- External and Internal “customer” focus
- Purchasing: approval of suppliers
- Control of monitoring and measuring devices
- Human Resources
- Quality objectives - goals

Resources and Product (service) realization

- External and Internal “customer” focus
  - External “customers” – patients, outside physicians such as urologists, state, CDC, etc.
  - Internal “customers” – physicians, nurses, supervisors, other departments, etc.

Figure 1a: Intent to Refer Outcome

I would refer a friend or family member to Boston IVF. (Q96)

Number of respondents = 536
Average = 9.2
Standard deviation = 1.8

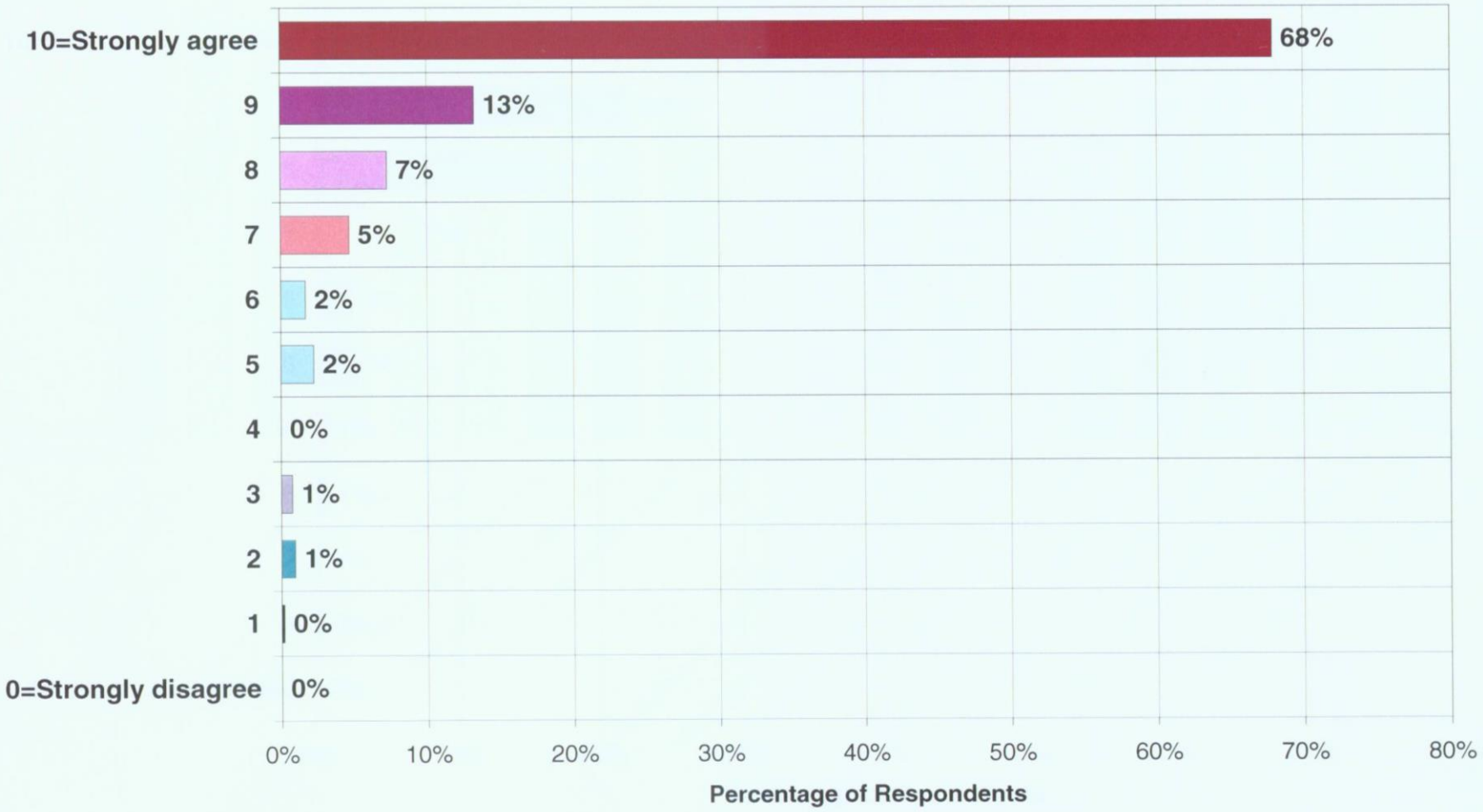

Figure 2: Factors in the care delivery environment

This chart shows respondents ratings of various aspects of the environment in which they receive care at Boston IVF. Higher average ratings are desirable.

Resources and Product (service) realization

- Purchasing: approval of suppliers

Vendor	Date of initial use	Method of approval	Approved by
Alert Scientific	<2004	service performance/cost	lab director
Advanced instruments	<2004	service performance	lab director
American Health	<2004	service performance	lab director
Bayer HealthCare, LLC.	<2004	QC of products	lab director
BeaconMedaes	<2004	service performance/cost	lab director
Billups-Rothenberg Inc.	<2004		lab director
Boc Gases	<2004	availability of service	lab director
Brooklyn Tool, Inc.	<2004	specific product manufactering	lab director
B & D	<2004	specific product manufactering	lab director
Caley & Whitmore	<2004	reputation, recommendation	lab director
Calibrate, Inc.	<2004	reputation, recommendation	lab director
Cardinal Health-Medical	<2004	cost/QC of products	lab director
CEA Instruments, Inc.	<2004	availability of service	lab director
Cooper Surgical	<2004	QC of products	lab director
Dade Behring, Inc./Siemans	<2004	QC of products	lab director
DSC Optical Services, Inc.	<2004	reputation, recommendation	lab director
Embryotech Laboratories, Inc.	<2004	reputation, recommendation	lab director

Resources and Product (service) realization

- Control of monitoring and measuring devices
  - Calibration of CO_2 and O_2 monitors
  - NIST traceable calibration thermometers

Resources and Product (service) realization

- Human Resources

Current ASRM Recommendations

# of lab cycles	Minimum # embryologists
1-150	2
151-300	3
301-600	4
>600	1 additional embryologist per additional 200 cycles

High-performing IVF center staffing

(Van Voorhis et al., Fert Steril 94:1346, 2010)

Personnel Category (1 FTE per # cycles)	Average # IVF cycles per year (fresh & frozen)
Physicians	173
Registered nurses	114
Nurses plus other nursing categories	52
Sonographers	198
Lab (embryologists and andrologists)	127

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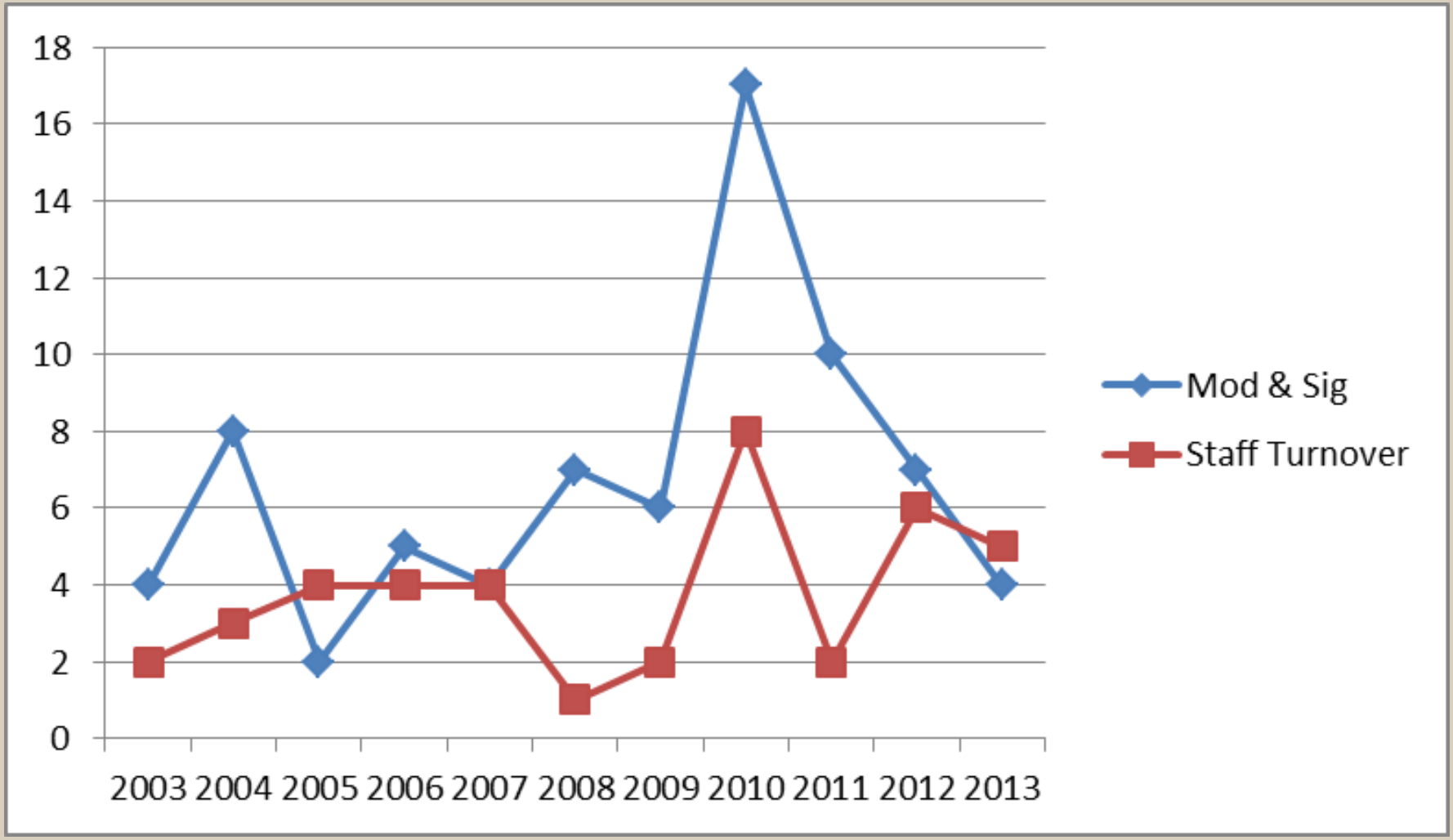
Number of embryologists/andrologists

Number of cycles	ASRM (minimum #)	High performing labs
250	3	2
500	4	4
1000	6	8
1500	9	12
2000	11	16
3000	16	24



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Monitoring Embryologist competency

		UT scientist							
Q110-Q410	Q210-Q111	Q310-Q211	Q410-Q311	Q111-Q411	Q211-Q112	Q311-Q212	Q411-Q312	Q112-Q412	N
39.8	39.1	39.2	40.2	41.1	40.3	40.7	43.1	44.7	2798
2.2	1.1	-5.5	-6.9	1.5	-1.8	5.1	9.8	0	76
-0.4	-2	-5.1	-6.1	-3.5	0.5	1	-1.2	-5.2	162
-1.4	-0.6	0.7	1.5	-1.9	1.3	-0.5	-2.1	-3.6	90
0.9	0.8	2.8	4	6.9	9.7	3.5	2	2.7	78
0.8	0.5	1.5	2.6	1.8	5.2	5.3	8.8	6.9	128
-7.2	-3.2	-4.1	-3.2	0.6	4.5	9.6	9.8	7.8	238
4.1	0.6	-6.7	-7.2	-6.2	-1.6	2.5	2.1	5.3	138
-0.7	2	6	5.1	4.3	-1	-3.7	-5.7	-8.3	88
-2.6	0.1	3.3	5.1	6.3	4.8	-1.3	-2	-0.2	137
0.3	1.7	6.8	2.3	1.6	1.8	-1.3	2.4	5	157
-0.2	1.1	2.7	3.8	5.4	6	5.9	4.8	3.9	185
-9.9	-5.6	-4.1	-1.8	2.1	5.5	6.3	1.8	0.7	229
			0.7	-1.6	-2.7	-2.7	-4.7	-2.6	318
					-8.2	-2.4	1.1	1.4	310
								-1.6	65
						26	11.8	10.2	51

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Staffing

- Be careful who you hire
- Be open about mistakes and describe lab policy
- Monitor for technical proficiency
- Counsel when needed
- Monitor mistakes and let go when needed, each situation is unique

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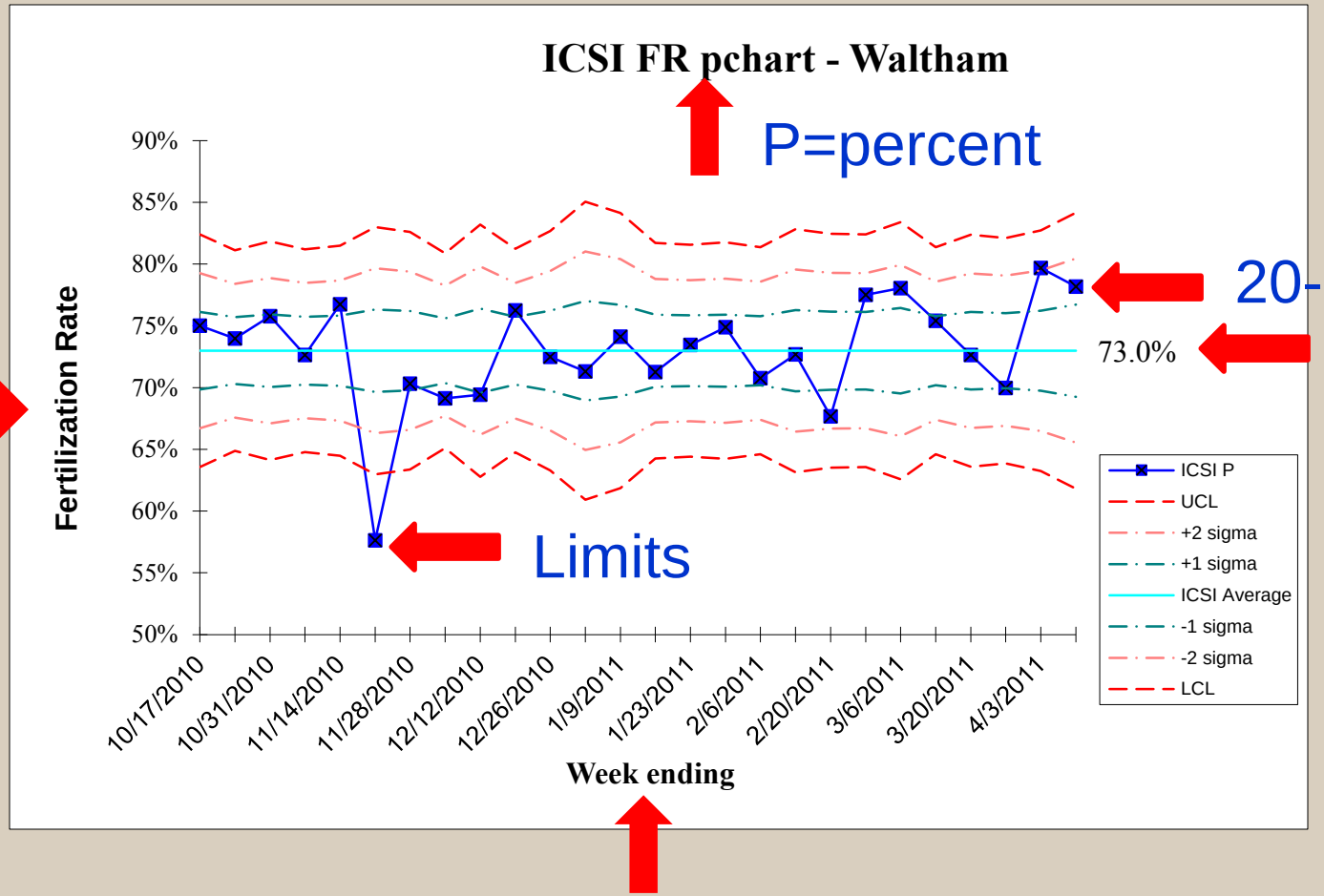
Resources and Product (service) realization

- Quality objectives - goals

#	Quality Indicator	Quality Objective	Measurement Tool	Report interval	Report by Report to
	General				
1	Technician Competency	in range values for 4 Q	Individual Statistical Analysis	Quarterly	Data coordinator Lab director
2	Process Monitoring	Compliance with the quality system	Nonconformance reports	Quarterly	Employee Lab manager/director
3	Lab Administration And/Emb.	<5 errors per category with record keeping	Logic checks Database audits	Monthly	Lab QI supervisor
	Andrology				
4	QC program	External PT results within agency guidelines	CAP and AAB PT events	Biannual	Lab QI supervisor
5	Daily QC review	100% in range values	Daily QC worksheets	Monthly	Lab supervisor
6	SA paperwork review	100% accuracy	Daily SA worksheets	Monthly	lab supervisor
	Embryology				
7	Outcome Measures	Maintain FR, embryo development, PR, thaw rate, incubator PR, etc.	pChart, rolling average	Weekly-quartlerly	Lab QI supervisor
8	QC program	All bioassay tests pass	Mouse QC bioassay	As needed	Lab supervisor

Monitoring and measurement of performance

- Quality Objectives
  - By department
  - Customer satisfaction
  - Fertilization rates, pregnancy rates, etc.



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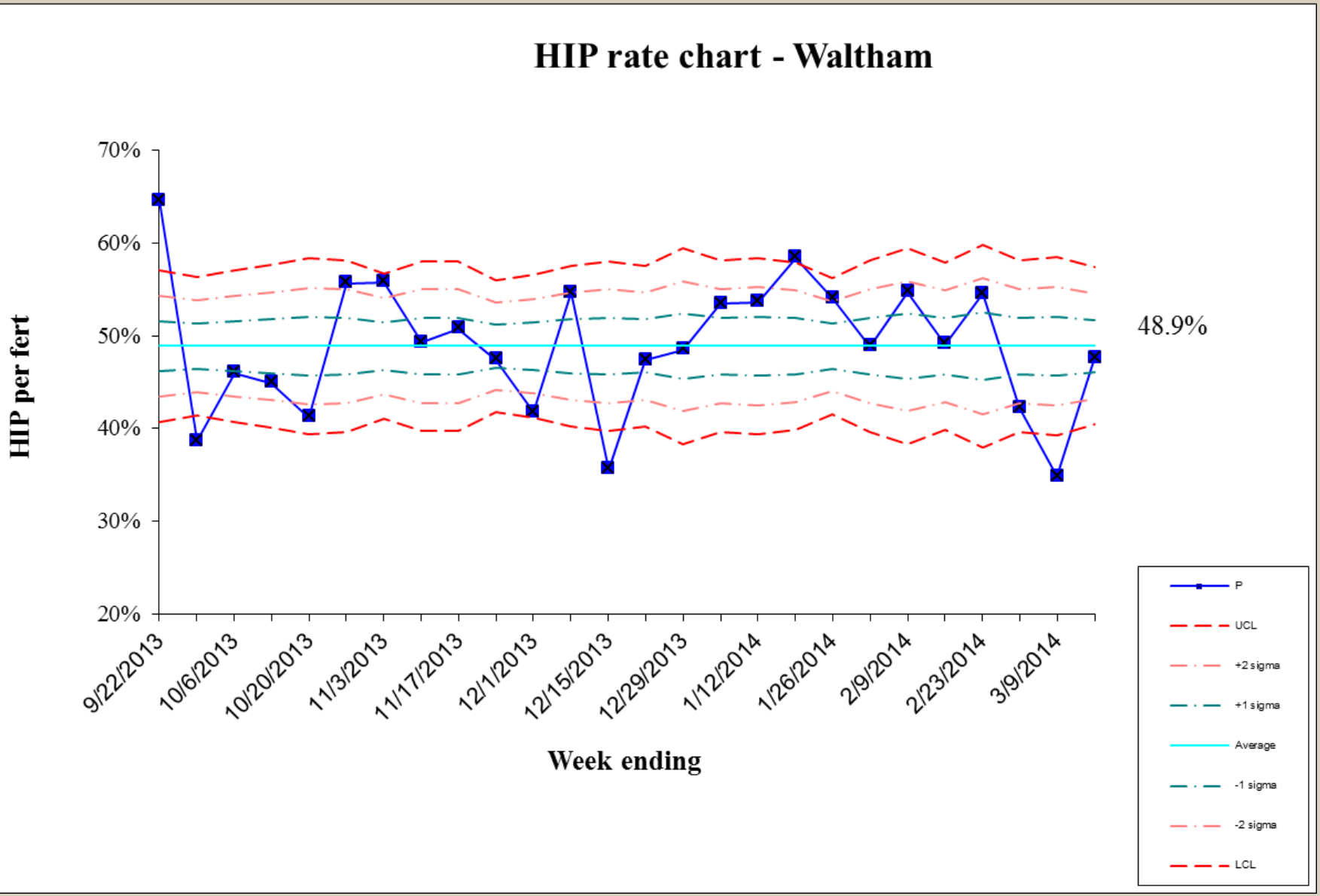
HIP rate chart - Waltham
HIP per fert
70%
60%
50%
40%
30%
20%
9/22/2013
10/6/2013
10/20/2013
11/3/2013
11/17/2013
12/1/2013
12/15/2013
12/29/2013
1/12/2014
1/26/2014
2/9/2014
2/23/2014
3/9/2014
Week ending
48.9%
P
UCL
+2 sigma
+1 sigma
Average
-1 sigma
-2 sigma
LCL

Monitoring and measurement of performance – internal audits

- Ensure that Boston IVF conforms to ISO 9001 standard, to our own requirements and is effectively implemented and maintained
- Internal auditor committee
- Employees trained to monitor quality
- Internal auditors assess other departments and have a chance to learn about other parts of the company

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Internal audits

- Performed on an on-going basis
- Employees trained to perform audits
- Benefits
  - Employees get to know all parts of company
  - Identify employees who have an interest in quality
  - Create a group to assist MR in maintaining quality

Boston IVF ISO 9001:2008 Internal Audit Report©

Audit Information

Audit number: 342

Date of audit: 2/16/2012

Department audited: Andrology/Embryology

Center: Waltham

Auditor 1 (team leader): Marianne Cristello

Auditor 2:

Name of supervisor who received report:

ISO 9001:2000 Sections Audited

- ☒ Document control (4.2.3)
- ☒ Record control (4.2.4)
- ☒ Quality Policy (5.3)
- ☒ Quality objectives (5.4.1, 8.2.3, 8.2.4, 8.5.1))
- ☒ Job descriptions: responsibility and authority (5.5.1)
- ☒ Provision of resources, infrastructure, work environment (6.1, 6.3, 6.4)
- ☒ Human resources: competence, awareness, training (6.2.2)
- ☒ Planning of product realization: process maps, documents, records (7.1)
- ☒ Customer related processes: consents, flow sheets, communication, etc. (7.2)
- ☒ Purchasing (7.4)
- ☒ Service provision: procedures, validation, etc. (7.5)
- ☒ Monitoring and measuring devices (7.6)

Process maps and processes audited	Documents audited	Records audited	Quality objectives audited
all 7	all 274		All

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Audit Information

Audit number	119		
Date of audit	4/2/2004	**Department audited**	IVF Nursing
Center	Waltham		
Auditor 1 (team leader)	Marianne Cristello	**Auditor 2**	
Name of supervisor who received report	Sharon Edwards		

ISO 9001:2000 Sections Audited

Section 1	7.1 Planning of product realization	**Section 2**	
Section 3		**Section 4**	

Scope of audit

Describe **specifically** what you audited (e.g. a process map, quality objective, documents etc.). Be sure to name the documents audited and, if only a portion of a process or document was completed, describe what was completed.

3 areas of nursing were reviewed.

1. work flow for lab results
2. review of patient charts
3. new patient visits

Donna-KLT, Francesca-ASP, Kris-float, Maureen-MMA, Heidi-MJB and Susan RHR were all contacted and each described their work flow.

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Positive Observations

All centers followed the same procedures for New patient visits. All took a brief history, vitals, height, weight....
All lab results were reviewed and signed by a MD and nurses were able to review the patient charts at some point prior to the appointment

Opportunities for Improvement

Minor, isolated problems that are found during the course of the audit. Examples would include finding a single form that is not in the Master List, a missing authorization on a document or an incorrect process on a process map. A number of findings in the same area would constute a nonconformance.

There were variations between the team with regards to the use of the patient studies form, who pulls the patients charts and when and how the MD communicates the results of a new patient visit and which tests are to be ordered. Some of

Monitoring and measurement of performance

- External audits
  - Conducted by outside organization which is regulated by ISO
  - Annual audit with full audit every 3 years
  - Generally 2 days and all locations are visited

Improvement – control of nonconforming product

- Before ISO:
  - No clear, company-wide guidelines for reporting problems
  - Some problems would get reported to a specific doctor, others would go to a supervisor
  - Often no record of problem, no way to trend problems, no follow-up
- After ISO:
  - Company-wide nonconformance procedure and database
  - Provides a simple, uniform means for reporting problems to the appropriate supervisor, following trends and ensuring that follow-up occurs

Nonconformance database

- 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

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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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Serious or recurring problems: Corrective Action

- Serious or recurring problems require corrective action
- A plan is documented, implemented and an audit is conducted following implementation

Corrective Action

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

Preventive Action

- How can we improve the system?
- “Suggestion box”
- For use when there is not a nonconformance – it is designed to prevent nonconformances

ISO 9001:2008 Summary

- **One quality manager** over entire system
- **Documents and records** are controlled, organized and available
- **Equipment** properly maintained
- **Measurements** of quality
- **Audits** (internal and external)
- Dealing effectively with **problems**

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Thank you!

- Denny Sakkas and Michael Alper
- All embryologists, andrologists and med techs at Boston IVF

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