ISO and Quality Management in the IVF Lab

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Laboratory Director Boston IVF
Disclosure

• Consultant and lab director for ReproSource Fertility Diagnostics
“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
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.
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

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<th>Phase</th>
<th>Percent of errors</th>
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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
PROCEDURE
Andrology processing

Tech. prints daily IUI and SA schedules from eIVF

Patient arrives in Andrology lab

Type of appt confirmed?

Tech. checks for updated schedule, questions pt., takes all pt. information and consults clinical staff

Yes

IUI appointment?

Pt. completes Drop-off record F-AE-1036, provides a photo ID and labels container

No

SA appointment?

No, ART appt.

Yes

Does patient provide?
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
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
<table>
<thead>
<tr>
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<tr>
<td>Andrology_Embryology Lab (AE)</td>
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<td>Clerical (CL)</td>
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<td>DomarCenter (DC)</td>
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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
WORK INSTRUCTION

Out of protocol specimen drop off and verification

Review and Revision History

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<tr>
<th>Revision Number</th>
<th>Authorized Signature(s)</th>
<th>Date</th>
<th>Description of change (If no changes, write N/A)</th>
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<td>2/22/12</td>
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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

10=Strongly agree 68%
9 13%
8 7%
7 5%
6 2%
5 2%
4 0%
3 1%
2 1%
1 0%
0=Strongly disagree 0%
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
<table>
<thead>
<tr>
<th>Vendor</th>
<th>Date of initial use</th>
<th>Method of approval</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>Alert Scientific</td>
<td>&lt;2004</td>
<td>service performance/cost</td>
<td>lab director</td>
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<tr>
<td>Advanced instruments</td>
<td>&lt;2004</td>
<td>service performance</td>
<td>lab director</td>
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<td>American Health</td>
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<td>lab director</td>
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<td>&lt;2004</td>
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<td>lab director</td>
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<td>BeaconMedaes</td>
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<td>Billups-Rothenberg Inc.</td>
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<td></td>
<td>lab director</td>
</tr>
<tr>
<td>Boc Gases</td>
<td>&lt;2004</td>
<td>availability of service</td>
<td>lab director</td>
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<tr>
<td>Brooklyn Tool, Inc.</td>
<td>&lt;2004</td>
<td>specific product manufacturing</td>
<td>lab director</td>
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<td>Embryotech Laboratories, Inc.</td>
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<td>lab director</td>
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Resources and Product (service) realization

- Control of monitoring and measuring devices
  - Calibration of CO\textsubscript{2} and O\textsubscript{2} monitors
  - NIST traceable calibration thermometers
Resources and Product (service) realization

• Human Resources
# Current ASRM Recommendations

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<th># of lab cycles</th>
<th>Minimum # embryologists</th>
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<td>1-150</td>
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<td>151-300</td>
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<td>301-600</td>
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<td>&gt;600</td>
<td>1 additional embryologist per additional 200 cycles</td>
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## High-performing IVF center staffing
(Van Voorhis et al., Fert Steril 94:1346, 2010)

<table>
<thead>
<tr>
<th>Personnel Category</th>
<th>Average # IVF cycles per year (fresh &amp; frozen)</th>
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<tr>
<td>Physicians</td>
<td>173</td>
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<tr>
<td>Registered nurses</td>
<td>114</td>
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<tr>
<td>Nurses plus other nursing categories</td>
<td>52</td>
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<tr>
<td>Sonographers</td>
<td>198</td>
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<tr>
<td>Lab (embryologists and andrologists)</td>
<td>127</td>
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### Number of embryologists/andrologists

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<th>Number of cycles</th>
<th>ASRM (minimum #)</th>
<th>High performing labs</th>
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### Monitoring Embryologist competency

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<th>UT scientist</th>
<th>Q110-Q410</th>
<th>Q210-Q111</th>
<th>Q310-Q211</th>
<th>Q410-Q311</th>
<th>Q111-Q411</th>
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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
Resources and Product (service) realization

• Quality objectives - goals
<table>
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<tr>
<th>#</th>
<th>Quality Indicator</th>
<th>Quality Objective</th>
<th>Measurement Tool</th>
<th>Report interval</th>
<th>Report by Report to</th>
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<td>Technician Competency</td>
<td>in range values for 4 Q</td>
<td>Individual Statistical Analysis</td>
<td>Quarterly</td>
<td>Data coordinator Lab director</td>
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<td>Process Monitoring</td>
<td>Compliance with the quality system</td>
<td>Nonconformance reports</td>
<td>Quarterly</td>
<td>Employee Lab manager/director</td>
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<td>&lt;5 errors per category with record keeping</td>
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<td>Monthly</td>
<td>Lab QI supervisor</td>
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<td>4</td>
<td>QC program</td>
<td>External PT results within agency guidelines</td>
<td>CAP and AAB PT events</td>
<td>Biannual</td>
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<td>5</td>
<td>Daily QC review</td>
<td>100% in range values</td>
<td>Daily QC worksheets</td>
<td>Monthly</td>
<td>Lab supervisor</td>
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<td>6</td>
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<td>100% accuracy</td>
<td>Daily SA worksheets</td>
<td>Monthly</td>
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<tr>
<td>7</td>
<td>Outcome Measures</td>
<td>Maintain FR, embryo development, PR, thaw rate, incubator PR, etc.</td>
<td>pChart, rolling average</td>
<td>Weekly-quarterly</td>
<td>Lab QI supervisor</td>
</tr>
<tr>
<td>8</td>
<td>QC program</td>
<td>All bioassay tests pass</td>
<td>Mouse QC bioassay</td>
<td>As needed</td>
<td>Lab supervisor</td>
</tr>
</tbody>
</table>
Monitoring and measurement of performance

- Quality Objectives
  - By department
  - Customer satisfaction
  - Fertilization rates, pregnancy rates, etc.
ICSI FR pchart - Waltham

Fertilization Rate

Week ending

Limits

20-30 points

Mean and 3 sigma

P=percent

73.0%

ICSI P
UCL
+2 sigma
+1 sigma
ICSI 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
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
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: all 7
Documents audited: all 274
Records audited:
Quality objectives audited: All
Audit Information

Audit number: 119
Date of audit: 4/2/2004
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.
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 constitute 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
<table>
<thead>
<tr>
<th>Type of nonconformance</th>
<th>Document problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of occurrence</td>
<td>09/09/2013</td>
</tr>
<tr>
<td>Supervisor</td>
<td>Brent Barrett</td>
</tr>
<tr>
<td>Department Head</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td>Andrology/Embryology</td>
</tr>
</tbody>
</table>

**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.
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
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
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
Thank you!

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