Quality Management in a Small Public Health Laboratory: All Hands on Deck!

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Disclosures

No conflicts-of-interests, hidden financial transactions, clandestine deals with rogue nations, or anything remotely interesting to disclose.

In a not-so-subtle attempt at humor, there will be references to the animated feature-length film “Despicable Me 2” which is owned and trademarked by Universal Studios Hollywood.
Objectives

1. Provide an overview of the South Dakota Public Health Laboratory.

2. Define the quality management needs of the SDPHL.

3. Review of strategies used to ensure quality management in our small public health laboratory.

4. Data-driven analysis of quality management strategies at the SDPHL and a vision for the future.
SDPHL Fun Facts

Fee-for-service state public health laboratory
- 55% of budget from laboratory fees
- 45% of budget from federal cooperative agreements

Centrally located in Pierre, South Dakota
- Predominantly rural state with ~865,000 residents
- 5\textsuperscript{th} lowest nationwide in population and population density
- 8.8% of population is Native American (3\textsuperscript{rd} in US)
- Member of the Northern Plains Consortium
Northern Plains Consortium

• Network of public health laboratories in Idaho, Montana, North Dakota, South Dakota, and Wyoming

• Common public health challenges
  – Large geographical area
  – Predominantly rural
  – Few cities
  – Limited budgets
  – PHL staff few in number
Quality Management Questions

1. How do we ensure quality management with diverse needs for each diagnostic section?
   • Medical Microbiology = CLIA
   • Environmental Chemistry = EPA
   • Forensic Chemistry = ISO17025 (2018)

2. How do we ensure quality management with such a lean staff?

3. Should we consolidate QM duties to one laboratorian – a single, laboratory-wide Quality Manager?

4. Should we delegate QM duties among lab staff – a Quality Manager for each diagnostic section?
Quality Management at the SDPHL

❌ 1 Quality manager for the entire laboratory
   The QM must know CLIA, EPA, and ISO17025

✔️ 1 Quality Manager in each diagnostic section
   Each QM must know subject matter-specific regulations
   Responsibility/authority is consolidated to each section QM

✔️ No Quality Manager but lots of quality management minions
   Spread QM “love” among numerous laboratory staff
   No centralized expertise or authority
   Responsibility is delegated to numerous staff
CLIA and A Tale of Two Strategies: Delegated Quality Management

**Scenario**
- 2013-2015
- One year without a Laboratory Director
- CLIA Director maintained monthly visits
- No CLIA Quality Manager
- But...1 microbiologist with CLIA expertise

**SDPHL CLIA Team**
- Interim Director
- CLIA Director
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- Medical Microbiology
  - Support Services
- Environmental Chemistry

**CLIA Minion**

[South Dakota Department of Health logo]
Realities of Delegated Quality Management

The Upside:
• Many hands make for lighter work
• Collective experience can be an asset
• The potential for higher level of staff engagement

The Downside:
• Multiple interpretations of regulations
• Everyone is in charge so no one is in charge
• No defined leadership to guide QM activities
• No real authority to ensure QM activities

Average Day at the Lab

Then CLIA shows up...
CLIA and A Tale of Two Strategies: Consolidated Quality Management

Scenario

- 2015-2017
- Very new, very nervous Laboratory Director
- CLIA Director maintained monthly visits
- Quality Manager in-place with staff support and Laboratory Director oversight

SDPHL CLIA Team

- Technical Director (Gru)
- CLIA Director
- CLIA Quality Mgr (Dr. Nefario)
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- CLIA Minion
- Medical Microbiology Support Services
- Environmental Chemistry

CLIA Quality Manager

Director
Realities of Consolidated Quality Management

The Upside:
• Single point-of-contact and go-to for CLIA questions
• Promotes a single interpretation of regulations
• Provides some degree of authority to ensure QM activities
• Promotes consistency

The Downside:
• Significant responsibility in addition to daily testing duties
• Requires cross-discipline knowledge
• Over-consolidation of expertise

<table>
<thead>
<tr>
<th>CLIA Deficiencies</th>
<th>Corrective Action Summary</th>
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<tbody>
<tr>
<td>Failed to properly document corrective action for unsatisfactory proficiency test result.</td>
<td>1. More thorough documentation to include corrective action will be performed in the event of an unsatisfactory proficiency test result.</td>
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<td></td>
<td>2. Technical Supervisor and CLIA Director will review documentation and provide oversight to the proficiency testing corrective action process.</td>
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<td>Failed to perform biannual method comparison study on the 3 Applied Biosystems Instruments (ABI) for pertussis, norovirus, influenza, measles, and mumps.</td>
<td>Comparison studies were performed for pertussis, norovirus, and measles, the only testing performed on multiple ABI.</td>
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*Ten recommendations to include: update virology manual, remove procedures from manuals that are no longer in use, standardize biosafety procedures, update package inserts, clarify specific duties of CLIA Director, Technical Supervisors, General Supervisors, ensure competencies and proficiencies are signed by testing personnel, Technical Supervisor, and CLIA Director, etc.*
# Outcomes-Based Analysis:
Consolidated Quality Management (2015-2017)

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<td>Ensure quality control logs, competency and calibration results, and proficiency</td>
<td>1. Counsel CLIA Director to not sign incomplete documents; relevant documentation must be signed by testing personnel and Technical Supervisor <strong>before</strong> CLIA Director signature.</td>
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<td>attestations are signed by the testing personnel, a Technical Supervisor other than</td>
<td>2. Perform section-wide retraining.</td>
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<td>the testing personnel, and CLIA Director.</td>
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<td>Ensure expired controls are not used for serology testing.</td>
<td>1. Serology analyzer software upgraded to recognize and reject expired controls before testing of patient specimens.</td>
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<td>2. Controls are discarded upon reaching expiration date.</td>
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<td>Maintain a weekly log to indicate bleach solution is made fresh each week in the PCR suite.</td>
<td>Appoint 1 laboratorian to maintain weekly bleach log in the PCR suite.</td>
</tr>
</tbody>
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*No Recommendations from the 2017 inspection*
Summary and Interpretation

2013-2015: Delegated Quality Management
- One administrative deficiency
- One science deficiency
- Multiple recommendations regarding administration of CLIA regulated testing
- Good staff morale but room for improvement

2015-2017: Consolidated Quality Management
- Several administrative deficiencies (see 2013-2015 RECOMMENDATIONS!!)
- Two science deficiencies
- No recommendations
- Improved staff morale

Which approach will the SDPHL use moving forward?
SDPHL Quality Management Vision

Based on our CLIA experiences, the SDPHL is establishing a Quality Manager in each diagnostic section. Each QM will be responsible for regulatory requirements in that section and will have the authority to ensure QM activities are performed. At this time, the SDPHL has no plan for a single Quality Manager to meet all quality management needs of the laboratory.
In Review:

1. The SDPHL is a centrally located public health laboratory that performs medical microbiology, environmental chemistry, and forensic chemistry testing.

2. The SDPHL does not have a Quality Manager.

3. The SDPHL has used several strategies to meet quality management needs including both delegation and consolidation of QM duties.

4. Data (albeit minimal), but more importantly staff morale, indicate that each SDPHL diagnostic section needs a Quality Manager to oversee section-specific regulations.
Many thanks to...

Laurie Gregg CLIA Quality Manager

All the SDPHL CLIA Minions
CLIA Top Ten Deficiencies

#10: Maintenance and Function Checks
→ Maintenance must be performed as defined by the manufacturer and at least at the recommended frequency

#9: Calibration and Calibration Verification
→ Must be performed and documented at the recommended intervals

#8: Test Systems, Equipment, Instruments, Reagents, Material, & Supplies
→ Reagents cannot exceed expiration date or be of substandard quality

#7: Test Systems, Equipment, Instruments, Reagents, Material, & Supplies
→ Test systems must be used according to stated performance specifications

Taken From: CLIA Update 2016: Top Ten CLIA Deficiencies
Nancy Grove and Kristine Rotzoll, State Hygienic Laboratory of Iowa
http://webinars.aphl.org/session-handouts.php?id=17097
CLIA Top Ten Deficiencies

#6: Personnel Assessment Policies
→ Laboratories must establish and follow written policies and procedures to evaluate employee competency

#5: Test Report
→ Must include positive patient identifiers, name and address of the laboratory, test performed, and test report date among other information

#4: Analytical Systems Quality Assessment
→ Must establish and follow written policies and procedures for ongoing quality assessment including corrective action

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CLIA Top Ten Deficiencies...the Top Three!

#3: Procedure Manual  
→ Must include information about patient preparation, specimen collection, labeling, storage, and transportation among other information

#2: Evaluation of Proficiency Testing Performance  
→ Accuracy must be verified twice annually for non-regulated tests or procedures

#1: Test Systems, Equipment, Instruments, Reagents, Materials, & Supplies  
→ Define, monitor, and document storage conditions for specimens, reagents, and test system operations.

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