What is Laboratory Quality?

BCSLS Congress 2014 – Whistler
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Outline

1. Explore the definition of laboratory quality
2. Discuss how to achieve laboratory quality with these internal assessment tools:
   • Quality indicators
   • Audits
3. Stages of quality
Test Clickers 1: Where is your work site?

1. FH – Fraserhealth
2. NH – Northern Health
3. PHC – Providence Health
4. PHSA – Provincial Health Services Authority
5. IH – Island Health (Vancouver Island Health Authority)
6. IHA – Interior Health Authority
7. VCH – Vancouver Coastal Health
8. Lifelabs / BC Biomedical
Test Clickers 2: How long have you worked in our profession?

1. < 5 years
2. 5 – 10 years
3. 11 – 20 years
4. > 20 years
Institute of Medicine on Healthcare Quality

• “Health care quality is the extent to which health services provided to individuals and patient populations improve desired health outcomes.”
  

• “Health care harms patients too frequently and routinely fails to deliver its potential benefits.”
  
“One patient had an unnecessary mastectomy and another had a necessary surgery delayed at a Halifax-area hospital after their test results were switched with two other patients.”

Important Statements

- “Medical laboratory professionals are dedicated to serving the healthcare needs of the public.”

- Quality Policy – “provide consistently high quality laboratory services”
  - 2007 PLCO Laboratory Quality Manual QSE 1 template
Who defines high quality laboratory service?

1. CSMLS / CLSI / CAP / DAP / ISO 15189, or other organizations that set standards
2. My Supervisor / Manager / Director
3. Me
4. Patients / Physicians who use my laboratory service
5. Some of the above
6. All of the above
What does laboratory quality look like?
We are...

1. Accredited by: DAP, CAP, ISO, FACT, Health Canada, ASHI, other accreditation bodies
2. Error-free
3. Meeting our Turn-Around-Time goals
4. Meeting our budgetary goals
5. Physicians, patients, clients, and others are happy with our service.
6. All of the above
7. Not sure what quality means
Quality is defined as

“Degree to which a set of inherent characteristics fulfills requirements.”

Inherent Characteristics

**Quality Manual –**
**Quality System Essentials (QSEs)**

1. Organization
2. Customer Focus
3. Facilities and Safety
4. Personnel
5. Purchasing and Inventory
6. Equipment
7. Process Management
8. Documents and Records
9. Information Management
10. Non-Conforming Event Management
11. Assessments
12. Continual Improvement
QSE 11 Assessments

• External Assessments
  – Inspections / Accreditation assessments
  – Proficiency Testing / EQA

• Internal Assessments
  – Quality Indicators
  – Internal Audits
# Dimensions of Quality

<table>
<thead>
<tr>
<th>Institute of Medicine</th>
<th>Accreditation Canada</th>
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<tbody>
<tr>
<td>Patient – Centredness</td>
<td>Patient – Centred Services</td>
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<tr>
<td>Safety</td>
<td>Safety</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Effectiveness</td>
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<tr>
<td>Efficiency</td>
<td>Efficiency</td>
</tr>
<tr>
<td>Timeliness</td>
<td>Accessibility</td>
</tr>
<tr>
<td>Equity</td>
<td>Continuity of Services</td>
</tr>
<tr>
<td></td>
<td>Population Focus</td>
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<tr>
<td></td>
<td>Work life</td>
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</tbody>
</table>
### BC Health Quality Matrix

<table>
<thead>
<tr>
<th>Dimensions of Quality</th>
<th>Acceptability</th>
<th>Appropriateness</th>
<th>Accessibility</th>
<th>Safety</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care that is respectful to patient and family needs, preferences, and values</td>
<td>Care provided is evidence based and specific to individual clinical needs</td>
<td>Ease with which health services are reached</td>
<td>Avoiding harm resulting from care</td>
<td>Care that is known to achieve intended outcomes</td>
<td></td>
</tr>
</tbody>
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#### Areas of Care

- **STAYING HEALTHY**
  - Preventing injuries, illness, and disabilities

- **GETTING BETTER**
  - Care for acute illness or injury

- **LIVING WITH ILLNESS OR DISABILITY**
  - Care and support for chronic illness and/or disability

- **COPING WITH END OF LIFE**
  - Planning, care and support for life-limiting illness and bereavement

#### Examples

- **E.g.** Patient Satisfaction surveys
- **E.g.** Appropriate tests for patients needs and patient populations
- **E.g.** Turn Around Times
- **E.g.** Error rates, Non-conformities
- **E.g.** Productivity measures
Why do we need indicators?

• Indicators are integral to ensuring Quality:
  – Early detection of problems
  – Remediation and correction
  – Helps to prevent errors before they occur
What do we use indicators for?

1. For QC – control functions that have the potential to fail and will critically impact on quality of results
   - e.g. Refrigerator monitoring, pos/neg controls, in-process controls, etc.

2. For QA – measure the performance of complex processes with many inputs or multiple sequential activities
   - e.g. Order to Result TAT, patient ID accuracy, order entry accuracy, PT results, etc.

3. For QM – monitor the effectiveness of: overall system, planned improvements, and explore potential risks
   - e.g. Patients / physician satisfaction, staff safety / injury rate, competency assessments, error rates, cost / benefit ratio, etc.
Developing Quality Indicators

• What quality dimension(s) are the indicators aligned to?
• Define indicator parameters – the who, what, when, where, and how
• Monitoring indicators – defined beginning, middle and especially an end
• One time assessment or monitor over time
• PLAN-DO-CHECK-ACT
Why do we need internal audits?

• Evidence gathered directly from path of workflow, at workplace, where service is provided to patients/samples:
  - Objective
  - Real
  - Connects with staff
What do we use internal audits for?

1. For QA – to verify policies, processes, and procedures are implemented. To identify any inconsistencies in practice.

2. For QM – to improve quality, productivity and performance.
   - e.g. safety inspections, hand hygiene audits, patient identification audits, etc.
The 5Ws of an Internal Audit Program

• **Who**
  – Support from laboratory leadership team
  – Define Roles and Responsibilities
    » Sponsors
    » Audit program coordinator
    » Educator
    » Auditor(s) / auditee(s)

• **What**
  – Scope and objectives of each audit
  – Types of audits
    » Product / Service audit
    » Process audit
    » System audit
The 5Ws of an Internal Audit Program

cont’d

• **When**
  – Annual schedule
  – One-time or ongoing regular

• **Where**
  – QSE processes
  – Determine topics and/or areas to be audited using evidence:
    » Non-conforming events, past service problems, complaints, etc.
    » Or establishing a baseline
Conducting Audits

Pre-Audit preparation:
• Establish scope, type, where, criteria and all details
• Communication and notification plans

Direct Observation:
– Tracer methodology
– Follow the path of workflow in workplace

Desk Top Assessment
– Surveys/questionnaires
– Review flowcharts, procedures, results etc

Post-Audit:
• Communicate results with stakeholders, verbal / final report
• Follow up actions
• Evaluate audit process effectiveness
Where should we conduct audits?

- Laboratory errors reported:

<table>
<thead>
<tr>
<th>Table 1. Point of testing process</th>
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<tbody>
<tr>
<td>----------------------------------</td>
</tr>
<tr>
<td>Pre-analytic</td>
</tr>
<tr>
<td>Collections (51%)</td>
</tr>
<tr>
<td>Order processing or handling (25%)</td>
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<tr>
<td>Analytic</td>
</tr>
<tr>
<td>Post-analytic</td>
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CMPT 2012. Reporting Error in the Laboratory Part II.
Mandatory Requirement

• DAP LQI 3.5.19 – patient ID process is a key operational process; internal audits must be conducted for safety.
• Accreditation Canada – ROP: at least 2 client identifiers are used before providing any service or procedure.

Aligns to 2 quality dimensions: 
**Patient Centredness and Safety**
“An Ounce of Prevention is Better Than a Pound of Cure”

• Preventing errors is far superior than finding them after they happened

Quality is...

“Doing it Right the First Time, Every Time.”
Case for Electronic Positive Patient ID

Post Implementation:

• Laboratory sample identification errors = 0
# Stages of Quality

<table>
<thead>
<tr>
<th>Stage</th>
<th>Activities</th>
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<tbody>
<tr>
<td><strong>Total Quality</strong></td>
<td>Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction</td>
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<tr>
<td><strong>Quality Cost Management</strong></td>
<td>Measurement system for the economic aspects of the “cost of quality”</td>
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<tr>
<td><strong>Quality Management System (QMS)</strong></td>
<td>Systematic process-oriented approach to meeting quality objectives</td>
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<td><strong>Quality Assurance</strong></td>
<td>Planned and systematic activities to provide confidence that an organization fulfills requirements for quality</td>
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<tr>
<td><strong>Quality Control</strong></td>
<td>Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation</td>
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### My Laboratory – Stage of Quality

1. Total Quality
2. Quality Cost Management
3. QMS
4. Quality Assurance
5. Quality Control
Total quality is best defined as an attitude, an orientation that permeates an entire organization, and the way in which that organization performs its internal and external business.

People who work in organizations dedicated to the concept of total quality constantly strive for excellence and continuous quality improvement in all that they do.

“Quality is Everyone’s Responsibility.”

W. Edwards Deming