When Your Hospital CFO Asks: How We Show Our Lab’s Gains from ISO 15189 And QMS Programs

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Doug Wood, DC Wood Consulting

Oct. 21, 2014
Lab Quality Confab
## Stages of Quality

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

(Source: CLSI QMS-20)
# Stages of Quality – Adoption in Medical Laboratories

<table>
<thead>
<tr>
<th>Years</th>
<th>Stage</th>
<th>Quality Progress</th>
</tr>
</thead>
</table>
|             | QA    | 70s/80s – American “Quality Awakening”  
|             |       | • Deming and Juran influence American business to respond to Japanese competition  
|             |       | • QA principles are applied to laboratory                                                                                                                                                                           |
| 1990s – 2000s | QMS  | Early 90’s – rising popularity of ISO 9001 - General QMS requirements  
|             |       | 1999 – CLSI develops GP-26 - QMS guidelines for medical labs  
|             |       | 2003 – ISO 15189 - QMS requirements for medical labs                                                                                                                                                                  |
| 2010s       | CoQ   | 2014 – CLSI develops QMS-20 - guidelines for measuring quality costs                                                                                                                                              |
Avera McKennan Hospital & University Health Center – Our health system footprint

Avera McKennan Region & Avera McKennan Hospital

• Largest region of Avera Health
  o Large 545-bed tertiary hospital, 13 regional hospitals, 58 primary and 27 specialty care clinics
  o Heart hospital, behavioral health hospital, children’s hospital, cancer institute, transplant institute, neuroscience institute, research & genomics institute
  o Approx 6,000 FTEs
  o 1.3 million patient visits
Avera McKennan Hospital & University Health Center – Our laboratory footprint

• Employees (122.3 FTE’s)
  o 64.6 technical
  o 57.7 non-technical/support staff

• Testing specialties
  o Routine clinical specialties
  o Virology
  o Molecular diagnostic
  o Flow cytometry
  o HLA
  o Blood donor and procurement service

• Reference laboratory service line
  o 200+ outreach clients (SD, MN, IA)
Avera McKennan Hospital & University Health Center – Our laboratory footprint

- **Testing volume FY13**
  - Inpatient and outpatient – 1,056,000
  - Reference laboratory – 548,000

- **Revenue FY13**
  - Inpatient and outpatient – $114 mil
  - Reference laboratory - $8.5 mil

- **Accreditations**
  - CAP
  - AABB
  - FACT
  - UNOS
  - CAP 15189
  - FDA (regulated)
  - (ASHI-2015)
Avera McKennan Hospital & University Health Center – Our quality journey

• CAP Laboratory Accreditation and AABB

• LEAN – April 2004
  o Core lab, client service department, moved from main hospital to another location on campus, decreased staffing by 10+%

• CAP 15189\textsuperscript{SM} (ISO 15189) – January 2009
  o 2\textsuperscript{nd} Medical Laboratory in U.S.
  o 1\textsuperscript{st} Hospital Medical & Anatomic Pathology Laboratory in U.S.
  o 2\textsuperscript{nd} reaccreditation assessment Oct. 2014 (added HLA)
  o Current longest accredited CAP 15189 Laboratory in the U.S.
Avera McKennan Hospital & University Health Center – Our objectives

• Raise the bar on service and quality excellence for all patients and customers

• Enhance and assure an effective quality management system (QMS)

• Increase on our gains from LEAN

• Extend laboratory quality initiatives outside normal laboratory boundaries

• Engage staff in the quality process
Avera McKennan Hospital & University Health Center – Our ISO 15189 journey

• Our timeline and time investment
  o Quality manager hired – January 2008
Avera McKennan Hospital & University Health Center – Our recognized value of the changes

• Improved controls and management review
• Documented employee engagement and ownership
• Increased knowledge of program effectiveness and efficiency
• Enhanced continuous quality improvement
• Achieved impacts outside our normal boundaries
• Recognized financial benefits
Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP’s view

• Inspection Readiness
• Role in standardization of processes
• Prestige
Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP’s view

• Inspection Readiness
  
  o 3 inspections completed in 9 days
    - FDA (unannounced) September 30 – October 3
    - CAP 15189 reaccreditation October 7 – 9
    - CAP LAP Interim inspection October 10

  o Confidence expressed by our Regional President/CEO to our 2013 CAP LAP inspection team

  “the lab is the one department I don’t worry about”

-Dave Kapaska, DO
Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP’s view

• Role in standardization of processes
  
  o Use of process flow charts & root cause analysis
    − Going beyond Lean use of process charting to now using for financial aspect
  
  o Push-back to vendors ($100,000’s in savings)
    − Example – one test sent to referral lab, worked with sales representative to decrease cost of that test from $2300 to $500 for cost savings of $56,000 per year
    − ISO 15189 has increased our confidence level and prestige in organization
    − Genetic billing – look at expense for patient as well as for Avera McKennan. We know we are doing the right thing for our patients.
Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP’s view

• Prestige
  o Increased market share in competitive market
  o Recognition locally, regionally, nationally
    - Farming community as well as manufacturing familiar with ISO 9001 and recognize significance of ISO achievement
  o Influence on grant procurement & provision of insurance
    - Research branches
    - Avera Health Plans
“Sell” to Executive Level  (and fend off adding satellite labs - Cancer Institute, ED, etc.)

• Continuous Improvement

TAT for HGB for Feb 2014 thru Aug 2014
“Sell” to Executive Level

- Test Volumes/Billables Steady Increase

Billable Tests Per Fiscal Year
Critical Values – To Continuously Improve Change the View

- Prior to ISO – Critical Value monitoring
Critical Values – To Continuously Improve Change the View

- After ISO Assessment – Changed the view to push towards continuous improvement
Critical Values – To Continuously Improve Change the View

- 2014 – After auditing and CQI actions
# Blood Culture – Contamination Prevention

<table>
<thead>
<tr>
<th></th>
<th>2009**</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total BC*</td>
<td>8489</td>
<td>11464</td>
<td>10011</td>
<td>10093</td>
<td>9227</td>
</tr>
<tr>
<td>Total Line Draws</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Peripheral Draws</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Line Draws Contaminated</td>
<td>95</td>
<td>149</td>
<td>63</td>
<td>26</td>
<td>8</td>
</tr>
<tr>
<td>Lab Phlebotomy Draws Contaminated</td>
<td>84</td>
<td>79</td>
<td>166</td>
<td>122</td>
<td>105</td>
</tr>
<tr>
<td>RN Phlebotomy Draws Contaminated</td>
<td>92</td>
<td>191</td>
<td>90</td>
<td>91</td>
<td>133</td>
</tr>
<tr>
<td>% Total Contaminated</td>
<td>3.19%</td>
<td>3.65%</td>
<td>3.19%</td>
<td>2.48%</td>
<td>2.67%</td>
</tr>
<tr>
<td>% Lines Contaminated</td>
<td>1.12%</td>
<td>1.30%</td>
<td>0.63%</td>
<td>0.28%</td>
<td>0.09%</td>
</tr>
<tr>
<td>% Phleb Periph Contaminated</td>
<td>0.99%</td>
<td>0.68%</td>
<td>1.66%</td>
<td>1.25%</td>
<td>1.14%</td>
</tr>
<tr>
<td>% RN Periph Contaminated</td>
<td>1.08%</td>
<td>1.67%</td>
<td>0.90%</td>
<td>0.95%</td>
<td>1.44%</td>
</tr>
</tbody>
</table>

*Total Blood Cultures Ordered. Could include 1 (ex. Pediatric) or 2 (Aerobic & Anaerobic.) BC counted as contaminated if even on bottle contaminated.

**2009 represents 11 months of data.
**Blood Culture – Contamination Prevention**

- Continuous improvement through assessment, actions and feedback!
  - 2010 – Contamination rates exceeded <3.0 ASM/<2.5 CAP
    - QA Committee and Infectious Disease specialty reviews and recommendation = CQI initiative to decrease contamination rates
  - 2010-2011 – hospital initiative to eliminate collection through lines (rate 3.65 $\rightarrow$ 3.19)
  - 2012 – additional CQI actions taken (rate 3.19 $\rightarrow$ 2.48)
    - Staff training, purchased webinar, implemented specific orientation/training for new employees
    - Implemented rate tracking and employee feedback for individuals
What are the financial benefits?
We can use an example...

- What are the consequences of blood culture contamination?

<table>
<thead>
<tr>
<th>Article</th>
<th>Mean difference in length of stay</th>
<th>Difference in median total costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical and economic impact of contaminated blood cultures within the hospital setting <em>Journal of Hospital Infection, 2011</em> (study conducted in Ireland)</td>
<td>5.4 days</td>
<td>$2,513</td>
</tr>
<tr>
<td>Contaminant blood cultures and resource utilization. The true consequences of false-positive results <em>JAMA, 1991</em> (study conducted in Boston)</td>
<td>4.5 days</td>
<td>$4,385</td>
</tr>
</tbody>
</table>
This is the “cost of quality”

• Laboratory expenses can be initially divided into two areas.
  o The expenses of running the lab without errors, retesting, or any mistakes.
  o Expenses that involve mistakes, attempting to prevent mistakes, and dealing with the consequences of mistakes.
The value of cost of quality measures

“A properly understood and managed quality cost system will aid organizations in realizing costs savings while avoiding some of the serious pitfalls that can accompany cost cutting: decreases in product or service quality, increased customer dissatisfaction, added rework costs, or simple shifts in costs from one area to another.”

The expenses beyond ‘no errors’ can be redefined as:

- **Prevention expenses** are from proactive measures to improve quality and prevent errors throughout the laboratory.
- **Appraisal expenses** are from inspection and maintenance.
- **Internal Failure expenses** occur when something has gone wrong with the process.
- **External Failure expenses** occur when results have left the laboratory and failed to meet the requirements of customers for whatever reason.
Proportions of quality costs

- Prevention Costs
- Appraisal Costs
- Internal Failure Costs
- External Failure Costs

Costs axis:
- Proactive
- Reactive

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Applying the model – quality costs associated with blood culture contamination

• **Prevention Costs:**
  - Creating/maintaining systems of control for blood culture contamination

• **Appraisal Costs:**
  - Management audits
  - Data collection
  - Process reviews
Applying the model – quality costs associated with blood culture contamination (continued)

• **Internal Failure Costs:**
  - Additional supplies
  - Phlebotomist time, accessioning time
  - Culturing time, Gram stains & interpretation for retests

• **External Failure Costs:**
  - Increased length of stay, increased physician time to deal with individual cases
  - Consequences of patients not being diagnosed in a timely way, or misdiagnosed
## Annual quality costs

<table>
<thead>
<tr>
<th>Category</th>
<th>Before</th>
<th>1st year</th>
<th>2nd year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>$0</td>
<td>$809</td>
<td>$650</td>
</tr>
<tr>
<td>Appraisal</td>
<td>$816</td>
<td>$816</td>
<td>$1128</td>
</tr>
<tr>
<td>Int. Failure</td>
<td>$7245</td>
<td>$6210</td>
<td>$5175</td>
</tr>
<tr>
<td>Ext. Failure</td>
<td>$642,000</td>
<td>$550,000</td>
<td>$459,000</td>
</tr>
<tr>
<td>Total</td>
<td>$649,000</td>
<td>$557,000</td>
<td>$466,000</td>
</tr>
</tbody>
</table>
Example calculation formulas (Before)

Internal failure:

- Lab tests to work up contaminated blood culture
  - $14 per test x 9000 tests per year x 0.035 contamination rate
  - $4410

- Redraw/Repeat Blood culture
  - $9 per test x 9000 tests per year x 0.035 contamination rate x 0.2 redraw rate
  - $567

External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients

- Added pharmaceuticals
Example calculation formulas (Before)

Internal failure:

- Lab tests to work up contaminated blood culture
  - $14 per test x 9000 tests per year x 0.035 contamination rate
  - $4410

- Redraw/Repeat Blood culture
  - $9 per test x 9000 tests per year x 0.035 contamination rate x 0.2 redraw rate
  - $567

External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients
  - 3600 patients x 0.035 contamination rate = 126 affected patients

- Added pharmaceuticals
Example calculation formulas (Before)

Internal failure:
- Lab tests to work up contaminated blood culture
  - $14 per test x 9000 tests per year x 0.035 contamination rate
  - $4410
- Redraw/Repeat Blood culture
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External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients
  - 126 affected patients x 4.5 days per patient = 567 annual extra patient days
  - 567 annual extra patient days x $1000 per day = $567,000 Cost
- Added pharmaceuticals
Example calculation formulas (Before)

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  - $4410

- Redraw/Repeat Blood culture
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  - $567

External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients
  - 126 affected patients x 4.5 days per patient = 567 annual extra patient days
  - 567 annual extra patient days x $1000 per day = $567,000 Cost

- Added pharmaceuticals
  - 3600 patients x 0.035 contamination rate x $600 per day cost
  - $75,600 Cost
Annual quality costs: charts

All costs of quality

Prevention, appraisal, internal only
Annual quality costs: charts

Costs of quality - Prev & App only

Prev-App-Int

$9,000
$8,000
$7,000
$6,000
$5,000
$4,000
$3,000
$2,000
$1,000
$0

Before 1st year 2nd year

Prevention  Appraisal  Internal failure
Annual quality costs: charts

Costs of quality - External failure

External Failure

Before 1st year 2nd year

$700,000

$600,000

$500,000

$400,000

$300,000

$200,000

$100,000

$0

External Failure
Annual quality costs: charts

All costs of quality - dual axis

<table>
<thead>
<tr>
<th>Prev-App-Int</th>
<th>External failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>$0</td>
</tr>
<tr>
<td>1st year</td>
<td>$100,000</td>
</tr>
<tr>
<td>2nd year</td>
<td>$600,000</td>
</tr>
</tbody>
</table>

- Prevention: $0
- Appraisal: $10,000
- Internal failure: $80,000
- External failure: $600,000
CMS Emphasis on Quality – Inpatient Services

- Section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)
  - 0.4% reduction to inpatient payments beginning in 2005 for non-reporting hospitals
- Section 5001(a) of the Deficit Reduction Act of 2005 (DRA)
  - Increase reduction to 2.0% beginning in 2007 for non-reporting hospitals
CMS Quality Measures

CMS Inpatient Quality Measures

Number of Quality Measures

Year

0 10 20 30 40 50 60 70 80

CMS Emphasis on Quality – Outpatient Services

• Tax Relief and Healthcare Act of 2006
  o 2.0% reduction to outpatient payments beginning January 1, 2009 for non-reporting hospitals

• Similar to the inpatient quality reporting

• Began with the reporting of 7 quality measures versus 10 inpatient measures

• Expanded measures beginning in 2011

• 23 quality reporting measures as of 2014
Contact Information

• Cheryl Wildermuth, Avera McKennan
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• Doug Wood, DC Wood Consulting, LLC
  doug@dcwoodconsulting.com
References

1. CAP 15189 website www.cap.org/cap15189
