

Errors and Costs Requirements and Standards

Michael Noble MD FRCPC
Chair, CMPT
Chair, POLQM
Department of Pathology and Laboratory Medicine
University of British Columbia

In Session 1

- Introduction
- Definitions of Quality
- Modern history of quality from Taylor (1890) to Robert Galvin (2000).
- Development of international standards

Medical Laboratory

Seventy percent of clinical medical decision making is predicated on laboratory tests.

Diagnosis
Confirmation
Progress
Treatment

In the United States there are approximately
1 Billion tests performed per annum.

In British Columbia
laboratory testing accounts for
5-7% of provincial health budget

Significant Laboratory Errors

Significant Errors

Significant delay or inconvenience,
or treatment or decision error

Literature Average

1-3 per 5,000 samples
Sigma 4.8 - 5.1

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Significant Laboratory Errors

In the United States
600,000 SLE per year.

**In British Columbia
6,000 SLE per year.**

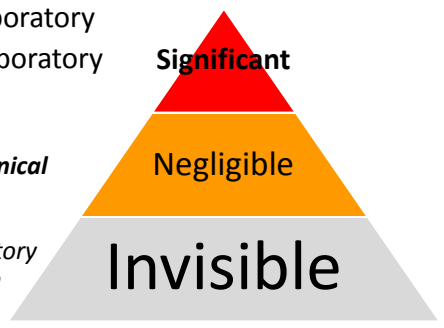
SLE are more common in
Smaller laboratories
Manual laboratories
Non-monitored laboratories

*Fortunately significant errors are uncommon
but...*

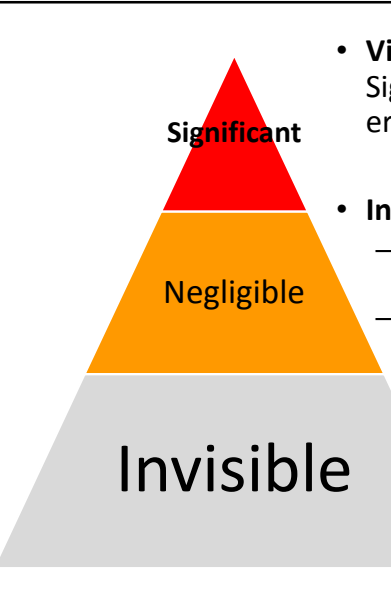
Significant Errors are the tip of the iceberg

- Factors directly associated with total error
 - Number of Personnel
 - Complexity of Laboratory
 - Distribution of Laboratory

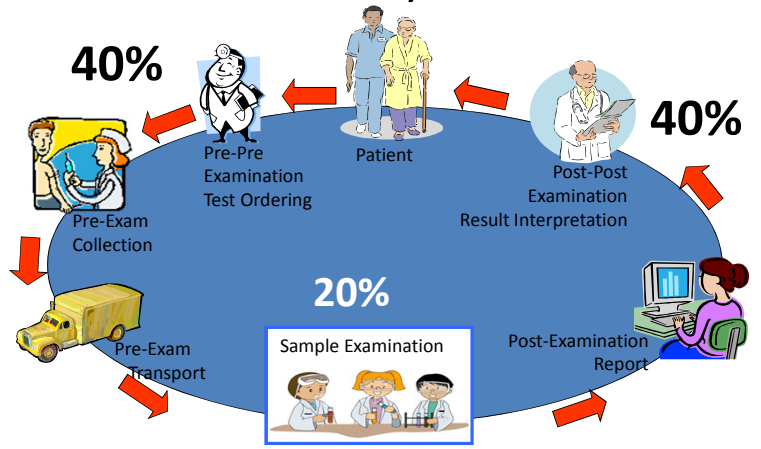
– **Note:**
 “Significant “ is a clinical definition.
 “Negligible” errors still consume laboratory time for remediation and correction



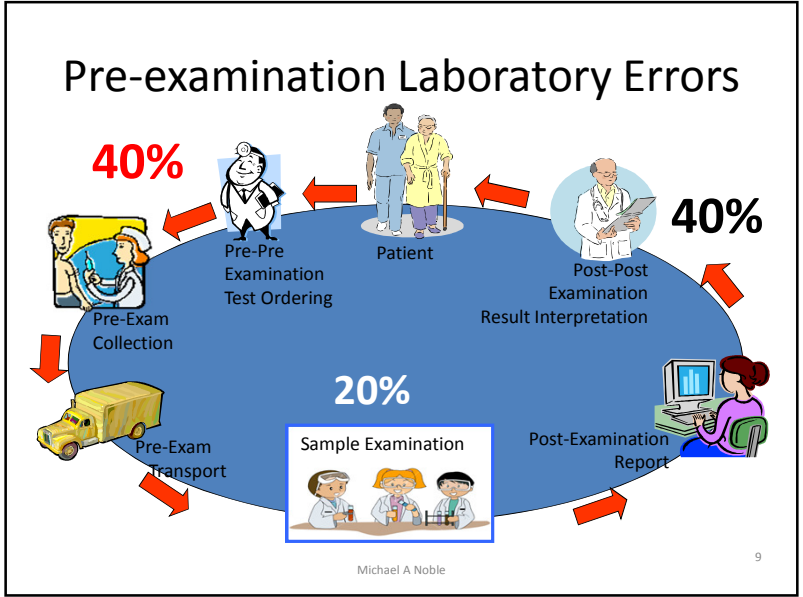
- **Visible errors**
Significant and Negligible errors are.
 - **Invisible errors**
 - An unreported error is an invisible error.
 - Most test results are normal or near normal.
 - Normal contaminated with normal is still normal.
 - The wrong patient’s normal is still normal.
 - Delayed normal is still normal.
- Invisible errors can become visible with costly consequence.*



Laboratory Errors



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Common Pre-Examination Errors

Wrong test ordered	5%
Patient not prepared properly	10%
Wrong collection tube	10%
Wrong Information (wrong patient, doctor, test, sample)	25%
Mislabeling	20%
Poor Transport (time, temperature)	10%
Lost in Transit	5%
Other	15%
	100%

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- ### Common Causes of Pre-Examination Errors
- **Systemic problems that result in:**
 - Collection and Preparation Error
 - Transport Error
 - Equipment or Software error
 - Data entry keyboarding errors
 - Bar Code Readers
 - Training deficiency
 - Document control error
 - Working with the wrong procedure.
 - Cognition Error (Misidentification)
 - Non-cognitive mistake
 - Distraction or Rushing
- Michael A Noble

- ### Why phlebotomy errors occur
1. Phlebotomy is a complex process that requires planning, dexterity, patience, compliance, cooperation and patient physicality.
 2. Tubes must be collected in the correct order, must be mixed correctly (neither over or under) at the correct time.
 3. Sick patients are less likely to have the required physicality for proper sample collection.
 4. Many opportunities for misinformation.
 5. Many opportunities for distraction.

Consequences of Pre-Examination Error

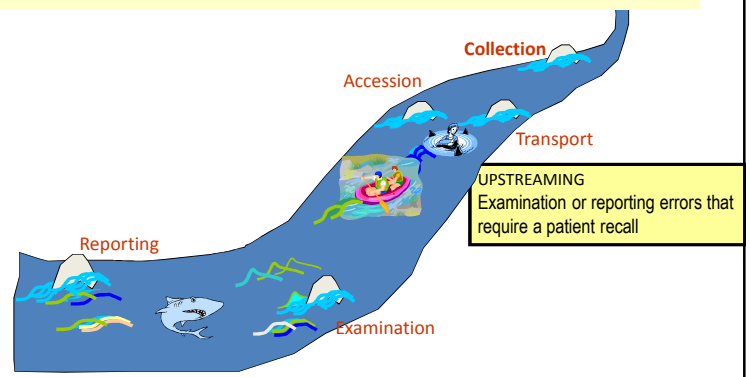
- Delayed report.
- Potentially damaged or lost sample.
- Increased intra-laboratory activity.
- Patient inconvenience.
- Physician inconvenience.
- Reputation impact.
- Cost impact.

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- **Most Pre-examination errors**
 - Are not identified until long after the fact
 - Lead to compounded downstream complications.

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Up and Down the CPQ River



Downstreaming CPQ
 Errors that occur early, but are not detected until much later. Downstreaming results in increasing complexity, impact, and cost.

In the blink of an eye

A few non-retrievable seconds slip by and translate into minutes, hours, days of consumed consequence.



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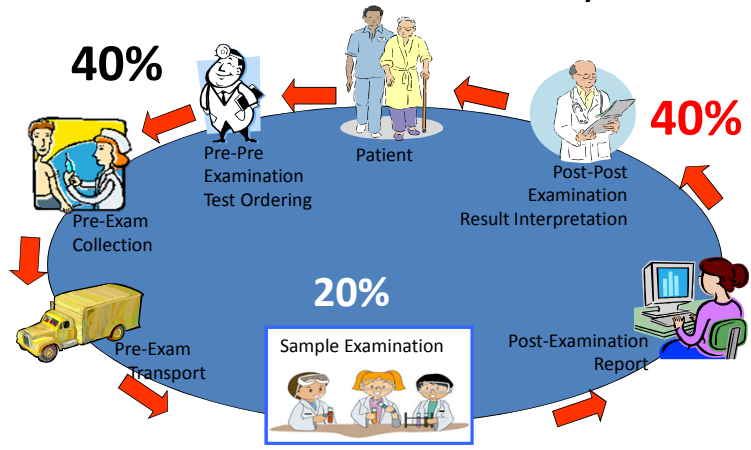
Pre-examination error with downstream consequence.

A 72 year old man presented to laboratory for collection of sample. Identification of patient is done casually and he and another patient with similar name wee mixed up. Sample was collected, processed, tested and reported.

Physician was sceptical of the report and contacted the laboratory. Upon investigation, which took 3 days the error is identified.

- **Initial results for both patients needed to be amended in LIS, MSP**
- **Both patient s had to be recalled.**
- **Sample collection and testing has to be repeated (no charge).**
- **Decision making based on test results delayed.**
- **Report for Quality system**

Post-examination Laboratory Errors



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Pre- and Post Examination Errors

Pre-Exam Errors

- High volume
- Time costly
- Mostly one-to-one
- Many outside direct laboratory control
- Many cause inconvenience
- Some cause privacy breach

Post-Exam Errors

- High Volume
- Time costly
- Mostly one-to-one
- Many outside direct laboratory control
- Many cause inconvenience
- Some cause privacy breach

Personal Post Examination Story

- In the lower mainland there are several Dr. Nobles.
- I received my first incorrect report within a week of coming to Vancouver.
- Since then on average I receive 10 incorrect reports a week (every week). This has never stopped over ensuing 31 years.
- More than **16,000** incorrectly delivered reports.
- **THAT IS ONE PHYSICIAN IN ONE PROVINCE.**

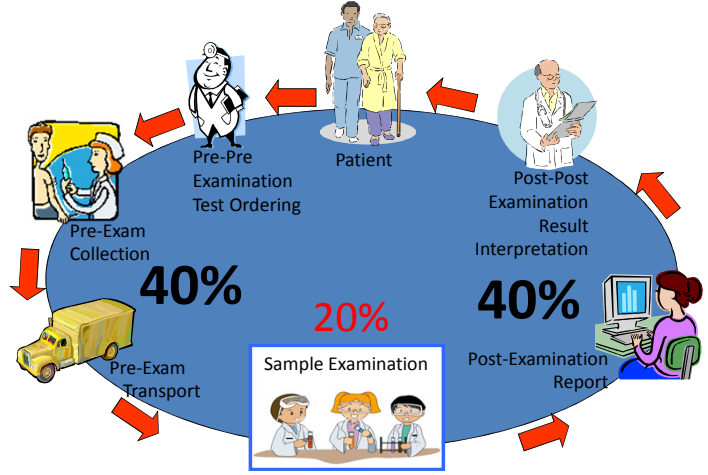
Wrong Reports from one month



Consequences of Post Examination Error

- Delay in reporting
- Breach in confidentiality
- Potential action error
- Cost and inconvenience of remediation
- Upstream activity for test repeats.

Examination Phase Error

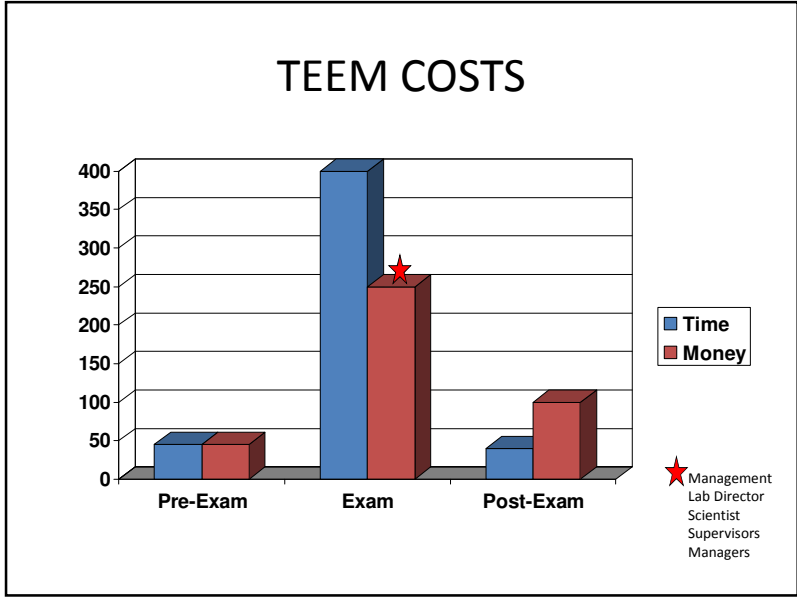


Examination errors

- Most easily identified.
- Tend to be of lower volume but:
 - More costly per error.
 - More likely to result in “one-to-many” impact
 - Most inside direct laboratory control
 - Many cause inconvenience
 - Many cause diagnosis and treatment complications
 - Some cause social disruption.

Occurrence – Outcome and Laboratory Cycle Phase Error

		Outcome			
		Nil	Inconvenient	Problem	Critical
Occurrence	Remote				
	Rare			Examination	
	Common		Pre-Examination Post-Examination		
	Frequent				




- ### Examination Errors have multiple causes
- **Personnel**
 - Slips
 - Training
 - Documentation
 - **Mechanical**
 - Internal systems
 - Data management
 - **Reagents and Supplies**
 - Contamination
 - Out-dated
 - Cross reactivity
 - **Sample Error**
 - Poor mixing
 - Inhibitors and Interference
 - **Environmental**
 - Temperature, Humidity

Plus the Rumsfeld factor...

There are known knowns;
there are things we know that we know.

There are known unknowns; that is to say,
there are things that we now know we don't know.

**But there are also unknown unknowns;
there are things we do not know we don't know.**



Characteristics of Examination Error

- Most occur **silently**.
- Many occur **quickly**.
- Most occur on a **“discontinuous”** basis.
- Some occur from pre-existent sample compounding cross-reaction factors.
- Very difficult to prevent.
- Very difficult to predict.
- Relatively easy to detect

The Sad Reality Is...

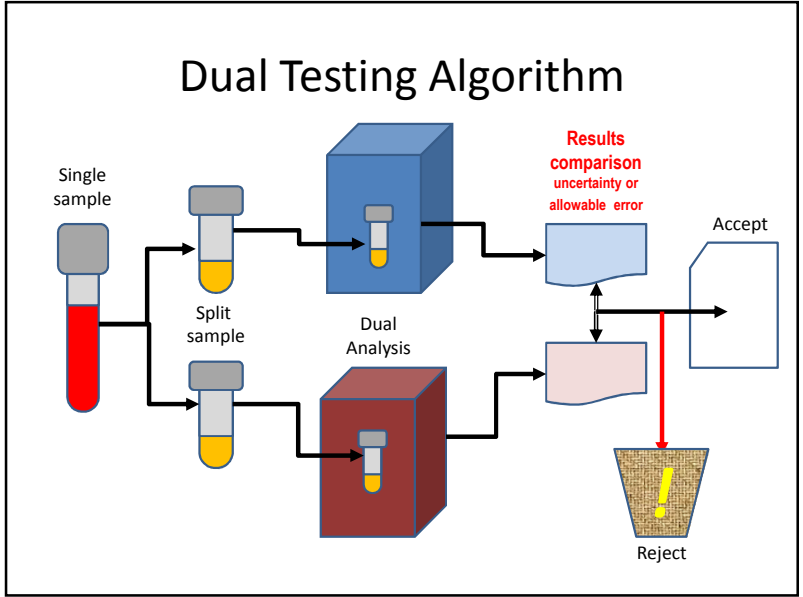
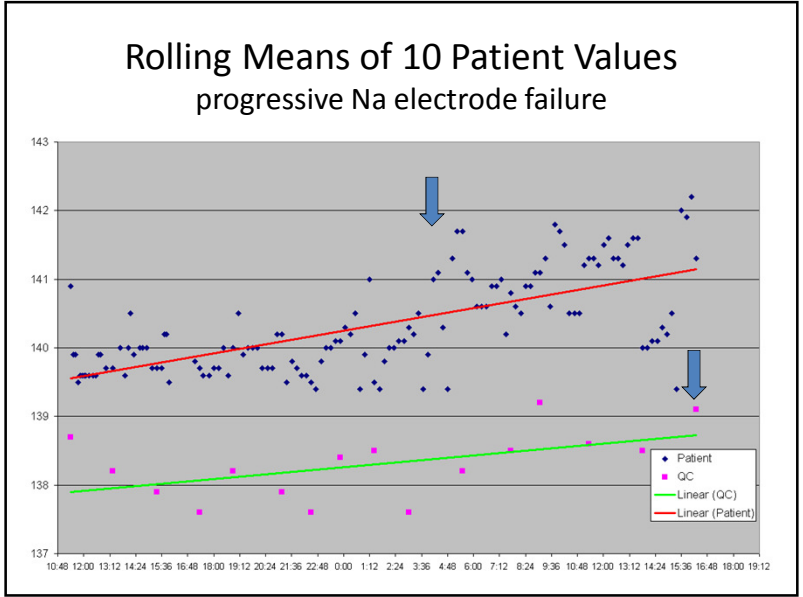
- Examination Error is **inevitable** because
 - Testing volumes far exceed manual testing
 - Complex analyzers have too many moving parts
 - Complex analyzers require complex information transfer (middleware)
 - Trained analyzer operators are far too limited.
 - Too many unknowns factors in patient samples.
 - Unreasonable expectations often result in undue time pressures.

What We **CAN NOT** Do

to prevent examination error

- Reduce dependency on automation.
- Increase preventive maintenance.
- More intensive training of personnel.
- More personnel.
- Assume that maintaining Accreditation or Certification will make the problems go away.
- Assume that maintaining Quality Management System will make the problems go away.

If you can't stop examination errors,
you might be able
to detect them sooner
or reduce their impact
through
more effective Quality Control and Testing strategies.



Better Middleware

Software to:

- Capture patient data
- Capture QC data
- Examine for duplicate sample testing
- Examine for rolling means
- Alarm potential breaches.

Change Turnaround Time Expectations

If results could be held back until they can be viewed and analyzed, many examination errors could be caught before being released.

So...
Can we reduce Examination Error?

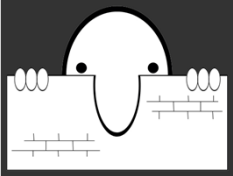
1. Increase and diversify Quality Control Monitoring.
 Activity specific monitoring
2. Increase Proficiency Testing or equivalent testing.
 Higher volumes to better detect system error
3. Different approaches to Real Time QC.
 Look more closely at "stable" patient results as a prediction model
 Repeat testing
4. Delay release of automated reports
 Do we have REALISTIC turnaround time expectations.

Costs and Quality

Cost of Quality
 Costs of Quality
 Cost of Poor Quality
 Costs of Poor Quality
 Cost of Non-Conformance

Costs of Poor Quality

- Virtually ignored in the Public Sector.
- Virtually ignored in the Medical Laboratory.
- Barely recognized in the Private Sector Medical Laboratory.



Why we ignore CPQ
at our peril

- Management glaringly sees the costs of Appraisal and Prevention.
- Management sees to costs attributed to spectacular failure.
- Management never sees the savings recovered from internal and external failure.
- **Net savings due to Quality management and accreditation 0.15 – 3.0% of turnover**

Crosby:
the cost of nonconformance

*“Take everything that would **not** have to be done if everything were done right the first time and count that as the price of nonconformance.”*

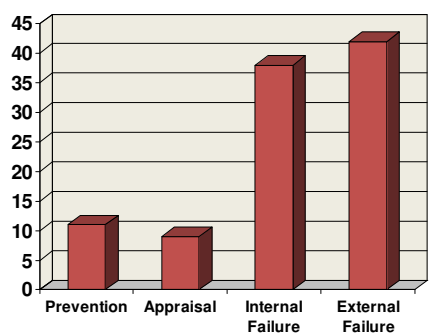
*Quality Without Tears:
The Art of Hassle-free Management
1984*

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Juran Model Categories

Prevention Costs	Facility controls Quality system Staff training Consultants
Appraisal Costs	Quality Control Accreditation Proficiency Testing Internal Audits
Internal Failure Costs	Costs arising when an error is found BEFORE it is released.
External Failure Costs	Costs arising when an error is found AFTER it is released.

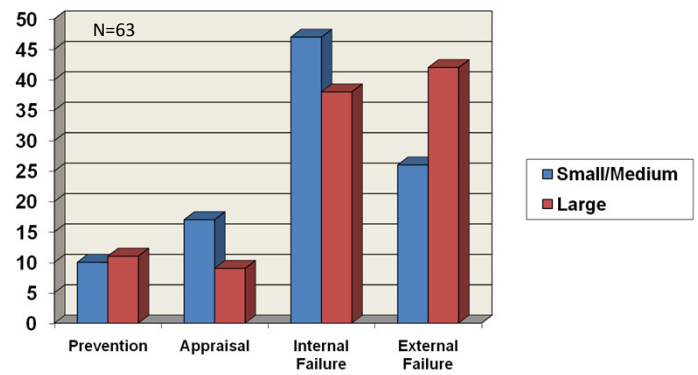
Comparative Weights of Quality Costs



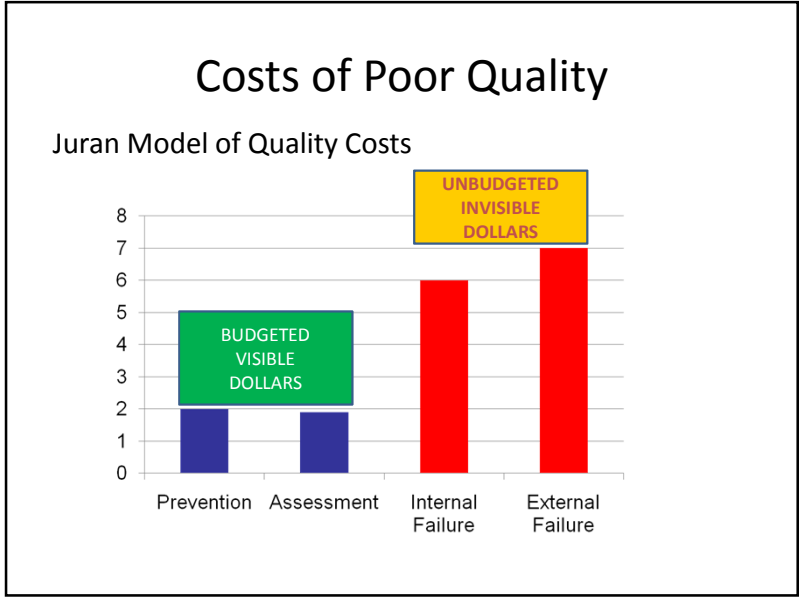
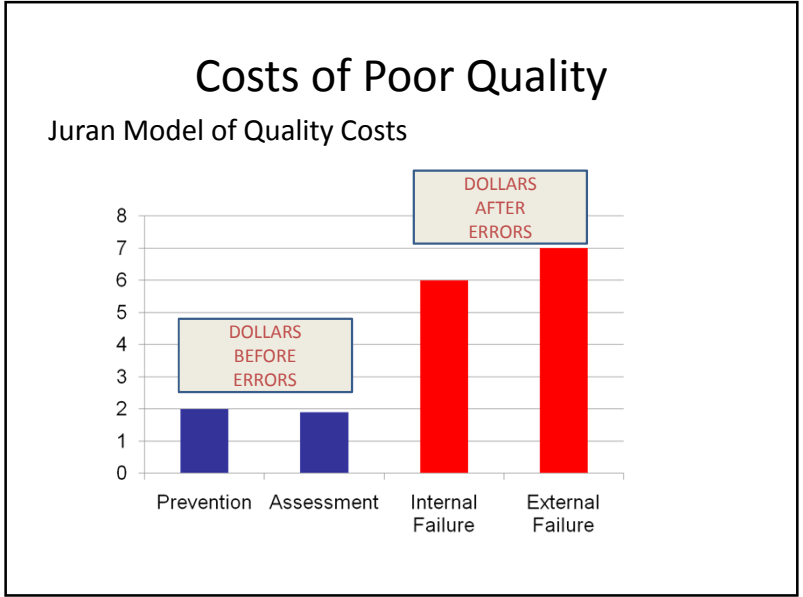
*S. Rodchua
ASQ, Quality Management Jour
V16-1, 2009*

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Comparative Analysis Quality Costs and Organization size



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- ### Steps that Juran did not include, but Crosby did
- Stop the system
 - Find the error sample(s)
 - Retrieve the original sample(s) (if possible)
 - Purge the wrong result(s)
 - Start-up the system
 - Re-test the original sample (if possible)
 - Notify everyone who might have received the wrong result
 - Retrieve the original report
 - Amend the report
 - Create internal incident form
 - Internal incident form –action plan
 - Create an external incident form
 - External incident form – action plan

What do reported incidents Cost?

Revision Required	Time (minutes)
Change of identifier information	25-35
Change of reported information	40-975
Patient Recall (laboratory time)	40-80
Mean time to amend reported incidents	140

Note: our calculations underestimate time consumption, and do not include attention breaks, refocus time, return to normal activity time

What is not included...

- Patient time on telephone
- Patient return-to-laboratory time
- Patient re-accession and wait time
- Patient collection time
- Patient return to home time
- **Average Patient Time for Recall is 180 minutes**
- Physician Office notification time
- Physician Office recall and revise chart time
- Physician Office re-contact patient
- Physician Office patient consultation.
- **Average Physician Office Time for Recall is 20 minutes**

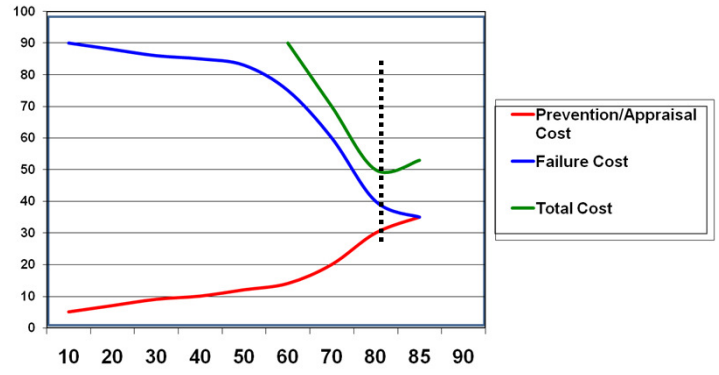
Total Quality Costs

The Juran Model

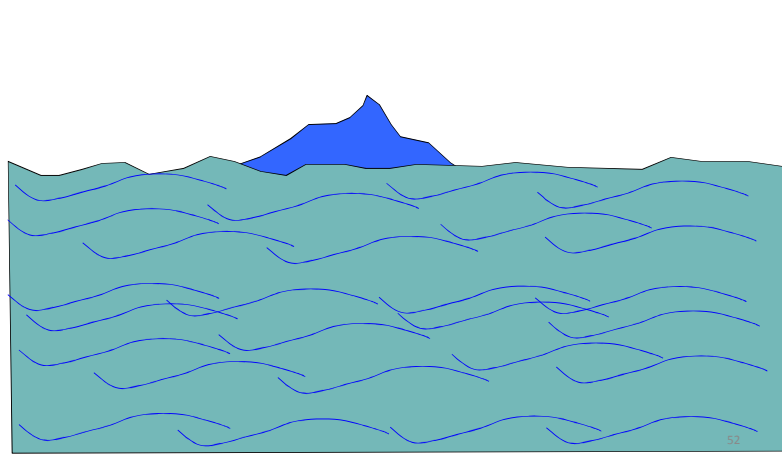
- The sum of all costs for all activities associated with ensuring an accurate and timely product or service:
 - Prevention Costs
 - Appraisal Costs
 - Costs associated with Internal Failure
 - Costs associated with External Failure

Juran: The Quality Economic Model

Percent conformance and Costs

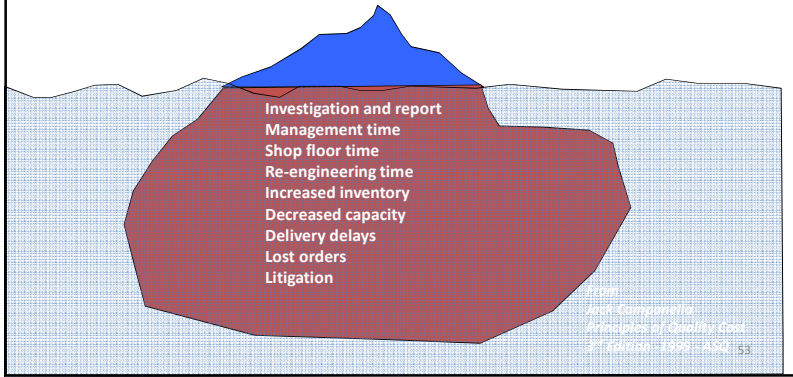


Impacts of Poor Quality costs



Impacts of Poor Quality costs

- More than what meets the eye!



Dimensions of Poor Quality in the Medical Laboratory

more than just money!

- ✗ Staff Time
- ✗ Clinical decision delays
- ✗ Patient time and inconvenience
- ✗ Productivity
- ✗ Turn around Time
- ✗ Reputation
- ✗ Liability
- ✗ Accreditation performance

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Some errors are costlier than others

	Minutes
Pre-examination patient demographic error	25
Pre-examination labeling error	40
Examination mechanical	400
Examination mechanical (retesting required)	600-1000
Patient recall for test and retest	200
AVERAGE ERROR	130

Medical Laboratory Error

excluding complaints, quality, finance, HR, IT

	Errors per DAY	Time per DAY
Demographic	5-10	200
Labeling	5	200
Examination mechanical (20+ patients)	0.2	100
Examination mechanical - retesting	0.2	140
Patient recall	2	400
AVERAGE DAY CPQ TIME LOST		1040

Percent FTE Consumption for Error

All Errors per day	Minutes Lost	10 FTE	30 FTE	100 FTE	250 FTE
1	140	6.9			
5	700	34.6	11.5		
10	1400		23.0	6.9	
15	2100			10.4	
20	2800			13.8	5.5
25	3500				6.9
30	4200				8.3
40	5600				11.1

Impact of Error Minutes Per Day on laboratories

Effective hours per person per worked day
 Increase with increasing personnel
 Decrease with increasing complexity

Size	Small	Intermediate	Large	Very Large
Employees	15	30	100	200
Effective Hours per day	6.0	6.25	6.5	6.4

Medical Laboratory Losses

Observations

1. Laboratory Errors result in time loss and costs throughout the laboratory testing cycle.
2. Laboratory Losses and costs involve all profession groups and all reasons.
3. Poor Quality Impacts are often felt downstream from the error and,
4. Poor Quality Impacts are usually borne by people who did not directly cause the problem.
5. Creating loss take trivial time compared to investigation, remediation, and correction.
6. Inconvenience, Reputational damage, Liability, and Risk are common consequences

How to monitor medical laboratory CPQ

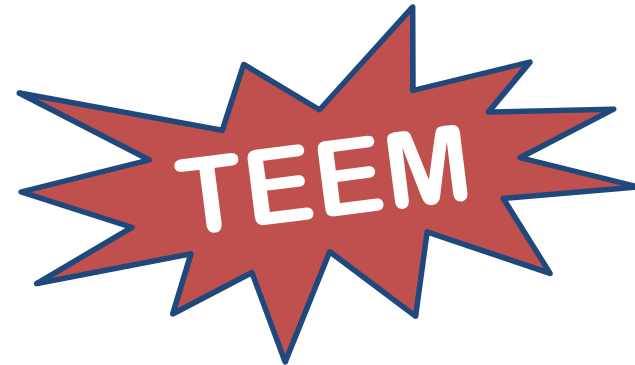
- Index
 - Near-miss time
 - Sample repeat times
 - Patient complaints
 - Physician complaints
 - Opportunity For Improvement reports
 - Critical events reports
- Process
 - Investigate, capture time and finances losses
 - Compile
 - Internal targets until benchmarks become available.
 - Management Review leading to Action Plan.

About monitoring for medical laboratory CPQ

- It is probably unreasonable and inappropriate to try to capture all costs at all times.
- A sequence of point-in-time calculations can equally monitor trends.

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Poor Quality Costs More Than Money



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Quality Standards, Guidelines and Best Practices Documents

Michael A Noble MD FRCPC
Chair CMPT and POLQM
Department of Pathology and Laboratory Medicine
University of British Columbia

How often do you hear ?

- Well CLSI says...
- I was reading an article that says that we need to...
- At St. Paul's they do it this way...
- That guy who gave that presentation at the conference said...
- We run our operation based solely on best practices.
- We strive to meet and exceed all requirements.
- DAP says we have to do it this way, but that is just not going to happen.

Warning

All of these may lead to change,
but rarely to credible change.

Quality is the meeting of Requirements.

Standards

- An **authorized** set of statements that represent requirements that are applied either voluntarily or by licensure, regulation, or legislation.
- Consensus based statements created by recognized standards development organizations which have wide support.
- Usually horizontal in scope.
- Are designed and written as stable and long term (5 years).

Guidelines

- A set of statements, usually based upon consensus that can be applied on a volunteer basis.
- Guidelines are often written and endorsed by recognized expert panels or working groups within professional organizations.
- Guidelines should be reviewed regularly.

Best Practices

- A collective opinion, often from an “expert” group with regards to the most efficient and effective mode of accomplishing a task or delivering a particular outcome.
- Best Practices guides are vertical in scope.
- Best practices should be viewed as short term and evolve as improvements are discovered.

The Consensus Process

- Documents are written and proposed within a working group.
- Widely distributed to increasing broader circles of reviewers.
- All reviews are addressed, although not necessarily incorporated.
- General Agreement
- Not all people have to agree with the final product, but **none** should be in a position where they **can not** work within their constraints.

A Good Sign for Non-Consensus



Another level of requirement *myth or reality?*

- The courts have the authority to dictate what should be deemed a requirement.
- The courts are not constrained by authority, or consensus, or majority opinion.
- The courts may be constrained by appeal.

ter Neuzen v. Korn

- G. Korn in 1985 provided a sample of semen for AI from a sperm bank to patient. Standard practice was undertaken. The patient became infected with HIV.
- The court said that since there was a precedent letter in a journal, Korn was liable.
- Korn appealed to the BC Court of Appeal who in 1993 agreed that his standard of practice defence was appropriate.
- ter Neuzen appealed to the Supreme Court of Canada in 1995, but was rejected.
- A new trial was considered but rejected.

Conclusion from This Case

- In this case, a case-report manuscript was insufficient information to justify an expectation of extraordinary action.
- In Canada, the accepted standard of practice by common peer applies.

Personal communication

If there is a required action by an authorized standard, even if were generally ignored by common peer, it would still be recognized as the requirement.

When and How to Implement a new requirement

1. If it is a requirement from an authorized body.
2. If it is part of a voluntary compliance with an established process.
3. If it part of a **planned** quality improvement process.
4. If it is part of a **planned** operational change.

Sources of Laboratory Standards in British Columbia

Mandatory

- Health Canada
 - (in vitro diagnostics)
 - Transfusion Medicine
- Transport Canada
- BC Health Practitioners Act
- BC Ministry of Health Services
 - BC Medical Services Plan
- Diagnostic Accreditation Program.
- BC College of Physicians and Surgeons
- Worksafe BC

Voluntary

- ISO15189:2007
- College of American Pathologists
- US FDA

Sources of Guidelines for Use in BC Laboratories

- BC Ministry of Health Services,
 - Medical Services Commission
 - Guidelines and Protocols

The Clinical Practice Guidelines (the "Guidelines") have been developed by the Guidelines and Protocols Advisory Committee **on behalf of** the Medical Services Commission. The Guidelines are intended to give an understanding of a clinical problem, and outline *one or more preferred approaches* to the investigation and management of the problem. The Guidelines are not intended as a substitute for the advice or professional judgment of a health care professional, **nor are they intended to be the only approach to the management of clinical problems.**

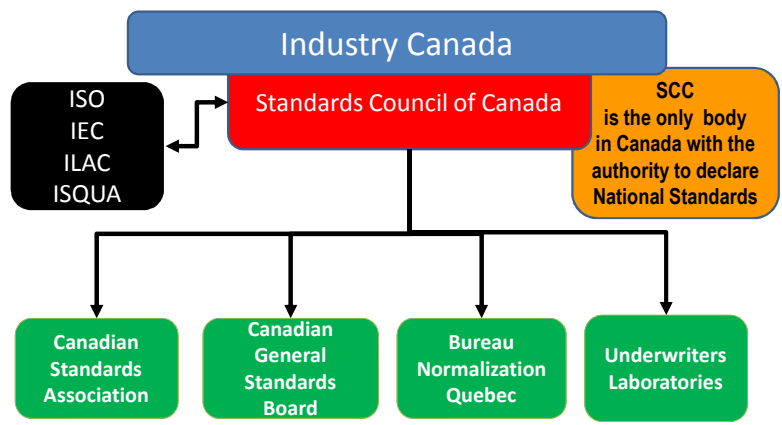
BC Guidelines and Protocols

- Erythrocyte Sedimentation Rate updated April 2007
- Antinuclear Antibody (ANA) Testing for Connective Tissue Disease. upated April 2007
- Infectious Diarrhea - Guideline for Ordering Stool Specimens. dated March 2009
- Viral Hepatitis Testing dated 2005
- Liver Chemistry Abnormalities in Adults - Evaluation and Interpretation. Updated 2007
- Vitamin D Testing Protocol dated 2010

Sources of Guidelines for Use in BC Laboratories continued

- Clinical and Laboratory Standards Institute
- ISO 15189:2007
- College of American Pathologists
- Canadian Association for Pathology
- Canadian Society for Clinical Chemistry
- Canadian Standards Association
- Canadian General Standards Board

Canadian Standards Network



ISO 15189:2007

Medical Laboratories: Particular Requirements for Quality and Competence.

International Organization for Standardization

International Inaugural Meeting :	June 1995 in Philadelphia
Responsible Technical Committee :	ISO Technical Committee 212
First Publication :	ISO 15189:2003
International Adoption 2003:	33 countries
Designated Canadian National Standard:	2004
Second Iteration:	ISO 15189:2008
International Adoption 2009:	74 countries
Third Iteration:	ISO 15189:2013(?)

ISO 15189:2007

- **Management Requirements**
 1. Organization
 2. Management Responsibilities and Review
 3. Quality Structure
 4. Continual Improvement
 5. Records
- **Technical Requirements**
 1. Personnel
 2. Accommodation and Environment
 3. Pre-examination, Examination, and Post Examination procedures
 4. Assuring Quality
 5. Reporting of Results

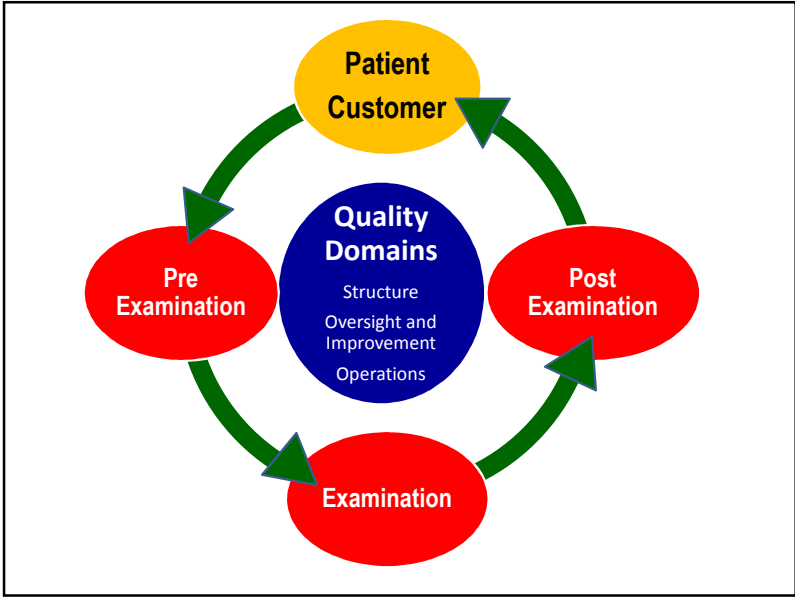
Elements of Quality

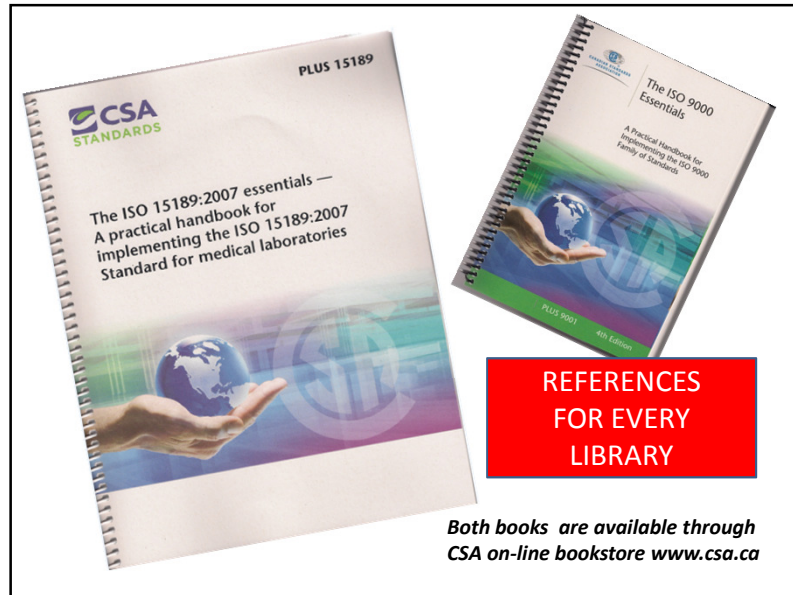
CLSI Quality Essentials

1 - Documents & Records 3 - Personnel 5 - Purchasing & Inventory 7 - Information Management 9 - Assessments 11 - Customer Service	2 - Organization 4 - Equipment 6 - Process Control 8 - Occurrence Management 10 - Process Improvement External and Internal 12 - Facilities & Safety
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Quality Domains

<p style="text-align: center;">Structure</p> <p>Organization Management Responsibility Personnel /Human Resources</p>	<p style="text-align: center;">Oversight and Improvement</p> <p>Assessment Occurrence Management Process Improvement Customer Satisfaction</p>		
<p style="text-align: center;">Operations</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Purchasing and Inventory Equipment Safety and Facilities</td> <td style="width: 50%;">Process Management Documents and Records Information Management</td> </tr> </table>		Purchasing and Inventory Equipment Safety and Facilities	Process Management Documents and Records Information Management
Purchasing and Inventory Equipment Safety and Facilities	Process Management Documents and Records Information Management		





Important Note

In Canada

ISO 15189:2007 is a National Standard

Ontario uses ISO 15189:2007 for Medical Laboratory Accreditation.

Quebec has legislated ISO 15189:2007 for Medical Laboratory Accreditation.

British Columbia Diagnostic Accreditation Program (DAP)

uses ISO 15189:2007 within the framework of their own standard.

One laboratory in BC has taken the extraordinary step of volunteer accreditation to ISO 15189:2007 for supplemental level of Quality.

In Summary...

- Errors and Costs are intimately linked.
Reducing error will save TEEM
- There are lots of suggestions to reduce error
 - Standards, Guidelines, Best Practice Documents
 - Know the difference BEFORE you get busy.
- Be part of the solution.

At their core...



Standards and Guidelines are the product of a bunch of guys sitting around a table.

One of them might just as well be...



you!