The Illusion of Quality:

A Discussion of Roadblocks to Laboratory Quality and Case Studies of How to Make Things Better

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Learning Objectives

- *List several areas of the specimen life cycle where risk assessment is needed*
- *Compare an equivocal QC plan with an IQCP*
- *Discuss available methods and techniques to acquire a current state assessment of laboratory quality*
- *Develop a plan to implement a change to current quality practices*
- *Demonstrate the positive outcomes of a successful quality redesign*

IQCP: At a glance

An IQCP requires:

– Risk Assessment (RA)

– Quality Control Plan (QCP)

– Quality Assessment (QA)

Outcomes of the IQCP Process

- After you complete this process, it is possible that you may determine that the amount of QC you have been doing all along is sufficient to achieve CLIA compliance.
- However, you could discover potential sources of error that you had not previously considered, and may need to implement additional QC activities.
- Anyone else think this is a trap?

Equivocal QC: The Good

- Minimal effort
- Majority of the responsibility on the producer (not the user)
- 2 or more levels of QC per day

  AND/OR
- No external QC if manufacturers' internal QC are adequate

Equivocal QC: The Bad

- Minimal quality set point
- Focus on assumption of performance
- Missed warnings provided from more extensive statistical QC

1. Perform the required number of external liquid controls per test per day
2. Continue to follow EQC procedures
3. Implement an IQCP

After January 1, 2016, EQC will no longer be a QC option.

IQCP: At a glance

An IQCP requires:

– Risk Assessment (RA)

– Quality Control Plan (QCP)

– Quality Assessment (QA)

Risk Assessment

What does it mean?

- Knowing and finding the weak points of your processes
  - Preanalytical
    - Mislabels
  - Analytical
    - Ineffective QC policy
  - Postanalytical
    - Transcription errors

Where do you look?

- Specimen
- Test System
- Reagents
- Environment
- Testing Personnel

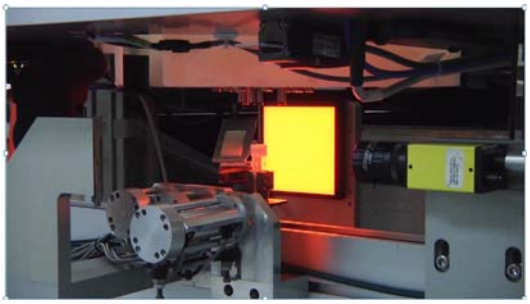
Examples of Findings/Symptoms

- Preanalytical
  - Mislabels: Mislabel rate high and found by physician inquiry. Incidental findings during the testing process.
- Analytical
  - Ineffective QC: Failed PT with QC that passed. 2sd QC policy with “repeat, repeat, repeat” as the troubleshooting guide. Problems that “come out of nowhere”.
- Postanalytical
  - Transcription errors: Results that fail to repeat (found by physician inquiry). Failed internal PT that are patient repeats. Troubleshooting unrelated find result discrepancies.

Formulating an IQCP

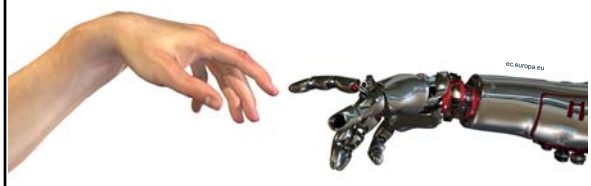
- Incorporating the RA findings: Mislabels
  - Track mislabels by month and report to staff
- Solutions:
  - Double checking
  - Triple checking
  - OCR multidimensional label reader

Courtesy of ARUP Laboratories (Dr. Charlie Hawker)



Roadblock #1

- No access to futuristic robots, Dr. Charlie Hawker, or the ARUP Automation & Bioengineering groups



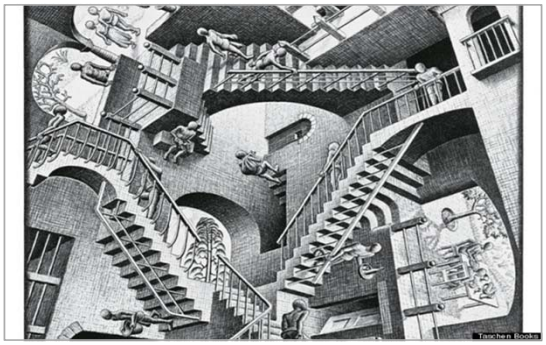
Formulating an IQCP

- Incorporating the RA findings: Transcription errors
  - Track corrected reports (performance appraisal metric)
- Solutions include:
  - Interfaces (electronic shuttling of data from instrument to LIS)
    - Autoverification
    - More quality checks
    - IT support is substantial
  - Double verification
    - Perform technologist different than verify technologist
  - DAR (daily activity review)
    - Person that reviews all results verified from the day before (retrospective)

Formulating an IQCP

- Incorporating the RA findings: Inadequate QC
  - Track PT failures
  - Track QC failures
  - Track troubleshooting success/failure
- Solutions:
  - Do nothing (if you're hitting the minimum requirement)
  - Take the opportunity to vet your QC
  - Enhance and optimize your QC
  - KNOW that your lab is generating high quality results

Finding the Path to Better Quality



Eye Opening Experiences for Me – TTE Lab

- Trace and Toxic Element Laboratory
- Inductively-coupled plasma mass spectrometry
- 20 staff members
  - 1 x Supervisor, 1 x Lead Technologist, 1 x Technical Specialist, 17 x Bench technologists
- 20 different assays
- *No QC failures for almost 6 months*

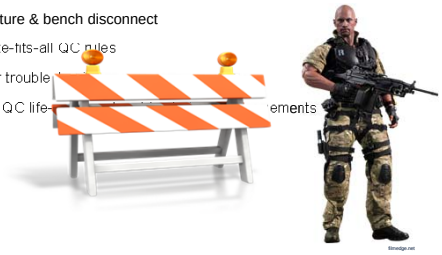
Eye Opening Experiences for Me – cont.

- PT Failures with no explanations
  - QC all passed on the day of PT
- Staff complaints of difficult workload
- Obsession with NY guidelines, PT acceptance criteria
- Apparent disconnect between several bench technologists and patients
- *A high quality lab that could be better – but didn't know it!*

Round 1

Roadblocks to Quality

- Roadblocks to Quality
  1. Lab culture & bench disconnect
  2. One-size-fits-all QC rules
  3. Unclear trouble
  4. Lack of QC life-ements



Quality Control: Getting back to basics

January 2013

TTE Staff Meeting

Topics to cover

- What is QC?
- What can statistics tell us about our QC process?
- How are we currently doing QC?
- How is QC reviewed currently?
- How could we change QC to enhance lab quality?

Why talk about QC?

- As the lab evolves, our quality measures must evolve.
- It is easy to disconnect from the *true goal of QC*.
- Change is good, but only if it is the right change.
- Reduce rework, increase efficiency, spend time on more appropriate aspects.
- Ensure we never forget our responsibility to the “patient in the tube”.

What is QC?

QC Strategy

- Intended to monitor the analytical performance of a measurement procedure and alert analysts to problems that might limit the usefulness of a test result.
- Tells the analyst if the unknown (patient) results are valid

1. Test and method specific (materials, rules, number, frequency)
2. Define an “analytical run” or batch
3. Run QC and have an appropriate response plan

Key Features of Good QC

- Prepped at the same time as patient samples and standards
  - *Any mistakes made with QC were likely made with patients too!*
- Represent the only known values and provide a reality anchor
  - *Like looking up the answers in the back of the book – VALIDITY!*
- Must be done consistently with ALL data collected, good or bad
  - *Allows a timeline of assay performance – PREDICTIVE and PREVENTATIVE*
- Rules identify real failures and are investigated to find a root cause
  - *Just enough QC with the right rules*

Features of Bad QC

- QC prepped independently of patients
  - *QC only validates calibration, can't find non-cognitive errors*
- QC repeated over and over until "it's in"
  - *5% of the time, good QC is out. 5% of the time, bad QC is in.*
- Reporting in the range of "good QC" and ignoring "bad QC"
  - *Might be fine once, but trends, shifts, and future problems are looming.*
- Running QC before the instrument is ready
  - *Introduces unwanted variability (long term monitoring skewed)*

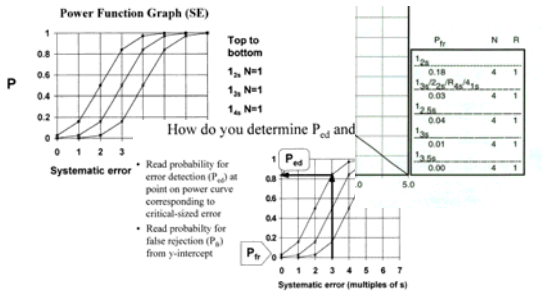
A Closer Look: Our Current State

Test	N	Set Mean	Obv. Mean	Set SD	Obv. SD -	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
Lead WB Venous	375	1.7	1.72	0.3	0.125643	0.08	0.044199	17.647059	7.287862	5.89	1.100-2.300
Lead WB Venous	320	5.2	5.27	0.5	0.553706	0.144375	0.032298	9.615385	10.502404	4.83	4.200-6.200
Lead WB Venous	292	22.8	22.76	2.2	1.525024	-0.016656	-0.076027	9.649123	6.699468	6.65	18.400-27.200
Lead WB Venous	253	83.1	85.40	8.3	4.290246	0.276585	0.1562	9.987966	5.023963	4.42	66.500-99.700
Mang, Serum	20	1	1.01	0.5	0.298946	0.02	0.484211	50	29.598566	30.04	0.000-2.000
Mang, Serum	16	4.6	5.41	1	0.472537	0.80625	0.953333	21.73913	8.740578	9.84	2.600-6.600
Mang, Serum	13	14.7	18.14	2.2	1.08285	1.562937	1.710744	14.965986	5.969911	6.27	10.300-19.100
Mang, Serum	15	27.2	32.26	4.1	2.074608	1.234146	1.314634	15.073529	6.4309	4.56	19.000-35.400

How do we do this?

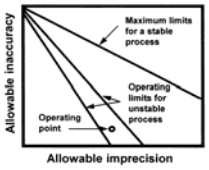
- Find and identify assay or workflow problems inhibiting best practices for QC
- Establish "appropriate targets" for all QC
- Standardize comments and troubleshooting steps
- Modify rules to ensure appropriate balance of control
  - *Not too much, not too little*
- Adhere to good QC practice at all times
  - *QC prepped with patient samples*
  - *No repeating of "out" QC*
  - *Root cause of failed QC*

Rule performance



QC Goals

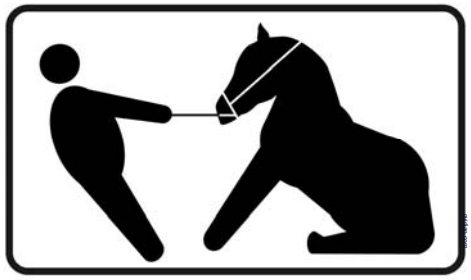
- Total allowable error
- Medical decision limits
- Assay bias
- Assay precision



What's next?

- Deeper analysis for all analytes in the lab
- Standardization of comments and troubleshooting steps
- Identify high yield, low false positive rules for each analyte
- Establish more accurate goals for QC ranges (based on performance)
- More fun, less work!

Progress Summary:
January 2013 to September 2013



Why was there no progress?

- Staff didn't believe there was a problem.
- Management didn't have the tools in place to change.
- Lots of *MY* ideas, lots of *MY* enthusiasm, no *STAFF* buy-in.

Round 2

The Beginning of Buy-in

- A few more failed PTs
- A supervisor and a lead “encouraged” to find the causes with a medical director that wouldn’t let up.
- Weekly Quality Assurance & Quality Control meetings
- Monthly QC review as a group
  - ***Viewing the lab from my point of view***
- “Is it possible our QC is not as good as we think?”

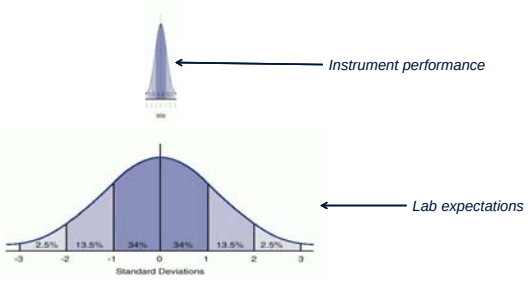
Outline

- Common Mistakes
- Necessary components of a QC plan
- Areas for continuous improvement
- Strategies for addressing quality weak points

Necessary Component #1

- Appropriate targets and ranges

#3 Unrealistic QC Targets



Identifying Weak Points

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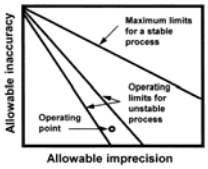
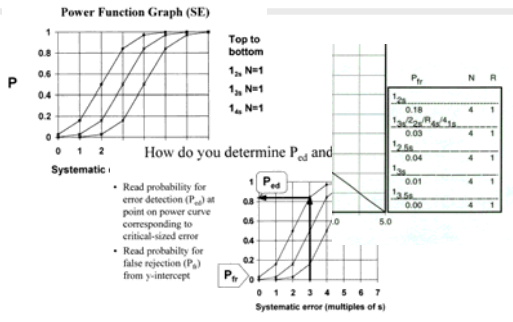
Necessary Component #2

- Rules that fit the assay

QC Goals

- Total allowable error
- Medical decision limits
- Assay bias
- Assay precision

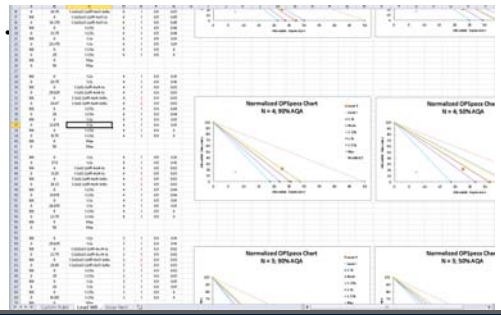




Almost…Not Quite

Current state assessment

Current state assessment



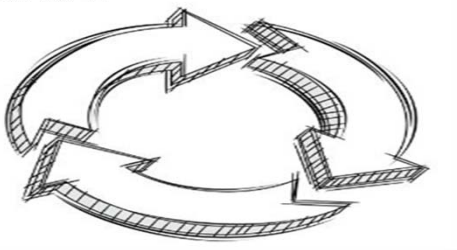
Ask the staff

Poor performing assays
Assays not working well
too busy
Solving problems individually
Lack of staffing
procedural inflexibility
short on time
pulling long hours
short term solutions
Instruments not functioning properly
very rushed
limited amount of automation
Personal opinion
always very rushed

QC rules evaluated on a continuous basis

QC troubleshooting plan optimization

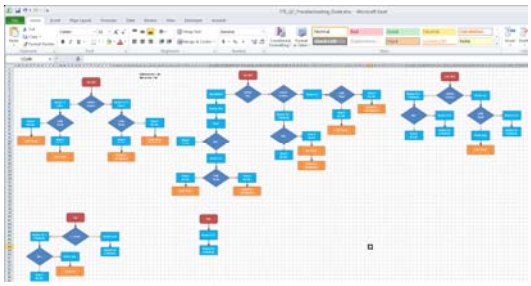
- Track success
-
-
-



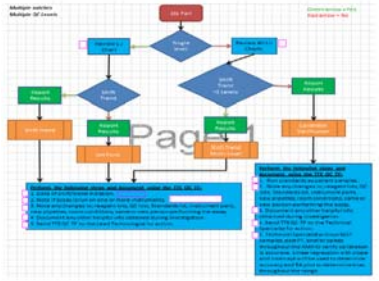
And Then it Happened

Current State Assessment Completed

Troubleshooting Workflow Developed – *By Me*



Troubleshooting Tools Developed – *With Staff*



Organizational Support

- QC Subcommittee formed from LIS SuperUsers
- SOP written based upon TTE Lab process
- Presentations to Group Managers
- Presentations to Supervisors
- Workshops organized for interested labs
  - Hands on with lab data

Organizational Current State

- Five full workshops with requests for more
  - Current State Assessment: Part I and Part II
- Follow-up workshops in preparation
  - Designing a QC Troubleshooting Plan: Part I and Part II
  - Pulling the trigger on your first change: Part I
  - Follow up post go-live: Part II

Where are we now?

TTE Lab: Current State Assessment 1.5 yrs. post "go-live"

- External PT failures to nearly 0
  - Several assays identified for R&D rework
- Monthly QC review < 15 minutes
- Laboratory staff engaged in quality
  - Looking at LJ charts "because they're interesting"
  - Amazing ideas about QC failures and what to do
  - Appreciation for what and why – "Patient in the tube"
- A nearly complete culture change

QC Strategy – Continuous Evaluation

- *Track success*
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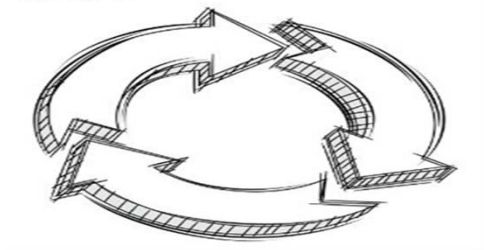
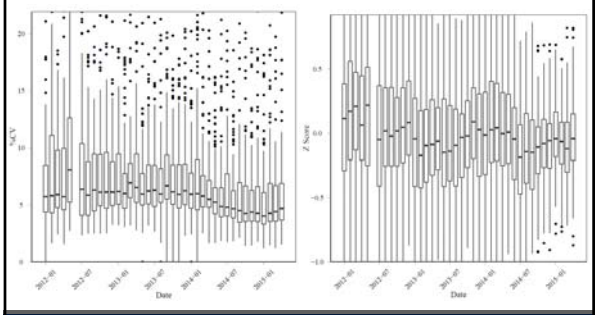


Quantifying Improvements in Quality



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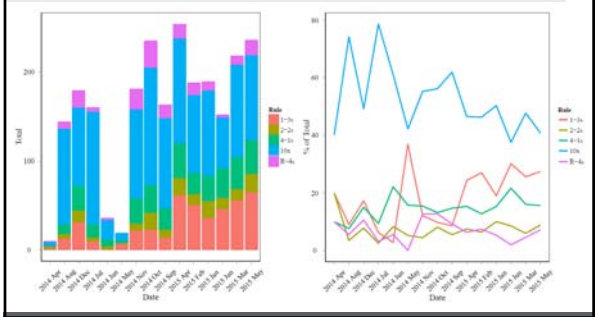
A Glimpse of What it Takes…



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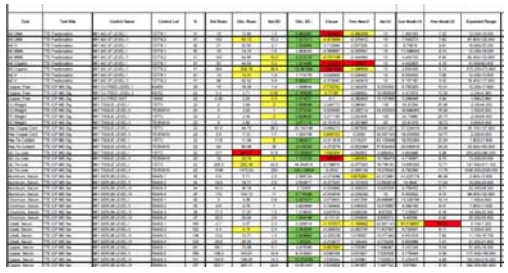
The Rewards: Then…



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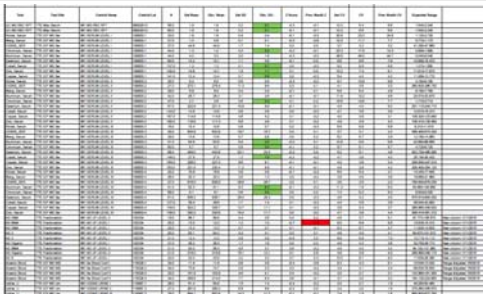
The Rewards: …Now



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What I learned from all of this.

- It is not enough to state the obvious.
- It is not enough to provide tools for change.
- Even though staff "should know this stuff" they don't always know how to apply it.
- Someone has to drive – preferably someone with a backbone.
- Everyone has to be involved somehow.
- Never give up – Never surrender

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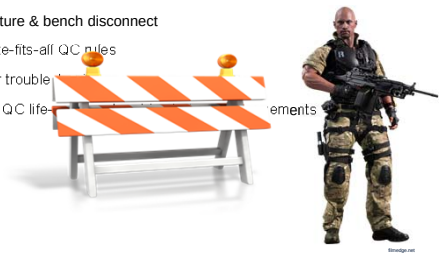
Roadblocks to Quality

- Roadblocks to Quality
  - ✓ 1. Lab culture & bench disconnect
  - ✓ 2. One-size-fits-all QC rules
  - ✓ 3. Unclear trouble
  - ✓ 4. Lack of QC life- ements



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