Individual Quality Control Plans (IQCP) Lessons Learned

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Misconceptions about IQCP

Misconception	Facts
• *EQC is being phased out, thus manufacturer's internal controls cannot be utilized*	• **EQC includes "alternative QC" procedures that have been evaluated to yield *equivalent* information to traditional external QC** • **Manufacturers' internal controls may be a part, or all, of the IQCP for POCT analytical phase of testing**
• *Laboratories will be required to enroll in a monthly peer QC program*	• **Not a requirement, but it is a tool in judging effectiveness of IQCP**
• *Intention is to reduce QC frequency*	• **CMS's intention is to have the "right QC" for each testing device and site**

Staff Fear Change

IQCP Contest

To Vote: Vote by Number. One vote per person unless you have a documented split personality!!! I will tally the votes and announce the winning entry by noon on August 6, 2015.

Entries

1. I Quit Clinical Pathology
2. Idiotic Questions Concerning Professionalism
3. Irritatingly Quixotic Confusing Proclamation
4. Involuntary Quantitation Cause Pain
5. Idiot's QC Perspective
6. Ignominious Queries Cauterize Progress
7. Imposed Quality Control Plan
8. Intuitively Questioning CMS Priorities
9. Inordinate Quantities Counterproductive Paperwork
10. I(one)Quirky Clueless Program
11. It's Quizzical Clinical Punishment
12. Imbecilic Quizzical Clinical Punishment
13. Insanely Queer/Quixotic/Quaky Crappy Policies/Procedures
14. Indiscriminate Quagmire Creating Panic
15. Idiot's Questioning Competent Professionals
16. Impetuous Quack's Competency Plan
17. Iconoclastic Quasi Competent People
18. Inconceivable Quack Criteria Policy
19. Intestine Quality, Controlled "Poop"
20. Intolerable Quagmire Constipating Progress
21. Ignorant Quibbling Corrupt Politicians
22. Inappropriate Quests Compromise Progress
23. Insignificant Questionnaire Confining Progress
24. I Question Clinical Point!
25. I Question Confusing Policies

What Have We Learned From Our IQCPs?

- What did we revise/develop as a result?
  - Revise CBTs for specimen collection & handling
  - Emphasis on pre-analytical processes
  - Developed job aids
  - Re-implement check codes monitor
  - Updated QC log for Avox
  - Developed job aids for reference ranges
  - Included QA review as part of POCC monthly review

Monthly POCC Review

Date	Investigations/ Corrective Actions/- Description of Problem	POCT Correction Request Forms (Incorrect sample type, Incorrect Parameters, Mis-ID's, Improper Specimen)	i-STAT Errors	i-STAT Hemolysis (POCT Correction request, POC Daily Critical Report, POC vs. Lab Comparison Report)	Corrective Action	Cartridge Type

Quality Scorecard

Monitor	Goal	YTD	Jan	Feb	Mar	Apr	May	Jun
Point of Care reagent inspection	100%	98%	99%	98%	96%	99%	98%	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
i-STAT Mis-ID's, % Variances/uos	0.200%	0.000%	0.000%	0.000%	0.000%	0.000%	-	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
i-STAT Hemolysis		0.037%	0.000%	0.442%	0.081%	0.096%	-	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
i-STAT Quality Check Codes, % Variances/uos	<=5%	1.737%	1.884%	1.726%	1.785%	1.836%	1.464%	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Gluc Meter Mis-ID's, % Variances/uos	0.200%	0.020%	0.020%	0.019%	0.000%	0.041%	-	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Clinitek Meter Mis-ID's, % Variances/uos	0.200%	0.000%	0.000%	0.156%	0.142%	0.152%	-	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Waived QC Compliance	100%	98%	100%	98%	97%	99%	99%	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Non-Waived QC Compliance	100%	99%	100%	99%	99%	99%	99%	-
Monitor	**Goal**	**YTD**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
Competency Compliance	90%		99%	99%	99%	98%	-	-

Outcomes of an Effective IQCP

when you know it was worth it

- Optimizes Efficiency & Productivity
- Reduces operating costs
- Improves safety performance
- Improves customer satisfaction
- Improves morale

What Did We Learn?

- We have an excellent team of experts (Lab and Clinical)

ISTAT IQCP
Daniel Cheek

All IQCPs
Karen Hrischuk
Dawn Smith

AVOX IQCP
Roman Baczara
James Galbreath

Hemochron IQCP
Harendra Arora
Marc Caruana
Cristie Dangerfield
Greg Griffin
Susan Martinelli
Brenda McClure
Christa Seaman

GEM5000 IQCP
Jenny Cayless
Shawna Evans
Michael Garrett
Loree Kimball
JoAnn Rich
Kathy Short
Mark Walker
Kimberly Young

- Thank you to our Lab/POC and Clinical Colleagues!

What Did We Learn?

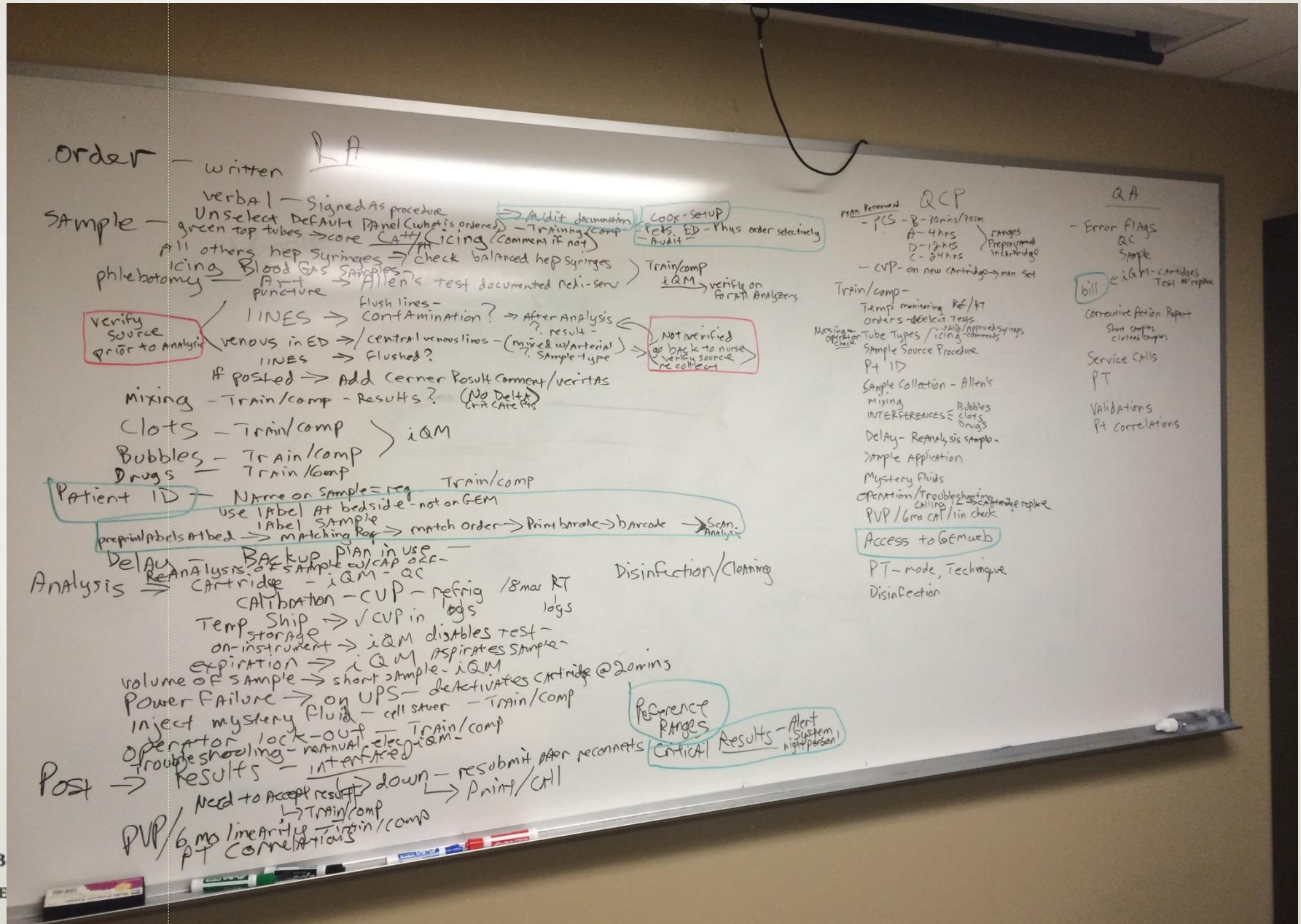
- We have an excellent team of experts (Lab and Clinical)
- Our current Lab/POCT Program is of high quality
- Large learning curve in practical application of risk management principles to Lab/POCT quality practices
  - » It's easy to get stuck in "analysis paralysis"→ Place in "parking lot" and come back to it later
- Working through the IQCP process is of value
  - » Validates non-traditional quality control testing that meets CLIA requirements and accrediting organization standards
  - » Helps identify opportunities for enhancing quality practices
  - » Promotes multi-disciplinary collaboration
  - » Supports cost-containment

Lessons Learned

- Time commitment is needed
  - » Evaluate risks and risk-based QA practices
  - » Develop and implement risk mitigation features
  - » Competes with time required for routine clinical service responsibilities, teaching and scholarly activities

- Lab/POCT QA based on risk-management principles
  - » Is good laboratory practice!
  - » Is an institutional endeavor necessitating multi-disciplinary leadership and staff expertise and buy-in

What Have We Learned From Our IQCPs?



What Have We Learned From Our IQCPs?

- Processes on different units were not uniform
  - Some used operator lockouts, other sites not setup
- IQCP supports QC rationale and resources
  - Each action is linked to a specific hazard
  - Gives meaning for why we do what we do rather than simply meeting a regulation
- Opportunity for improving efficiency
  - QC the device versus QC the reagent (i-stat)
  - Multi-site validations of reagent shipments
  - Monthly 3 level QC versus 6 month cal verifications

What Have We Learned From Our IQCPs?

- Before: (QC the device)
  - Shipments = 10 shipments/yr x 2 QC x 7 sites = 140 tests
  - Lot validations = 5 x/yr x 2 levels x 8 meters = 80 tests
  - QC monthly = 2 QC x 8 i-stats x 12 mos = 192 tests
  - 6 mo cal-ver = 8 i-stats x 3 levels x 3 reps x 2x/yr = 144 tests
  - 6 mo correlations = 10 patients x 8 i-stats x 2x/yr = 160 tests

  TOTAL = 716 tests

- After: (QC the reagent)
  - Shipments = 4 shipments/yr x 3 QC x 1 site = 12 tests
  - Lot validations = QC shipment, max 4x/yr x 5 pts x 2(old/new) 40 tests
  - QC monthly = 3 QC x 7 sites x 12 mos = 252 tests
  - If additional lot: 3 QC x 7 sites x 4 mos 84 tests
  - 6 mo cal ver and pt correl already done monthly QC/lot val = 0 tests

  TOTAL = 304/(388) tests

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Savings of nearly half each year!

Summary

- IQCPs are more than reducing the frequency of QC
- IQCPs provide opportunity for laboratories to interact with clinical departments on a shared QI project
- Improve workflow and operational efficiency
- IQCPs justify our actions, giving meaning to why we need to perform certain activities – beyond meeting regulations
- IQCPs enhance interdisciplinary communication

- I want to thank Lou Ann Wyer (Sentara) and Nichole Korpi-Steiner, Ph.D. (UNC) for use of their slides in this presentation!