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AACC Better health through laboratory medicine.

Best Practices in Risk Assessment and Risk Management

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Objectives

1. Define the Risk Management process
2. Identify CLSI EP23 guideline as a resource for risk management
3. Discuss what we have learned from developing IQCPs

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What is Risk?

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What is Risk?

- Risk – the chance of suffering or encountering harm or loss (Webster's Dictionary and Thesaurus, 1993 Landoll, Ashland, Ohio)
- Risk can be estimated through a combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51)
- Risk essentially is the potential for an error to occur
- Risk management is the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971)
- Risk management encompasses recognizing the potential for errors and taking steps to minimize or reduce those errors

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CLSI EP23 Risk Management Process

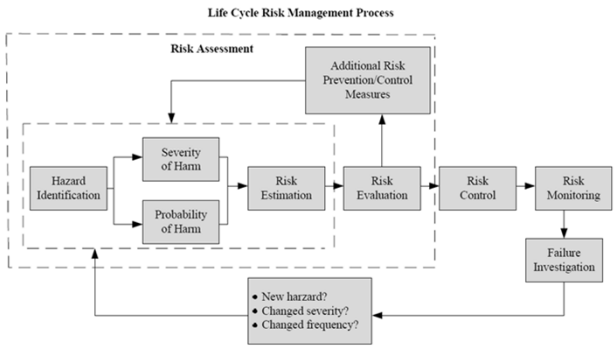

Figure 2. Risk Management Process

CLSI Document EP23

- *Laboratory Quality Control Based on Risk Management; Approved Guideline (EP23-A™)*
- James H. Nichols, PhD, DABCC, FACB, Chairholder of the document development committee
- EP23 describes good laboratory practice for developing a QCP based on the manufacturer's risk mitigation information, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting.

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Industrial Risk Management

- Manufacturers consider potential for errors and address how these hazards are mitigated or reduced in FDA submissions based on "use-case scenarios"
- Use-case scenarios describe real-world examples of how one or more people interact with a device
- For example:
  - A POCT device may be taken to the patient's bedside, or
  - A sample may be collected and transported to a device
- These two scenarios have different workflows and present different opportunities for error or risks!

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History

- QC is historical means of reducing risk in the laboratory!
- CLIA 88 requires 2 levels of QC each day of testing!
- Newer lab devices offer internal and engineered control processes that make daily liquid QC duplicative and redundant.
- IQCP allows laboratories to develop a plan that optimizes the use of engineered, internal control processes on a device and balances the performance of external liquid QC without impacting safety!
- CLSI EP23 introduces industrial and ISO risk management principles to the clinical laboratory
- CMS adopted key risk management concepts to develop the IQCP option for quality control

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New IQCP

- Two levels of liquid QC required each day of testing

OR

- Laboratory develops an IQCP:
  - Balance internal control processes with external controls
  - Reduce frequency of liquid QC to minimum recommended by manufacturer
  - Maximize clinical outcome, available staff resources and cost effectiveness in the lab
  - Considers the laboratory use-case scenario – process for testing and risk of errors at each step of the testing process!

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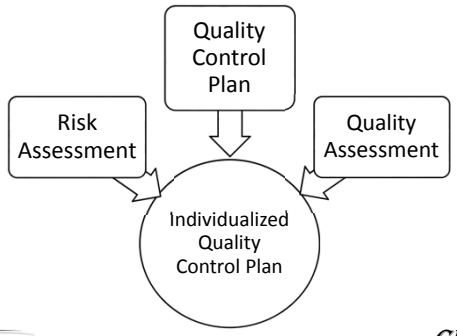
Individualized Quality Control Plan



CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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CLIA

Risk in the Laboratory

- There is no "perfect" laboratory device, otherwise we would all be using it!
- Any device can and will fail under the right conditions
- A discussion of risk must start with what can go wrong with a test (errors or nonconformities)
- Lab tests are not fool-proof!

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Where is the Risk in the Process?

What Could Possibly Go Wrong?

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Falsely Decreased Glucose Results

- Complaint from an ICU of sporadic falsely decreased glucose results
- Immediate repeat test on same meter, gave significantly higher "clinically sensible" values
- Inspection of unit found nurses taking procedural shortcuts to save time
- Bottles of test strips dumped on counter in spare utility room
- Some strips not making it into trash, falling back on counter and being "REUSED"

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Risk of Error from Open Reagents

- Glucose test strips exposed to air for as little as 2 hours have been shown to cause -26% bias.[1]
- Strips left on counters pose risk of reuse, leading to falsely low results.
- Some meters catch reuse and "error" preventing a result. Other meters do not![2]

1. Keffer P, Kampa IS. *Diabetes* 1998; 47; abs 0170.
2. Silverman BC, Humbertson SK, Stem JE, Nichols JH. Operational errors cause inaccurate glucose results. *Diabetes Care* 2000;23:429-30.

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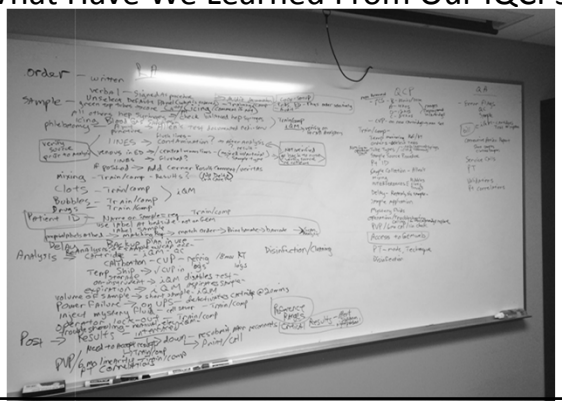
What Have We Learned From Our IQCPs?



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What Have We Learned From Our IQCPs?

- Processes on different units were not uniform
  - Some units complained that they couldn't print a barcode for blood gas specimens until after sample collected. (because order hadn't been communicated to lab and blood gas system) staff created workarounds, skipped steps, labeling sample at analyzer rather than at bedside
  - In reality, workflow issue that simply required some retraining. Staff print order entry barcode, then match to order/requisition at bedside, collect and label at bedside, scan at analyzer
  - Simplified uniform process hospital-wide, safer for pts

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What Have We Learned From Our IQCPs?

- Devices not setup uniformly
  - IQCP development revealed that operator lockout used for most devices
  - One model of POCT coag device was not setup with operator lockout – compliance concern, anyone can test!
  - Corrected problem
- Harmonized use of lockout across devices. Discrepancy was discovered by multidisciplinary meetings and communication about practices!

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What Have We Learned From Our IQCPs?

- Device/reagent shipments check-ins are inconsistent
  - New cartridge shipments = analyze 2 levels QC each site
  - New lot of cartridge = 2 levels QC on all i-stats
  - QC each i-stat monthly, 2 levels of QC on all i-stats
  - 6 mo cal verification = 3 levels x 3 (triplicate) x each i-stat
  - 6 mo correlation = 10 patients per i-stat
- We QC the i-stats, but chemistry is in the cartridge not the analyzer! Each site receiving different lots of cartridges at different times and not performing QC across all lots each month!

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What Have We Learned From Our IQCPs?

- Revised based on IQCP
  - Low, normal, high QC are same vials as in linearity set, so analyzing 3 levels QC is same as a 3 level linearity check!
  - Reduce replicates and emphasize on cartridge lots
  - Consolidate shipments (ie life-flight 7 locations), central shipment, validation then distribute cartridges to sites
  - Each shipment, 3 levels of QC
  - New lots, 3 levels of QC, 5 pts old lot to new lot, 1 i-stat
  - Monthly 3 levels of QC each cartridge type, 1 i-stat at each site documents cartridge viability at site storage and satisfies 6 month linearity (already done each month)

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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

Savings of nearly half each year!

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What Have We Learned From Our IQCPs?

- i-Stat IQCP now controlling the reagent not the device
- Improved quality - Operators now perform all the required testing – before the POCT staff would analyze linearities and perform 6 mo comparisons
- Enhanced efficiency – fewer cartridges required for non-patient testing, saves cost and resources
- Better quality assurance of cartridges – QC each lot of cartridges monthly (the i-stat has internal checks)!

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Benefits of Developing an IQCP

- Promotes multidisciplinary communication and collaboration
- Identifies weaknesses in the testing process
- Uncovers discrepancies between sites, allowing for harmonization of workflow and operations
- Establishes rational for actions – why we do specific activities – like QC and what hazards are addressed
- Improves efficiency and saves costs

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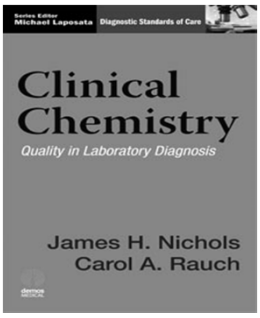
Resource for Reducing Errors

- Clinical Chemistry book recently released!
- Focus on errors in the Chemistry Laboratory including POCT
- Discussion of real-world errors and what can be done to detect and prevent errors.



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Don't Be Discouraged— Risk Management Is Documenting Much of What We Already Do!

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Summary

- Risk management requires the laboratory to follow the path of their specimens and look for weaknesses and sources of error in their testing process.
- Like industrial use-case scenarios – get out of the lab and monitor the processes, speak with the operators and understand how devices are being used
- IQCPs bring together the lab with the various users and provide opportunity to reveal discrepancies in practice
- We have uncovered a number of unexpected sources of error in developing our IQCP and the process has improved efficiency and quality of our POCT

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