Integrating Quality and Compliance into POCT:

I don't know but I've been told, POC Programs can be SMART and BOLD!

Speaker Financial Disclosure Information

- I am employed by Instrumentation Laboratory

Objectives
After this session the learner will be able to:

- Discuss ways to focus on quality management, risk reduction for performance improvement, and meet accreditation compliance

- Recognize available resources for POCCs, Managers, Lab Directors to help prepare POC staff for inspections
Integrating Quality-Risk Management & Quality Management

Risk Management is a systematic approach to:
- Analyze
- Evaluate
- Control
- Monitor risk

CLSI EP23 Risk Management Focus

Integrate Quality = Declare War on Errors (Risks)


CLSI. www.CLSI.org.
Quality Management-COLA

COLA NEWS RELEASE

• Laboratory Training and Education

Specimen collection, labeling, storage, and other steps of the pre-analytical testing phase account for 46 to 68 percent of laboratory errors in the Total Testing Process. Yet, often allied health professionals with limited laboratory experience and training are responsible for these functions. Furthermore, over 120 unregulated point-of-care testing analytes, which contribute to diagnostic decisions, require no specialized laboratory training at all. Regardless of the complexity of the test being performed, and regardless of the level of education possessed by the person doing the testing, maintaining and following the highest quality standards should be a universal priority. The laboratory should promote increased education and training on laboratory quality to all individuals performing any type or component of the testing process.

http://www.cola.org/4144

Quality Management-COLA

QA ASSESSMENT

1.1

There are established written quality improvement programs, complete with policies and procedures for ongoing evaluation of test results accuracy, cost control, compliance with the regulations, and laboratory team education and training. The program includes a formal quality improvement plan and a quality improvement committee that reviews the plan regularly.

The program should include the following:

• A formal quality improvement plan
• A quality improvement committee
• A formal quality improvement process
• A formal quality improvement procedure

The program should be reviewed and updated annually.

Quality Management-COLA

Prior to patient testing, have each of the following performance specifications been established and documented for each non-suspected test in medical (SBM)?

2019 Additions!

Other performance characteristics may be required for test performance including liveness by:

Usr 11.1

Note: the laboratory established requirements for species susceptibility, including storage temperature and specimen age requirements.

The test procedure must include criteria for specimen rejection, including specimen transport, storage, and age limitation criteria established by the laboratory and approved by the Laboratory Director.

Usr 11.2.2

In part of the method validation, the laboratory must evaluate the potential risk of cross-contamination between samples, and the procedure must include identification, investigation, and correction of errors due to cross-contamination.
The laboratory collects data on the following: Processes or outcomes related to handling specimens, including specimen collection, labeling, preservation, transportation, and rejection.
Quality Management-CAP

The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases
1. Patient/Specimen Identification
2. Test Order Accuracy
3. Specimen Acceptability
4. Stat Test Turnaround Time
5. Critical Result Reporting
6. Customer Satisfaction
7. Corrected/Amended Reports

Evaluating effectiveness of corrective actions
TIE TO YOUR HOSPITAL INITIATIVES TO HELP WITH LABORATORY REGULATORY AWARENESS

ECRI Institute
Patient Safety Organization
Laboratory Events by Phase

From the ECRI Institute PSS Deep Dive: An Examination of “Lab" Errors

Analytic | Post-Analytic | Pre-Analytic
4% | 22% | 74%
What are common pre-analytical errors in POCT?
Quality Management-SMART GOALS

Data!
"Show me the money!"

Quality Management-
Occurrence Management-Analytics
Reduction of redraws, rework

Quality Management - Data/Analytics
Use Your Data (Proof)

Corrective Action Report:
- already reviewing regularly & can help with redraw reduction strategies

Sample Handling:
- Can be key in reducing redraws

Quality Management - Analytics/Data
Help “train against” errors:
- Use pictures, mnemonics and/or patient safety stories

Swollen Finger means Errors Linger!

You don’t get the right results unless you mix well!

Use what you already review!
be bold

11/4/2019
Use a soft touch.....

Accreditation RESOURCES TO HELP

Resources are available-COLA
Resources are available-JC

Resources are available-CAP

Top POC Deficiencies Cited
- Competency for nonwaived
- Qualifications of TC
- QC Frequency-waived
- Monthly QC review
- Competency for waived
- QC Frequency-nonwaived
OBJECTIVE: To accurately, efficiently and effectively track elements of competency for the point of care testing (POCT) department at a multi-site pediatric hospital system via electronic means.

RESULTS & CONCLUSION: The first production interface run resulted in the update of approximately 1500 operators. This occurred in a matter of seconds. This report run is scheduled on a daily basis and an alert occurs within QML if issues arise. The implementation of an e-learning interface drastically reduces the number of hours needed each year to update POCT competencies. It allows the POCT department to smoothly meet regulatory compliance for competency assessment tracking and it also eliminates the number of errors that occur with manual editing of competency updates and QML operator records each year. The time saved in the POCT department will be used to concentrate on other quality initiatives, instrumentation and regulatory compliance.
In Summary

- Integrating Quality=War on Errors!
- Regulatory focus on performance improvement with quality indicators that focus on error detection, correction and prevention
- Use Connectivity, Data/Analytics & Resources to help improve regulatory compliance and staff inspection readiness
- Resources and Reference links available
  - EMAIL KSkala@ILWW.com

Resources

References
Questions & Wrap Up

- jmumfor3@jhmi.edu
- khalverson@ilww.com
- pmann@UTMB.EDU
- lwyer@cox.net
- kskala@ILWW.com

THANK YOU FOR ATTENDING!