

Reducing Laboratory Errors Through Risk Management

*James H. Nichols, PhD, DABCC, FACB
Chairholder*

EP23 Document Development Committee

Professor of Clinical Pathology, Microbiology and Immunology

Associate Medical Director of Clinical Operations

Vanderbilt University School of Medicine

Medical Director, Clinical Chemistry

Nashville, Tennessee, USA

james.h.nichols@vanderbilt.edu

Objectives

1. Identify common sources of laboratory error
2. Recognize CLSI EP23 guideline as a resource for risk management
3. Describe how to develop an Individualized Quality Control Plan to meet the new CLIA interpretive guidelines

History

- 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
- IQCP allows laboratories to develop a plan that optimizes the use of engineered, internal control processes on a device and the performance of external liquid QC

Definitions

- A “Quality Control Plan” –from CLSI EP23 – a document that describes the practices, resources, and sequences of specified activities to control the quality of a particular measuring system or test process to ensure requirements for its intended purpose are met.
- An “Individualized Quality Control Plan (IQCP)” – from CMS CLIA Interpretive Guidelines – a new quality control option based on risk management for CLIA laboratories performing nonwaived testing.

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

Risk Management

- Risk management is not a new concept; laboratories:
 - Evaluate the performance of new devices.
 - Troubleshoot instrument problems.
 - Respond to physician complaints.
 - Estimate harm to a patient from incorrect results.
 - Take actions to prevent errors.
- Risk management is a formal term for what clinical laboratories are already doing every day.

Risk Management Definition

- Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971)

Risk Definition

- Risk – the chance of suffering or encountering harm or loss (*Webster's Dictionary and Thesaurus*. Ashland, OH: Landall, Inc.; 1993).
- 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 that could lead to patient/staff harm.
- Detection mechanisms – like liquid quality control, can help detect and prevent errors before they impact patient care. (detection mechanisms lower risk)

Managing Risk With a Quality Control Process



Quality Control

- Advantages
 - QC monitors the end product (result) of the entire test system.
 - QC has target values: if assay recovers the target, then everything is assumed stable (ie, instrument, reagent, operator, sample).
- Disadvantages
 - When a problem is detected, one must go back and reanalyze patients since the last “good” QC.
 - If results are released, then results may need to be corrected.
- Need to get to fully automated analyzers that eliminate errors up front
 - Until that time, need a robust QC plan (QCP)

Types of Quality Control

- “On-Board” or Analyzer QC – built-in device controls or system checks
- Internal QC – laboratory-analyzed surrogate sample controls
- External QC – blind proficiency survey
- Other types of QC – control processes either engineered by a manufacturer or enacted by a laboratory to ensure result reliability



Laboratory- Manufacturer Partnership

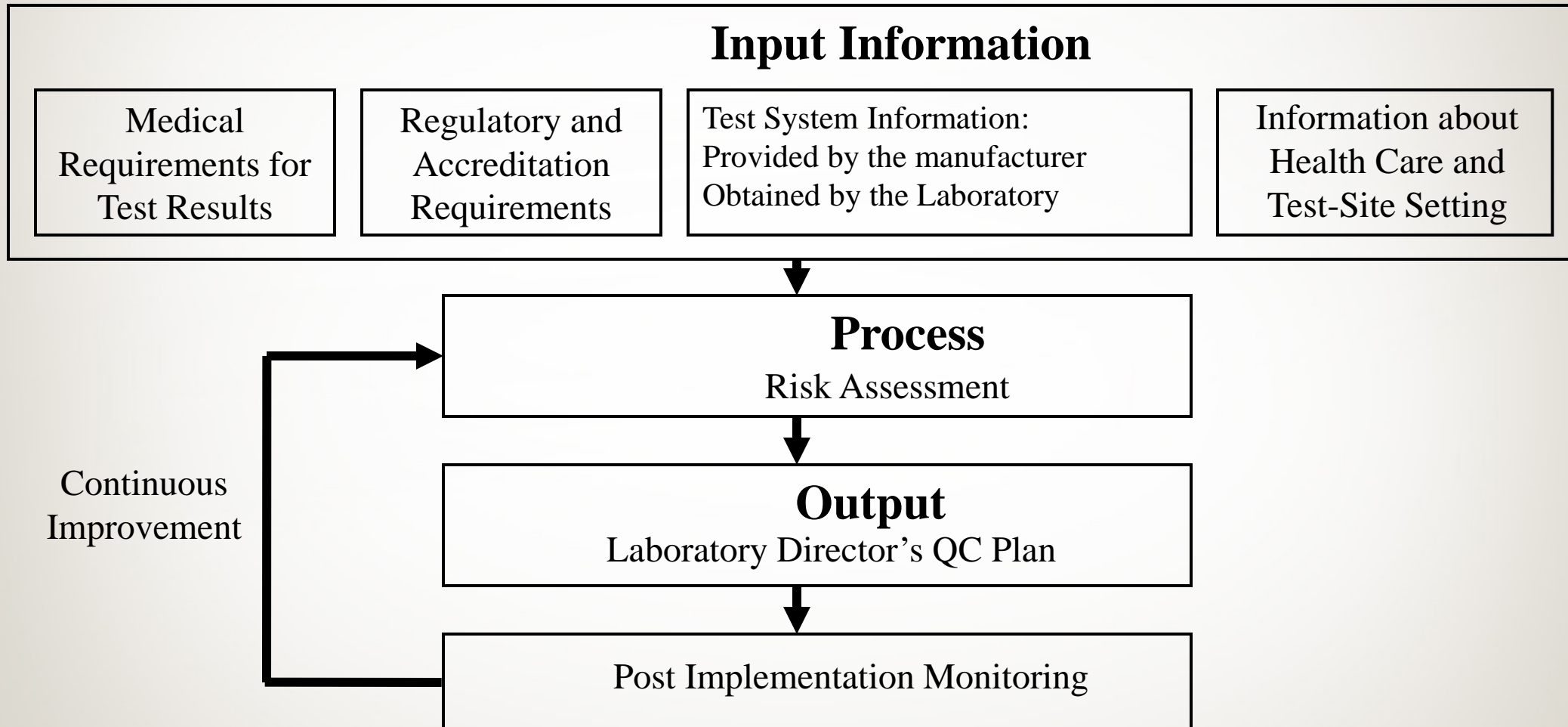
- No single QC procedure can cover all devices, because the devices may differ.
- Newer devices have built-in electronic controls, and “on-board” chemical and biological controls.
- Developing a quality plan surrounding a laboratory device requires a partnership between the manufacturer and the laboratory.
- Some sources of error may be detected automatically by the device and prevented, while others may require the laboratory to take action, such as analyzing surrogate sample QC on receipt of new lots of reagents.
- Clear communication of potential sources of error and delineation of laboratory and manufacturer roles for how to detect and prevent those risks is necessary.

ISO. *Clinical laboratory medicine – In vitro diagnostic medical devices – Validation of user quality control procedures by the manufacturer*. ISO 15198. Geneva, Switzerland: International Organization for Standardization; 2004.

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.

EP23 Laboratory QC Based on Risk Management



EP23 Laboratory QC Based on Risk Management

Create a Process Map
(Preanalytic – Analytic – Postanalytic)



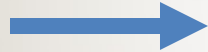
Identify Weaknesses in the Process



Define a Process that will Mitigate Risk



Summarize Processes and Actions in a
QC Plan



POCT

- Dozens of sites
- Hundreds of devices
- Thousands of operators!
- Too many cooks...
 spoil the broth!
- The number of sites, devices and operators plus the volume of testing creates a situation where rare events can become probable in every-day operations



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”

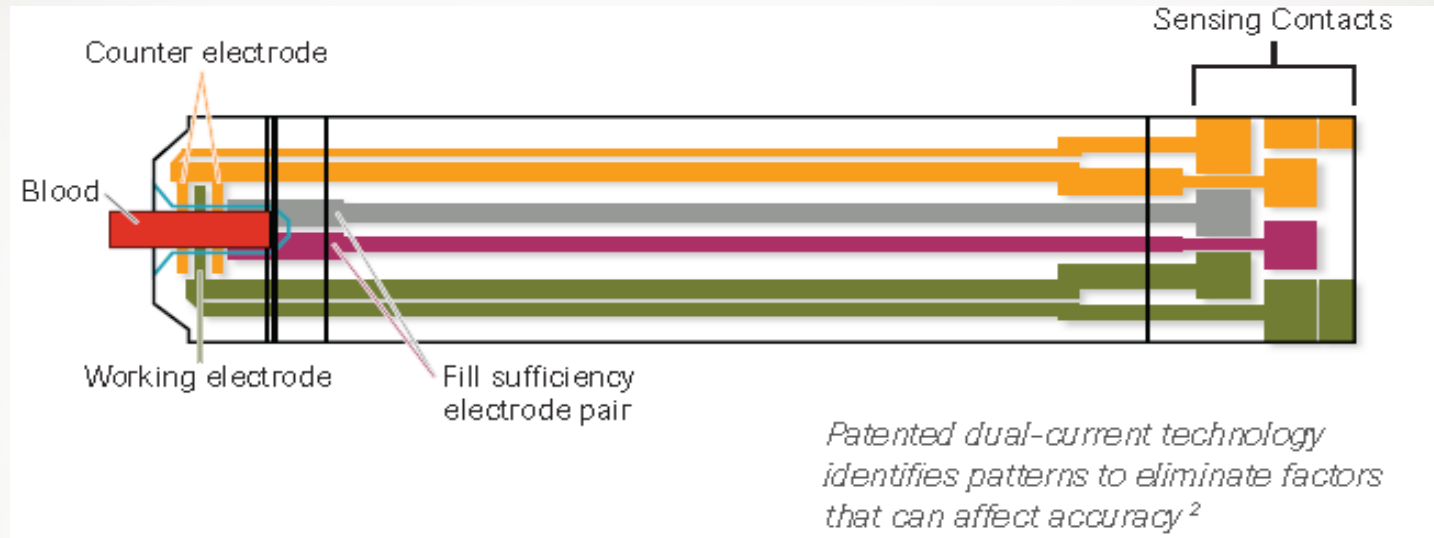
Risk of Error from Open Reagents

- 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

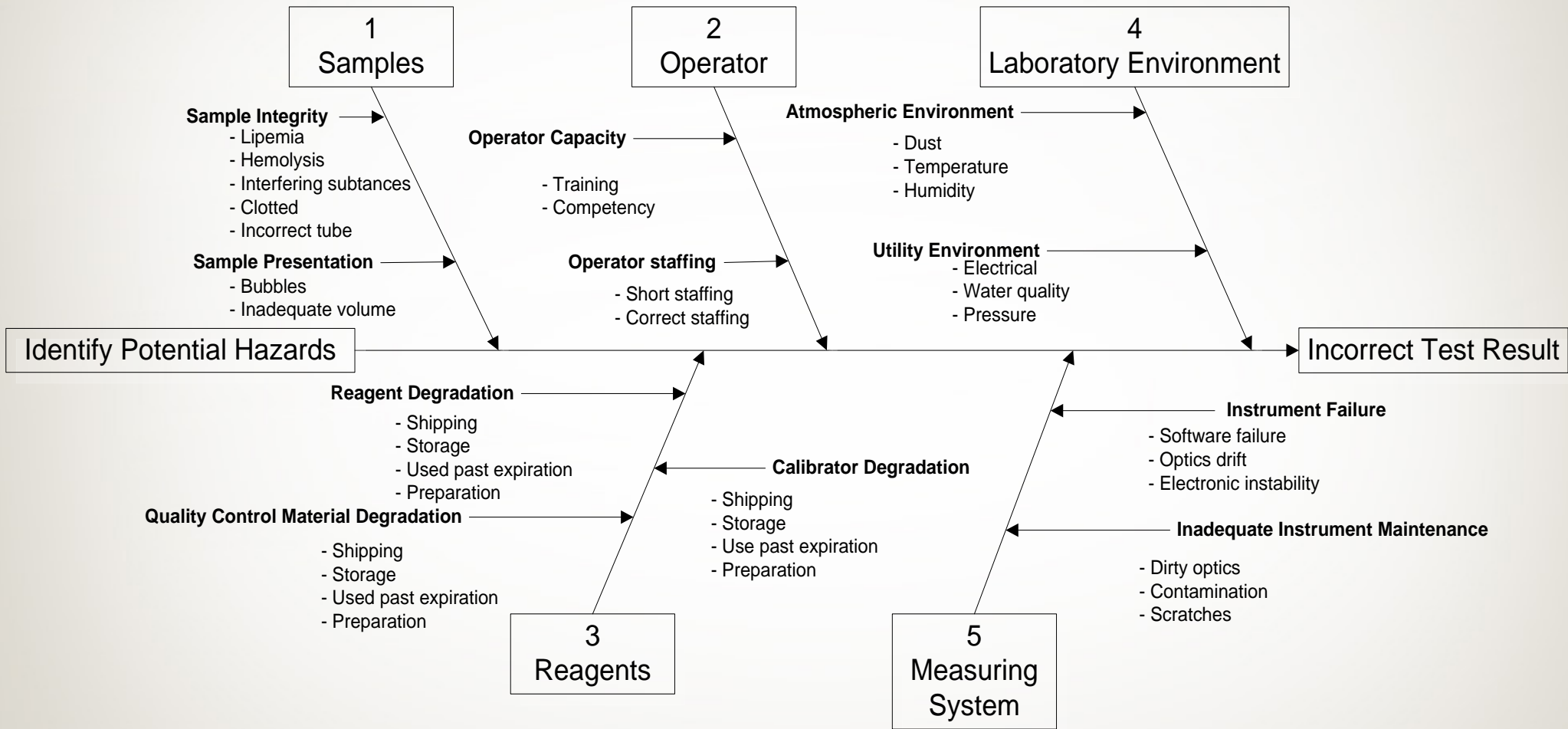


1. Keffer P, Kampa IS. *Diabetes* 1998; 47; abs 0170.
2. Silverman BC, Humbertson SK, Stem JE, Nichols JH. Operational errors cause inaccurate glucose results. *Diabetes Care* 2000;23:429-30.

Manufacturer Engineered Checks



- Internal test strip checks can detect damage or abuse to strip (scratches, humidity, temperature)
- Used or wetted test strips
- Strip and code key match
- Compensate for hematocrit and temperature

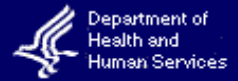


Sample Errors: Interferences

- Analytic error
- Maltose (Glucose dehydrogenase PQQ) falsely increased results
- Acetaminophen falsely increased results on glucose dehydrogenase and falsely decreased results on some glucose oxidase meters,
- Vitamin C falsely increases results on some glucose dehydrogenase and falsely decreases results on glucose oxidase meters.



U.S. Food and Drug Administration



CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

[FDA Home Page](#) | [CBER Home Page](#) | [CBER A-Z Index](#) | [CBER Site Map](#) | [Contact CBER](#)

- What's New
- Allergenic
- Blood
- Cellular & Gene Therapy
- Devices
- Tissues
- Vaccines
- Xenotransplantation

- Compliance & Surveillance
- Consumer & Healthcare Information
- eFOIA Reading Room
- Industry
- Meetings
- Product Information
- Research

Fatal Iatrogenic Hypoglycemia: Falsely Elevated Blood Glucose Readings with a Point-of-Care Meter Due to a Maltose-Containing Intravenous Immune Globulin Product

Ann Reed Gaines, Ph.D., MT(ASCP)
Office of Biostatistics and Epidemiology (HFM-220)
Center for Biologics Evaluation and Research

L. Ross Pierce, M.D.
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Patricia A. Bernhardt, B.S., MT(ASCP)
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiologic Health

INTRODUCTION

In July 2005, the Food and Drug Administration (FDA) received a case report of an elderly male diabetic patient who received a 10% maltose-containing intravenous immune globulin product (Octagam,¹ Octapharma Pharmazeutika Produktionsges m.b.H., Vienna, Austria) and experienced hypoglycemic coma and irreversible neurological damage secondary to excessive insulin administration. His insulin dosing was guided by falsely elevated blood glucose measurements that were obtained from a point-of-care glucose meter (Accu-Chek Inform meter,² Accu-Chek Comfort Curve test strips,^{2,3} Roche Diagnostics, Indianapolis, IN, U.S.). The glucose meter test strips used glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) methodology,⁴ which may overestimate measurements^{3,4} when blood maltose levels exceed 0.9 mmol/L.³

Adverse events have been reported for immune globulin products that contain maltose,⁵⁻¹⁰ which functions as a protein stabilizer¹¹⁻¹³ and an osmotic agent.^{14,15} Similar adverse events have been reported for Extraneal (Baxter

Search

powered by

CBER Information

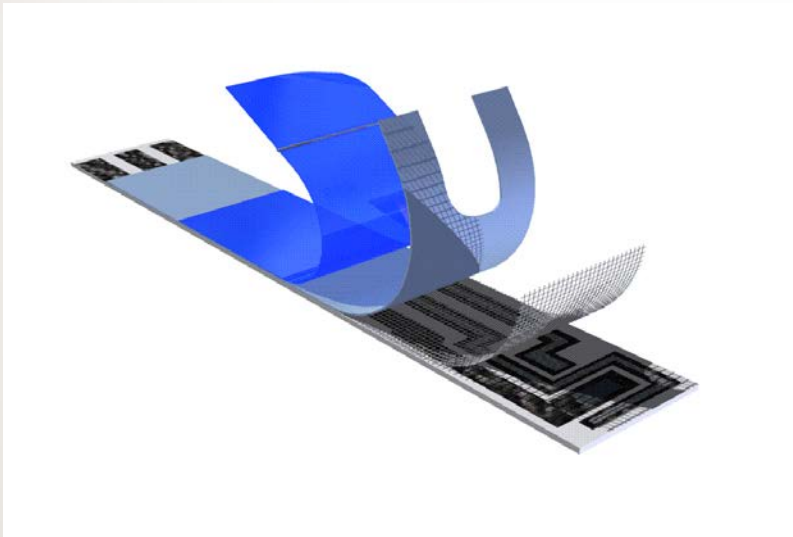
- About CBER
- CBER's Email Lists
- Contact CBER
- Frequently Asked Questions
- Jobs at CBER
- Organization Charts

Useful Government Sites

- USA.gov

Sample Errors: Interferences

- Minimize test interference at the bedside.
 - Select technologies not affected by common medication interferences
 - Watch for maltose, icodextrin, and other common substances like ascorbic acid known to interfere with glucose meters at elevated levels.
 - Assess bias from oxygen and hematocrit effects.

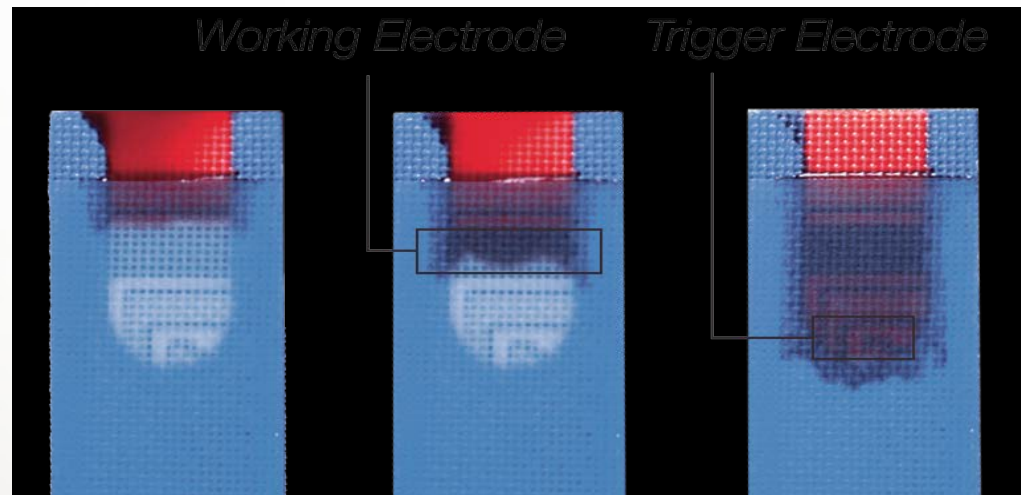


Sample Errors: Interferences

- No current control process for hemolysis
- Problem with whole blood sampling on blood gas and electrolyte analyzers for K⁺
- We centrifuge all whole blood samples before reporting K⁺ to detect hemolysis and comment results!
- What about applying too much/too little sample?

Sample Errors: Specimen Volume

- Some glucose meters recommend that operators visually inspect strips for uniform color development after each test (detects underfilling and bubbles)
- Other meters have automate sample detection. (Fill-trigger is designed to prevent short-sampling.)
- Test starts only when enough blood has been applied.



Operator Errors: Training/Competency

- Operator lockout
- Functions through number code or barcoded ID
- List of operators and training/competency dates maintained in data manager system–
- Devices can warn operators of impending certification due dates (in advance of lockout)
- Newer U.S. CLIA Interpretive Guidelines requires 6 elements of competency for moderate complexity tests
 - Includes – 1 observe test performance, 2 result recording, 3 intermediary worksheets (QC, PT, maintenance), 4 observe maintenance, 5 analyze sample of known concentration, 6 problem-solving – Competency documentation not fully automated!
- Infrequent operator competency, need intuitive devices
- Note – operators can share ID numbers to access override lockout!

Operator Errors: Performing QC

- Devices require periodic liquid QC
- Operators are patient focused and can forget to run QC, or fail QC targets, and proceed with patient testing.
- QC lockout shuts off patient testing if QC not performed or fails target ranges.
- Prevents patient testing unless QC documented
- Operators workaround QC lockout by performing patient testing in QC mode!
- Newer devices distinguish QC samples, prevent patient testing in QC mode and can also warn when operators run a high QC for low range QC and vice-versa.

Operator Errors: Patient Identification

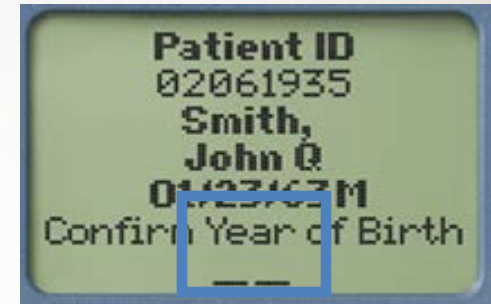
- Incorrect entry of patient identification can
 - Chart results to the wrong patient's medical record
 - Lead to inappropriate medical decisions and treatment
 - Improper billing and compliance
- Barcoded patient wristbands reduce the chance of misidentification, but patients can be banded with:
 - Another institution's identification
 - Outdated account numbers
 - A wrong patient's wristband
- Residual risk of error even with barcoded ID bands
- Barcoded ID entry alone doesn't satisfy requirement for patient safety - 2 unique identifiers

National Patient Safety Goals

- **Joint Commission:** *“Use at least two ways to identify patients. For example, use the patient’s name and date of birth. This is done to make sure that each patient gets the correct medicine and treatment.”*
- **College of American Pathologists:** *“Personnel must confirm the patient’s identity by checking at least two identifiers before collecting a specimen. For example, an inpatient’s wristband may be checked for name and unique hospital number; an outpatient’s name and birth date may be used.”*

Operator Errors: Patient Identification

- Some devices have positive patient ID
– ADT feed to device
- Two identifiers plus active confirmation (also satisfies Joint Commission time out)
- Positive patient ID reduced errors from 61.5 errors/month to 3 errors/month.¹ (unregistered patients; 2 ED and 1 non-ED) conducted over 2 months—38,127 bedside glucose tests.



J Pathol Inform

Technical Note

Reducing patient identification errors related to glucose point-of-care testing

Gaurav Alreja¹, Namrata Setia², James Nichols², Liron Pantanowitz³

¹Department of Internal Medicine and ²Pathology, Baystate Medical Center, Tufts University School of Medicine, Springfield, MA, ³Department of Pathology, University of Pittsburgh Medical Center, Pittsburgh, PA, USA

E-mail: *Liron Pantanowitz – pantanowitzl@upmc.edu
*Corresponding author

Received: 31 July 10

Accepted: 27 November 10

Published: 11 May 11

This article may be cited as:
Alreja G, Setia N, Nichols J, Pantanowitz L. Reducing patient identification errors related to glucose point-of-care testing. J Pathol Inform 2011;2:22.

Copyright © 2010 Alreja G. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Abstract

Background: Patient identification (ID) errors in point-of-care testing (POCT) can cause test results to be transferred to the wrong patient's chart or prevent results from being transmitted and reported. Despite the implementation of patient barcoding and ongoing operator training at our institution, patient ID errors still occur with glucose POCT. The aim of this study was to develop a solution to reduce identification errors with POCT. **Materials and Methods:** Glucose POCT was performed by approximately 2,400 clinical operators throughout our health system. Patients are identified by scanning in wristband barcodes or by manual data entry using portable glucose meters. Meters are docked to upload data to a database server which then transmits data to any medical record matching the financial number of the test result. With a new model, meters connect to an interface manager where the patient ID (a nine-digit account number) is checked against patient registration data from admission, discharge, and transfer (ADT) feeds and only matched results are transferred to the patient's electronic medical record. With the new process, the patient ID is checked prior to testing and testing is prevented until ID errors are resolved. **Results:** When assessed over a period of 2 months ID errors were reduced to 3 errors/

1. Alreja G, Setia N, Nichols J, Pantanowitz L. Reducing patient identification errors related to glucose point- of-care testing. J Pathol Inform 2011; 2: 22
[<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3097526/>]

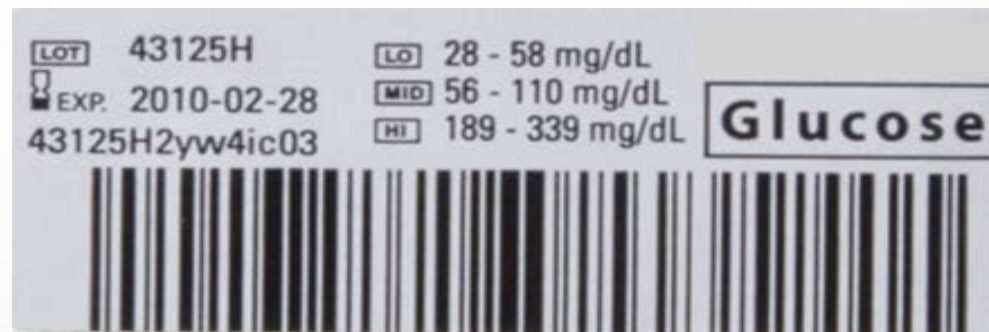
Operator Errors: Data Transfer

- POCT results may not get recorded in patient's medical record, particular problem for manual tests
- POCT data management ensures capture of data in device (QC and Patient results), but doesn't guarantee transfer until operators dock device
- Wireless ensures data transmitted to patient record. (Need continuous wireless or operators may forget to push send button)



Reagent Errors: Calibration

- Incorrect entry of calibration code can lead to inaccurate test results
- Devices have automatic calibration via barcode scanning of reagent vials/strips. (no code chips or risk of wrong calibrator codes)



Reagent Errors: Expired Reagents



- **Centers for Disease Control**
- “Check and record expiration dates of reagents/kits, and discard any reagents or tests that have expired.”¹
- **U.S. Food and Drug Administration**
- “Check the expiration date on the test strips. As a test strip ages, its chemical coating breaks down. If the strip is used after this time, it may give inaccurate results.”²

1. Ready? Set? Test! Centers for Disease Control booklet <http://wwwn.cdc.gov/dls/waivedtests/ReadySetTestBooklet.pdf>

2. Useful Tips to Increase Accuracy and Reduce Errors in Test Results from Glucose Meters, U.S. Food and Drug Administration <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109519.htm>

Strip Wastage When Outdated

- Operator must check manufacturer's expiration date prior to testing.
- Vials/strips and controls must be manually dated when opened by operator (prematurely expires once opened)
- Undated, opened vials must be discarded. (? expiration)

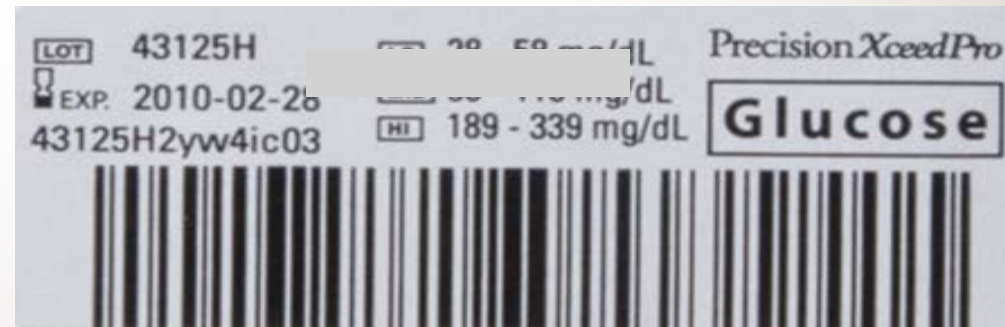


Discarded strips due to no date¹

1. Undated vials between September, 2010 and May, 2011, Willis-Knighton Medical Center, Shreveport, Louisiana

Reagent Errors: Expired Reagents

- Serialized vials/strips and controls barcoded for lot number and expiration date (good to stamped expiration date) can recognize individual vials on opening (30, 60 or 90 day open expiration)
- Automatic lockout for expired test strips and controls
- Some devices can also recognize exposure to humidity (few hours), wet or reused strips as additional control measure



Environment Errors: Temperature

- Devices can fail if used under temperature extremes
- Traveling nurses storing devices/strips and controls in cars during summer heat and winter cold
- We experienced increased temperature errors after switching glucose meters in our ambulances
 - Old temp range 0° - 46° C New temp range 15° - 40° C
- Worked with bioengineering student to design a heated carrier

Rust M, Carlson N, Nichols J. A thermo-modulating container for transport and storage of glucose meters in a cold weather environment. Point of Care 2012 in press.



Where is the Risk in the Process?



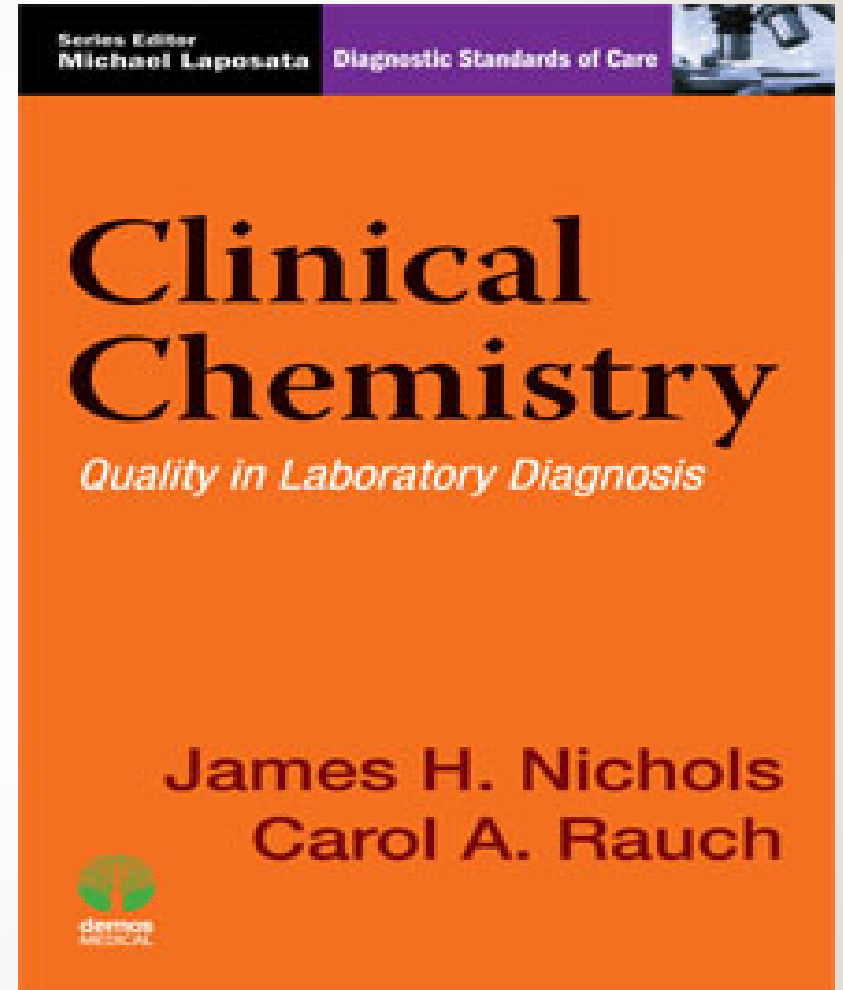
What Could Possibly Go Wrong?

Falsely Increased Hgb Results

- Spurious increased Hgb results 18 – 23 g/dL (55 – 70% Hct) on ICU patients
- Meter, QC and reagents examined and fine, no single operator tied to trend
- Continue to experience spuriously high results, trend went on for several weeks
- One day, POC coordinator watching operator perform Hgb test in spare utility room. Operator took shortcut (procedure is to load cuvette from fresh drop of well mixed sample)
- Instead, operator was filling cuvette from drop of blood remaining from glucose test. Test strip was absorbing plasma portion of sample and artificially increasing Hgb/Hct in remaining drop!
- Remedial action to retrain entire unit staff!

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.



The “Right QC” is IQCP

- CMS will incorporate key EP-23 concepts into CLIA Interpretive Guidelines (IG) as an alternative QC policy called IQCP (Individualized QC Plans)
- Effective Jan 1, 2014, IQCP will be implemented
- Existing CLIA QC & quality system concepts won't change
- No regulations will change!
- CMS' survey process won't change
- 2 year phase-in and educational process
- Accreditation agencies, CAP and Joint Commission will release more information in 2014.

The “Right QC” is IQCP

- Permits labs to develop an IQCP using many of their existing quality practices/information
- Is based on labs’ patient population, environment, test system, clinical uses, etc.
- Applies to CMS-certified non-waived labs
- IQCP is a choice & default is 2 external QC/day
- Labs must follow mfr’s. instructions if > CLIA
- Includes existing & new analytes/test systems

Individualized Quality Control Plan



Benefits of IQCP to Lab

- Single-use cartridge based methods – use engineered controls in lieu of 2 levels QC/day
- POCT analyzers – perform QC by lot of cartridge (using subset of devices) rather than every lot and each device.
- Core lab analyzers moderate and high complexity tests – helps labs identify weaknesses and appropriate actions to reduce risk of error (may need >2 levels QC/day)

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

© Original Artist

Reproduction rights obtainable from
www.CartoonStock.com

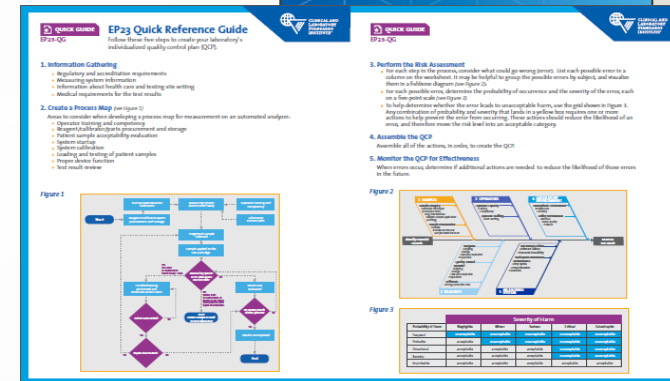
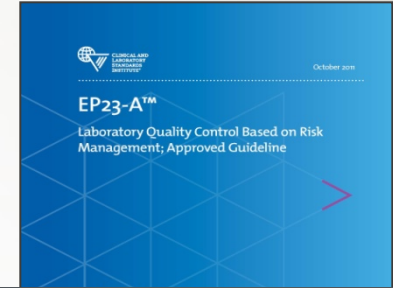


search ID: cwln2043

"It's called 'Shared Risk.' You taste the
Okra Casserole and I'll try the Tuna Surprise."

EP23 Online Workshop

- Education for individuals needing all the tools to help create the best IQCP
- Online program consists of 6 lessons:
 - Risk Management definition
 - Example IQCP
 - Workbook Tool
 - Worksheet Tool
 - CMS IQCP requirements
 - Summary
- Online program also contains homework and a virtual classroom discussion.



Summary

- Risk management is something laboratories are already doing. EP23 simply formalizes this.
- An IQCP assesses the medical need for test, performance requirements, and weaknesses in the testing process as well as actions to address those risks.
- Each IQCP is unique because the combination of device, setting, medical requirements and operators may differ between laboratories.
- An IQCP is the industry standard. It depends upon the extent to which the device's features achieve their intended purpose in union with the laboratory's expectation for ensuring quality results.
- Once implemented, the IQCP is monitored for effectiveness and modified as needed to maintain risk at a clinically acceptable level.