Risk Management in POCT: Eliminating Errors Before They Bite You!

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Objectives

1. Recognize common sources of laboratory error
2. Identify CLSI EP23 guideline as a resource for risk management and building an IQCP
3. Recognize the variety of engineered control processes manufacturers have built into POCT devices

History of Clinical Lab Risk Management

- 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.
- CMS implemented EQC in 2003 – equivalent QC
- 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 replaces 2003 EQC options currently in place.

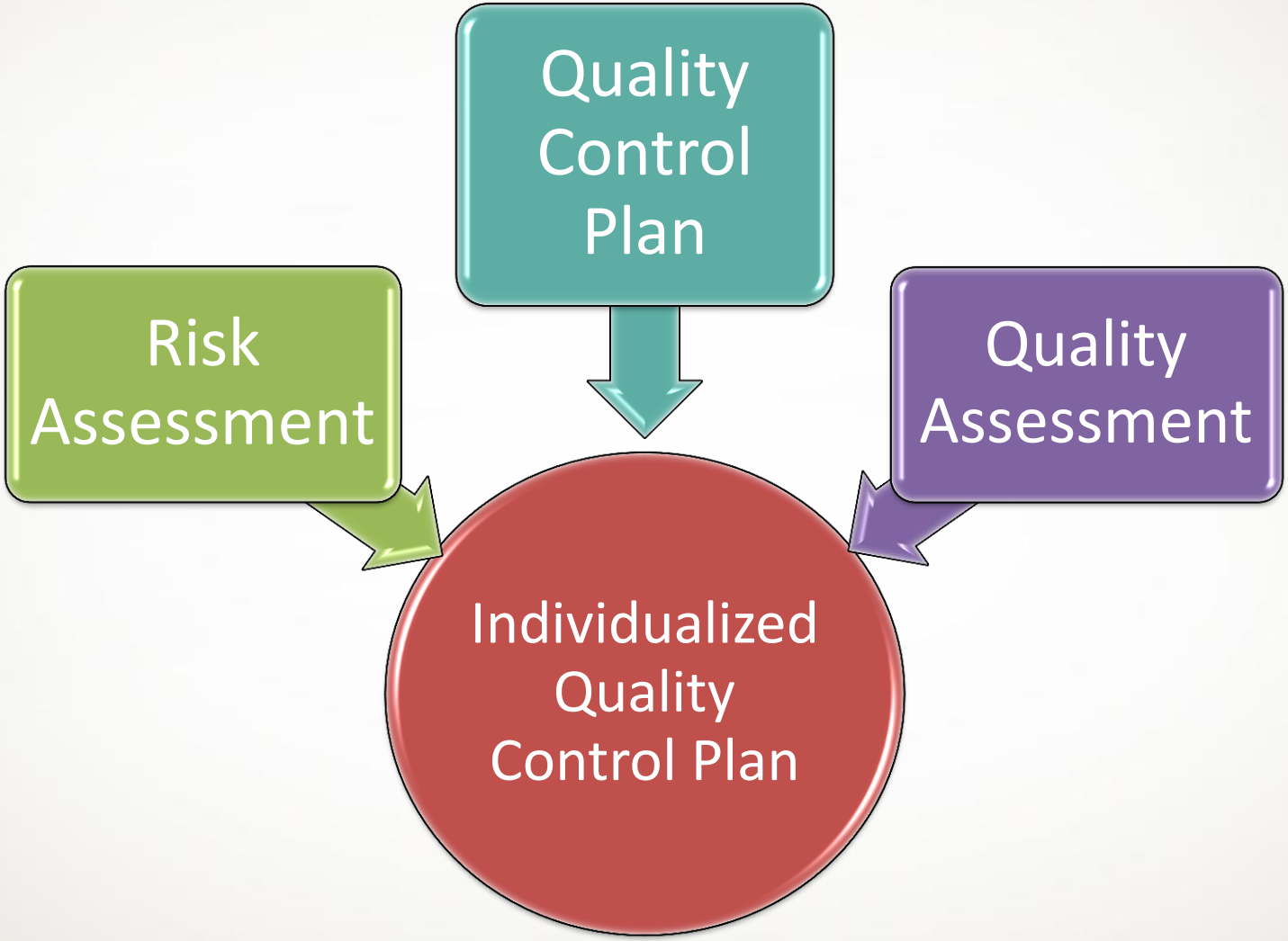
IQCP 2016

- 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

Individualized Quality Control Plan



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!

What Could Go Wrong?

Risk Mitigation

- Liquid quality control is historic means of detecting and preventing errors (nonconformities or incidents)!
  - Liquid controls detect systematic errors that affect every sample the same way (calibration errors, pipette errors, reagent degradation)
  - Liquid controls do a poor job at detecting random errors that affect a single sample uniquely (hemolysis, lipemia, clots, drug interferences)
  - For unit-use tests, liquid controls consume entire test and do not ensure performance of next test
- Newer devices have built-in electronic controls, and “on-board” chemical and biological controls.


IST-502T
Strep A Twist
Test Device
Strep A
LIFESCAN
BiliChek
RAPID FFN

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.

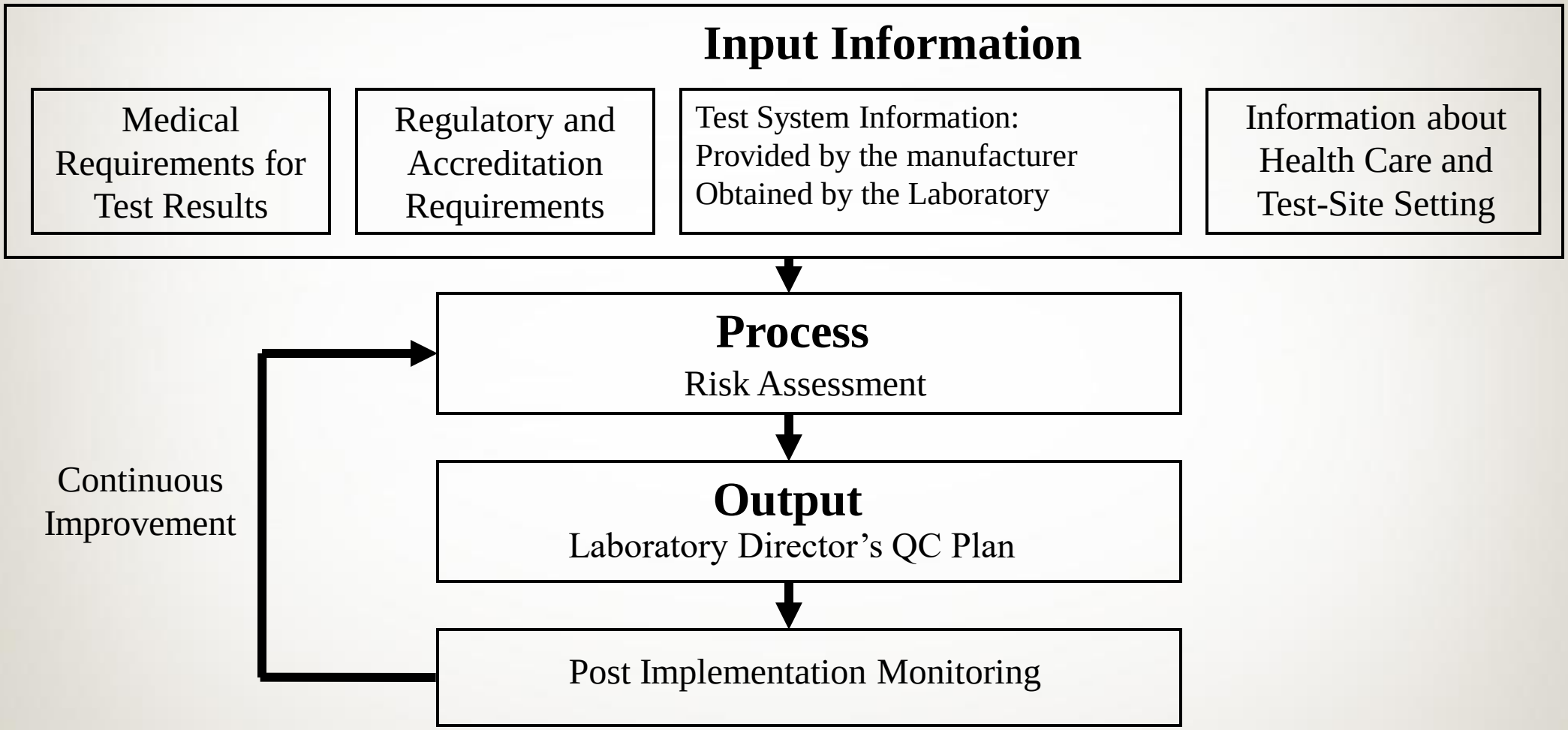
CLSI Document EP23

- *Laboratory Quality Control Based on Risk Management; Approved Guideline (EP23-A™)*

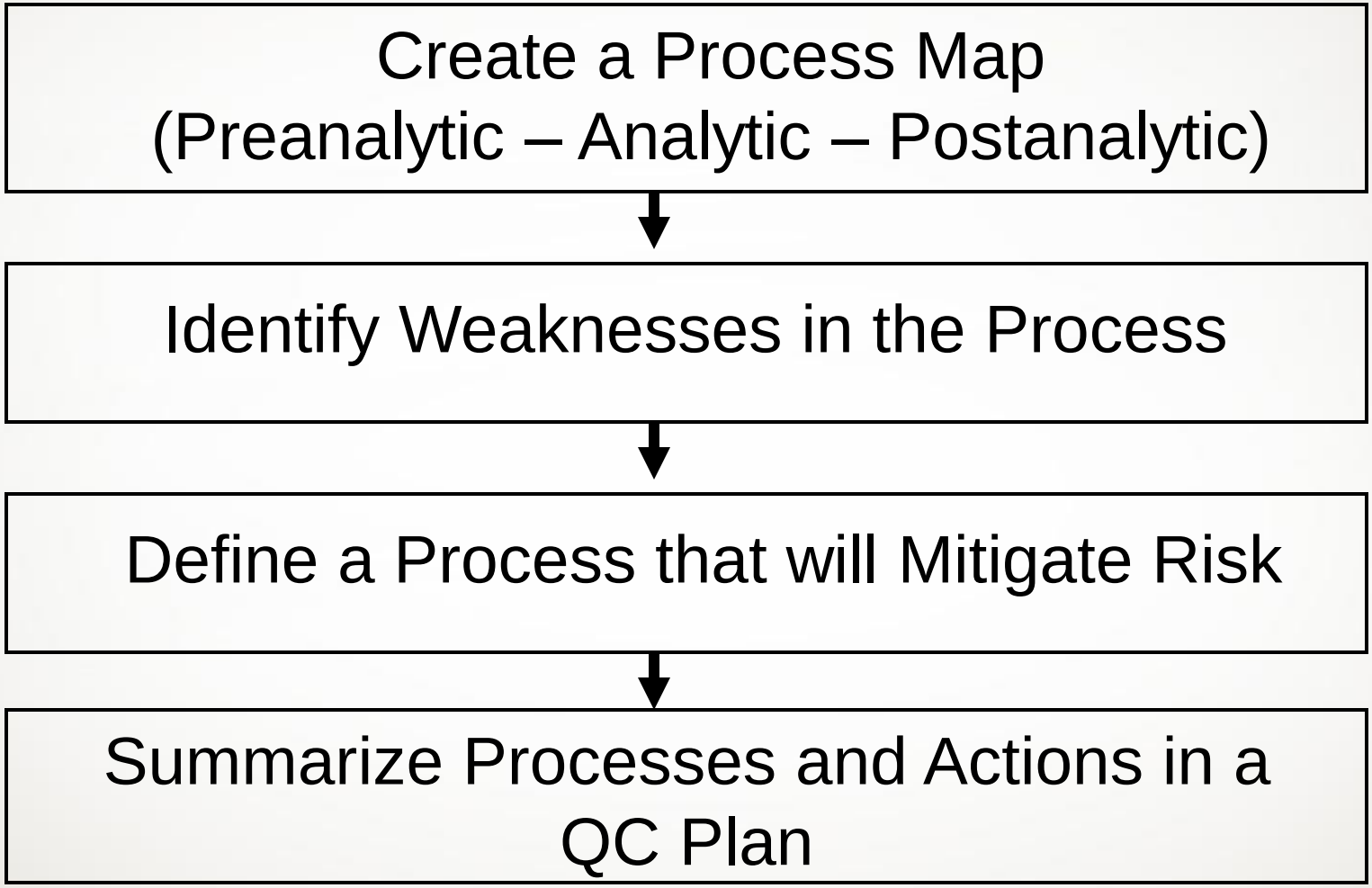
- James H. Nichols, PhD, DABCC, FACB, Chairholder of the document development committee

- 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

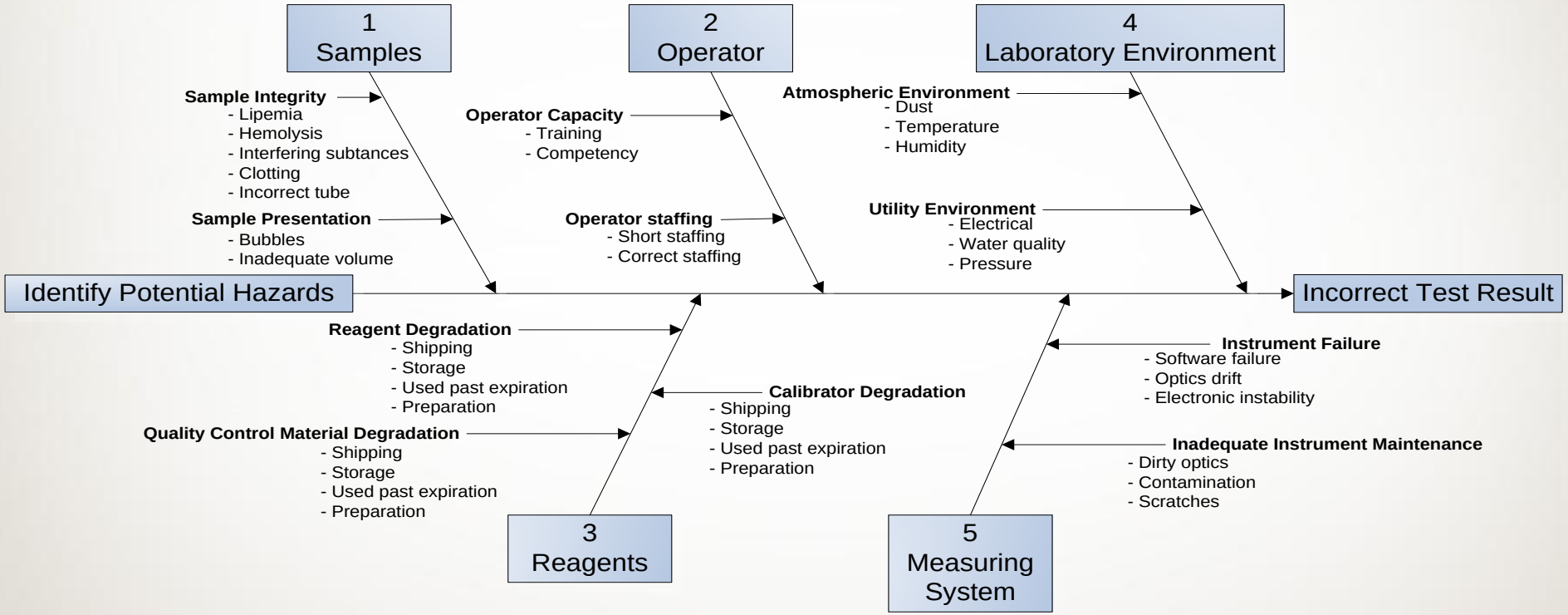


EP23 Laboratory QC Based on Risk Management



Developing a Process Map

- Compile information.
- Look for weaknesses in each step of process



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

Nothing is foolproof…

for a sufficiently talented fool!

(attributed to a distinguished colleague)

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!

Where is the Risk in Our Process?

Falsely Decreased Glucose Results

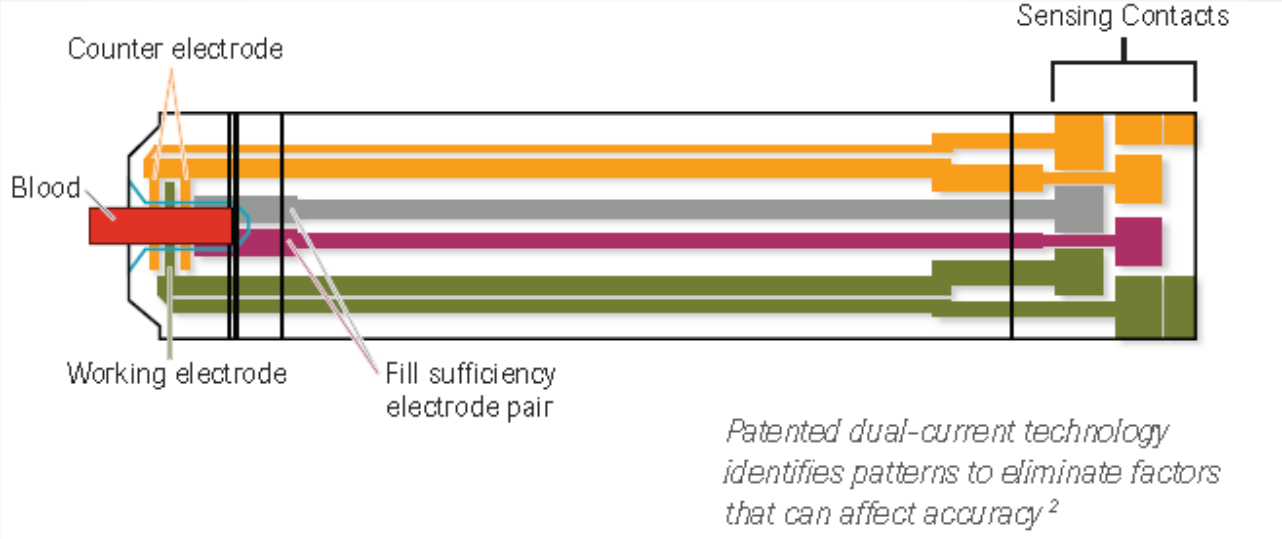
- Complaint from an ICU of sporadic falsely decreased glucose results
- Immediate repeat test on same meter, gave significantly higher “clinically sensible” values
- Inspection of unit found nurses taking procedural shortcuts to save time
- Bottles of test strips dumped on counter in spare utility room
- 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

Reagent Errors: Calibration

- Incorrect entry of calibration can lead to inaccurate test results
- Newer devices use automatic calibration
- Connectivity can distribute lot info and calibration to all meters in use

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.
- Biases from oxygen and hematocrit

Fatal Iatrogenic Hypoglycemia:

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

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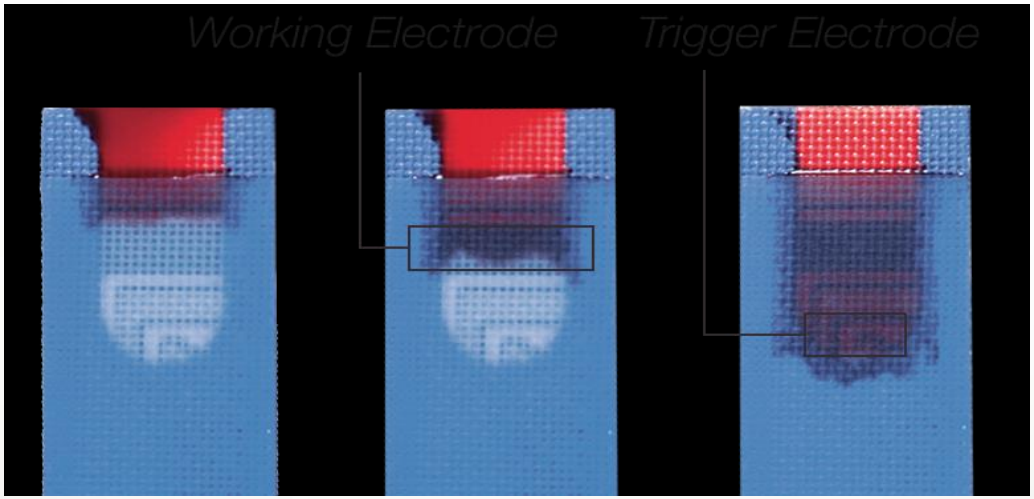
INTRODUCTION

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]

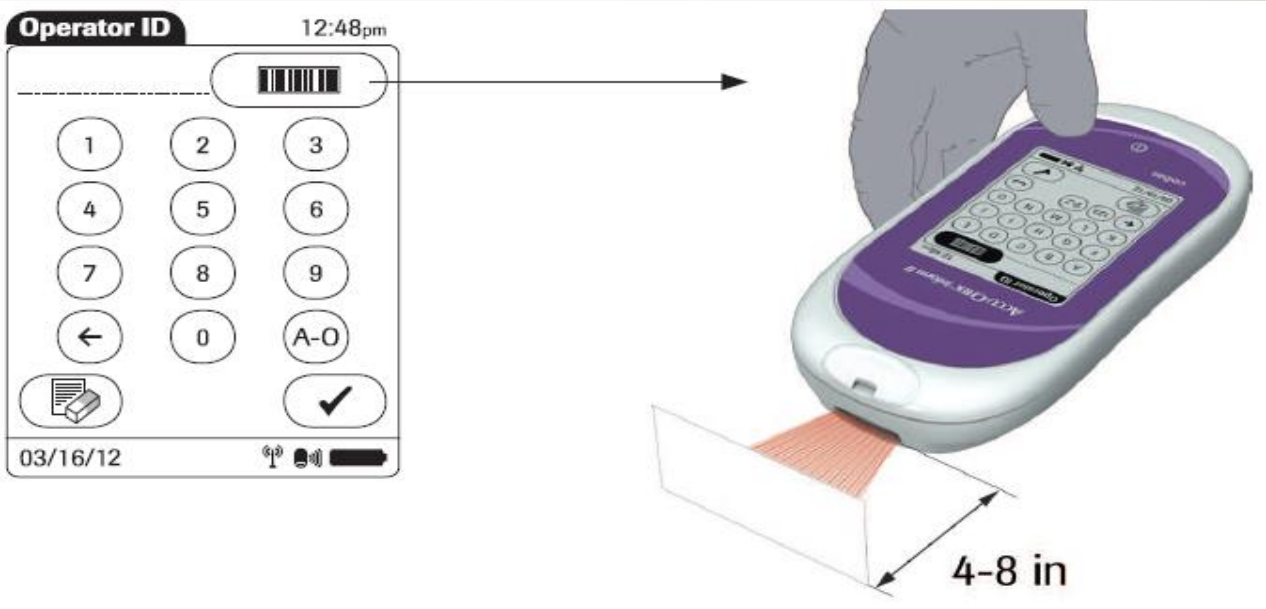
Adverse events have been reported for immune globulin products that contain maltose,[5-10] which functions as a protein stabilizer[11-13] and an osmotic agent.[14,15] Similar adverse events have been reported for Extraneal (Baxter

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.



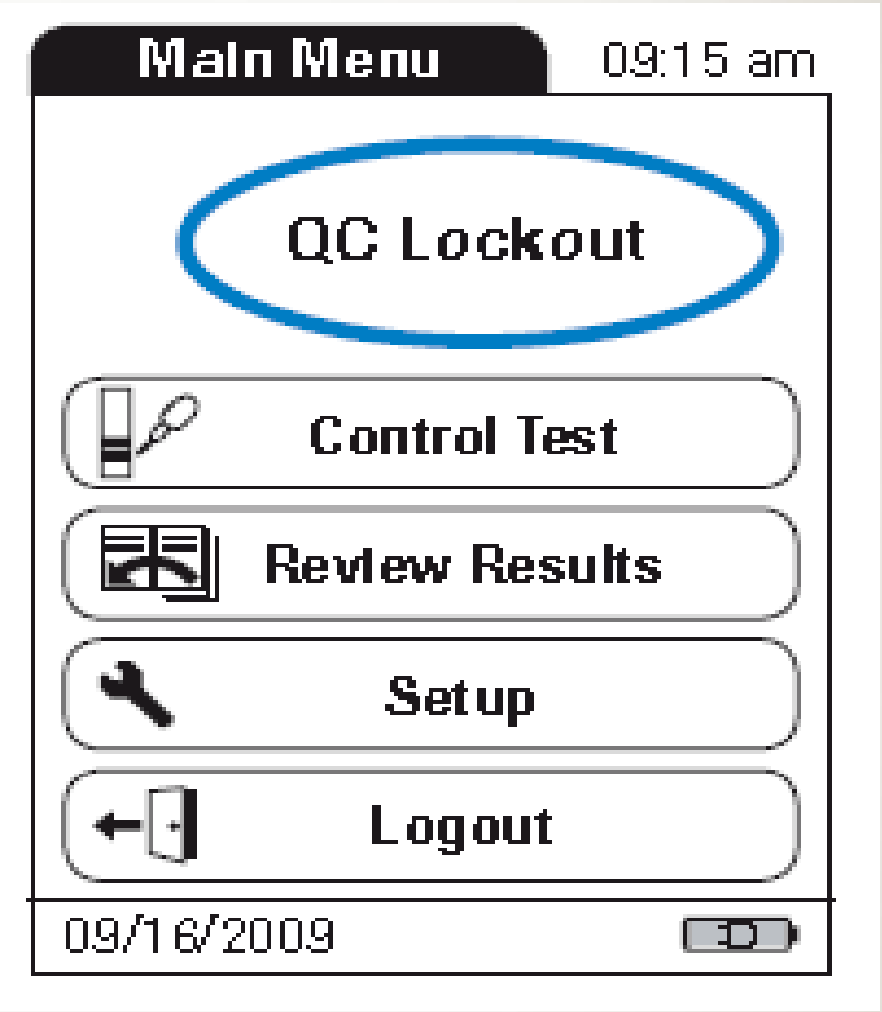
Operator Errors: Training/Competency



- Operator lockout
- Functions through number code, name 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)

Operator Errors: Performing QC

- Devices require periodic QC
- 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

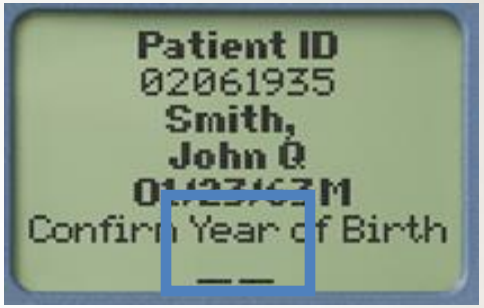


Operator Errors: Patient Identification

- 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

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

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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 averaged over a period of a month, 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/]

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

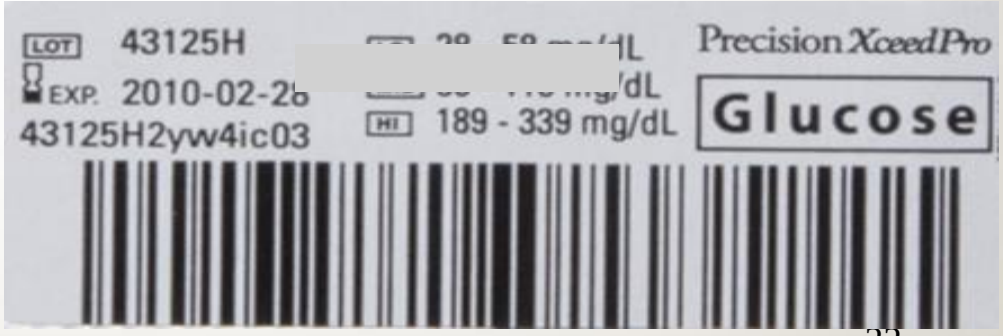
- Operator must check manufacturer's expiration date prior to testing.
- Vials/strips and controls must be manually dated when opened by operator (prematurely expires once opened)
- Undated, opened vials must be discarded. (? expiration)

Discarded strips due to no date[1]

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

Reagent Errors: Expired Reagents

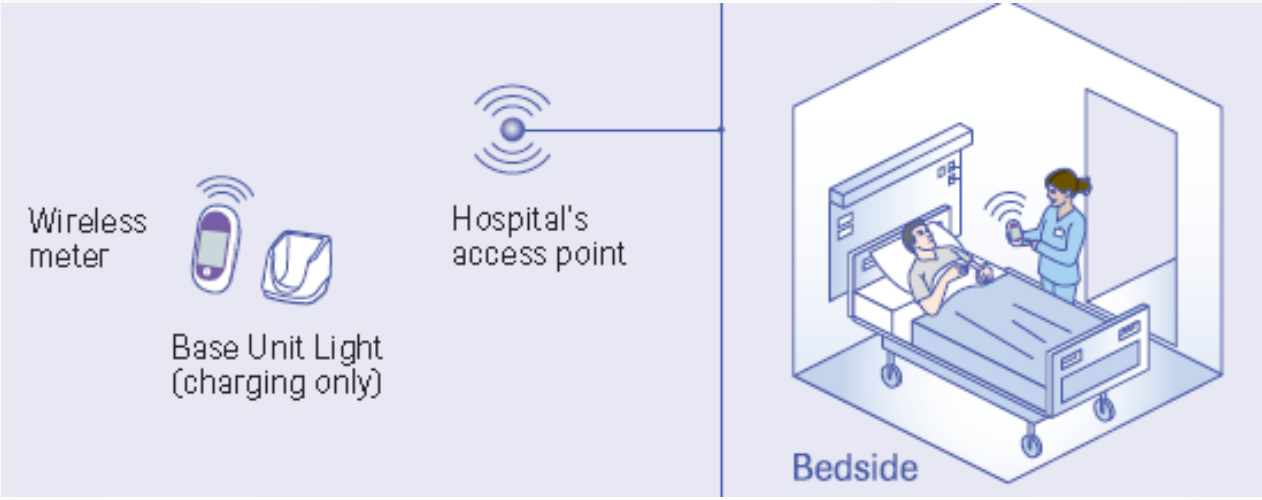
- Serialized vials/strips and controls barcoded for lot number and expiration date (good to stamped expiration date) can recognize individual vials on opening (30, 60 or 90 day open expiration)
- Automatic lockout for expired test strips and controls
- Some devices can also recognize exposure to humidity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



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)

Benefits of Wireless



- Real-time data transmission to EMR
- Physicians can immediately access results remotely
- Glucose results can transpose insulin dosage, INR with Coumadin dosage…for personalized patient management

Measuring System Errors: Contamination

- POC devices pose a risk of transmitting infectious organisms
- POC blood testing devices, such as glucose meters and PT/INR anticoagulation meters, should be used only on one patient and not shared.[1]
- If dedicating POC blood testing devices to a single patient is not possible, the devices should be properly cleaned and disinfected after every use as described in the device labeling.[1]
- POC devices need more durable plastics, fewer crevices and seams, and a design that prevents liquid egress into ports

1) US Food and Drug Administration. Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update. US FDA Medical Device Alerts and Notices. Updated November 29, 2010.

Device Cleaning

- POC devices need more durable plastics, fewer crevices and seams, and a design that prevents liquid egress into ports
- We replaced over 50 meters in first months after instituting new cleaning guidelines with our old meter!

Where is the Risk in the Process?

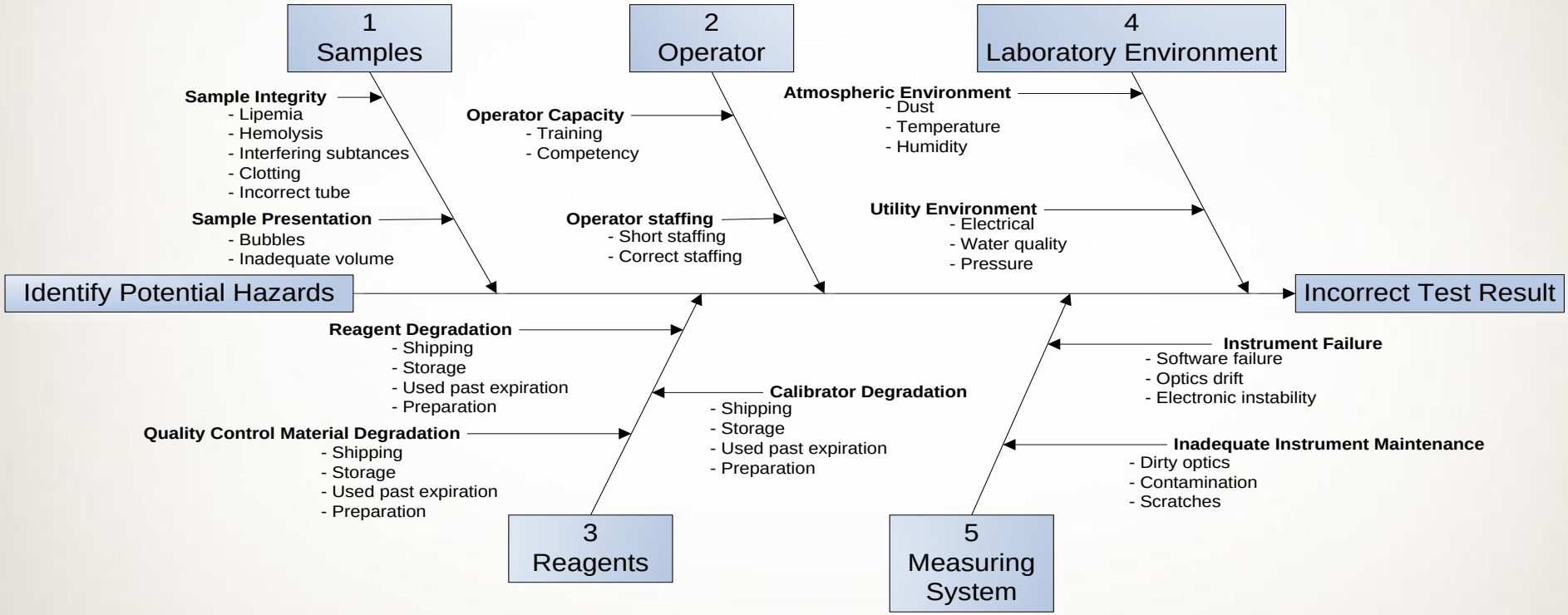
What Could Possibly Go Wrong?

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!

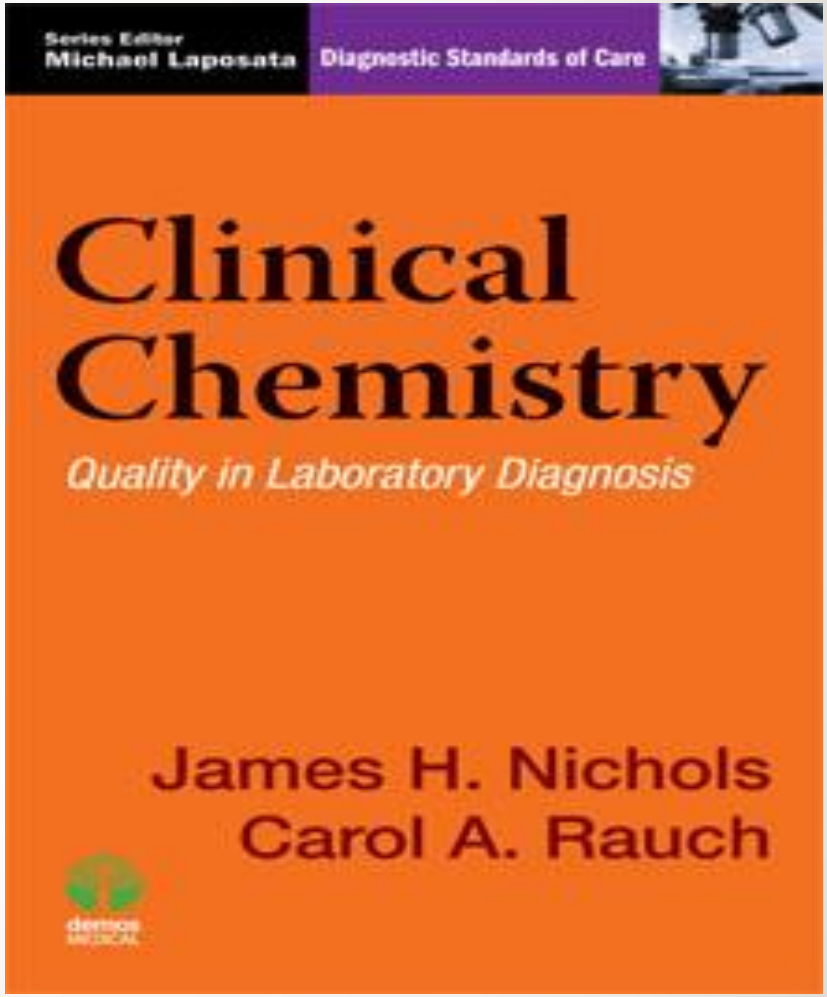
Developing a Process Map

- Look for weaknesses in each step of process

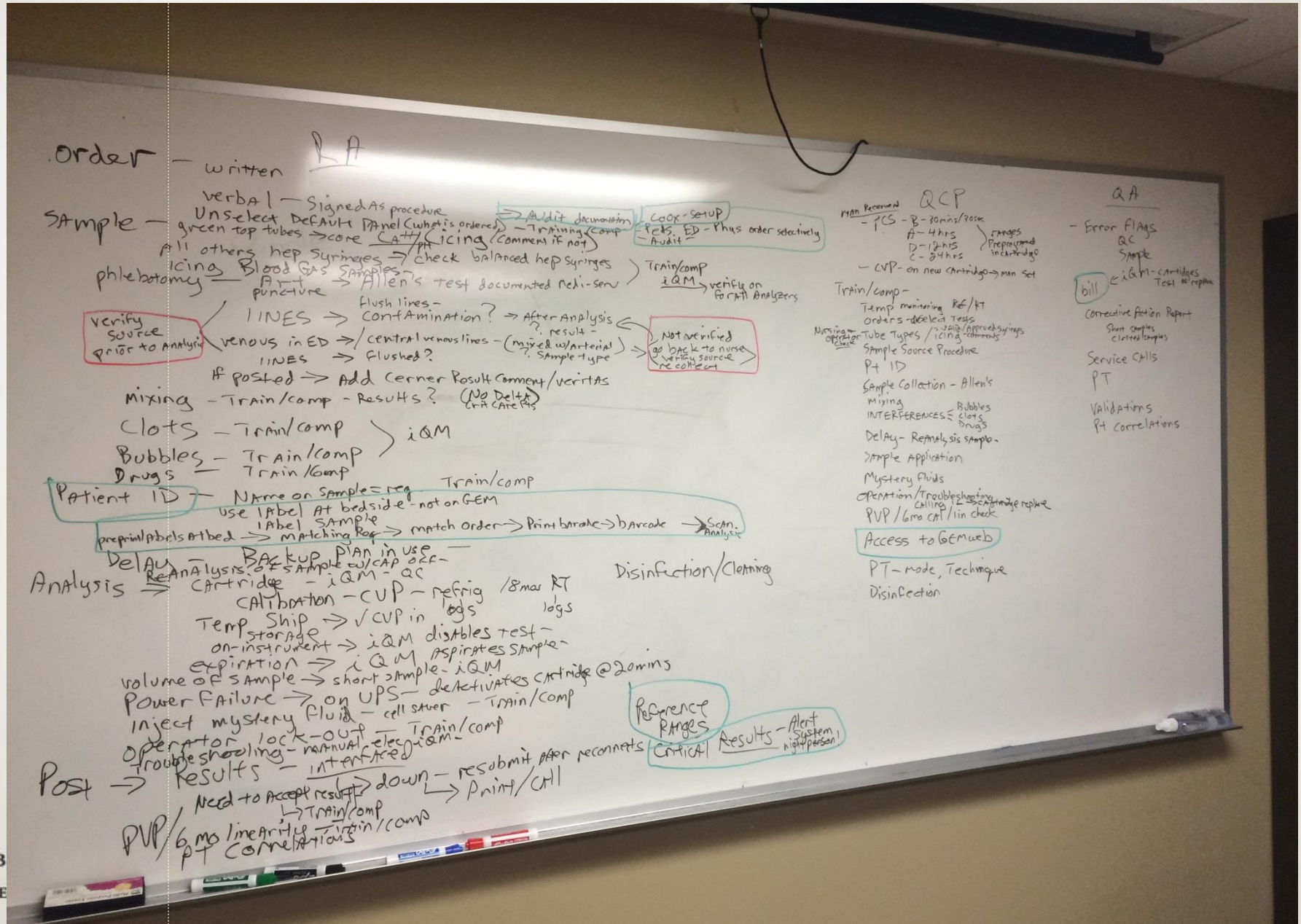


Resource for Reducing Errors

- 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.



What Have We Learned From Our IQCPs?



What Have We Learned From Our IQCPs?

- Processes on different units were not uniform
  - Some barcoded BG bedside, others waited to satellite lab
- 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

VANDERBILT UNIVERSITY MEDICAL CENTER

Savings of nearly half each year!

Summary

- Many sources of laboratory error!
- Risk management assesses workflow for weaknesses and allows labs to take action before errors occur
- 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