The Nursing-Lab Relationship in POCT: The Good, the Bad and the Ugly of Interdisciplinary Teams

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Objectives

1. Describe opportunities for laboratory staff to partner with the health care team on POCT
2. Identify differences between nursing and laboratory perspectives
3. Provide tips to improve POCT compliance

There is no conflict of interest

Hypothetical POCT Threats

- Moving testing to the bedside means fewer laboratory ordered tests
- Nursing performed POCT will eliminate the need for medical technologists
- Direct interaction of physicians with test results will reduce need for laboratory directors – no need to interpret the results

The Truth about POCT

- POCT introduces an additional technology
  - Different precision
  - Biases
  - Unique interferences
- POCT results do not necessarily agree with core laboratory results – different methodologies
- Quality concerns if manufacturers instructions followed and controls are not performed as required
- Additional testing is ordered when POCT results do not match core lab results or questions about the quality of results present - This is a problem for over-utilization

Point-of-Care Testing
Case Study

- Complaint from Gen Med Unit that glucose meter read high (mid 500's) but when insulin given patient became disoriented and next glucose was 36 mg/dL.
- POCT staff pulled meter, QC in, maintenance records/ proficiency surveys OK, pt sample accuracy checked.
- 63 y/o African American female admitted for CABG. History: ESRD, hypercholesterolemia, CHF, sickle cell trait, NIDDM (diet treatment). Post CABG developed L arm thrombosis, lysis therapy and developed DVT of L leg with pulmonary involvement

Point-of-Care Testing Case Study

- Day 0: (2 weeks post CABG)

  0130: shortness of breath, 2+ pitting edema L leg and arm

  1600: refused glucose level check

  2040: Glucose meter = 564 mg/dL

  2300 HO gave 14U insulin per Standing Order (351-400 = 8 units)
- Day 1

  0100 pt diaphoretic shakey, dextrose/OJ, gluc = 36 mg/dL

  0200 glucose normal
- Medical Records glucose:

  Day 0 0730 Lab **282** 0845 Meter **273** (9 mg/dL, 3%)

  Day 1 0758 Lab **255** 0800 Meter **270** (15 mg/dL, 6%)

  Day 2 0700 Lab **284** 0800 Meter **321** (37 mg/dL, 13%)

  (in-house verification study 96% within 15% of lab)

Point-of-Care Testing
Case Study

- Lab panic policy: No record of lab sample glucose, >400
- Why a POCT at same time as morning chem panels?
- Why 2.5 hrs elapse before clinical action? POCT more costly than lab, enough TAT for lab result
- Standing insulin orders: Set to laboratory methods not POCT, no standard scale, varies between departments.
- With poor circulation, should fingersticks be performed on this patient?
- Good record keeping was essential to troubleshooting, the excellent maintenance, QC and medical records worked to determine that the problem was more clinical vs analytical, but can’t rule out line-draw contamination!

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 11, 2016.

The draft of this document was issued on January 7, 2014.

For questions regarding this document, contact Leslie Landree at leslie.landree@fda.hhs.gov, or at 301-796-6147.

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ACCU-CHEK® Inform II

Test Strips and 1 Code Key

PROFESSIONAL USE

Cat. No. 05942861001

Limitations

- The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.
- The performance of this system has not been evaluated in the critically ill.

This limitation is new as of December 2012 for all glucose meters!

Final FDA BGMS Guidance

- Concerns raised regarding performance in some populations
- Patients in healthcare settings more acutely ill, medically fragile and present with physiologic/pathologic factors that could interfere with glucose measurements
- Errors in BGMS accuracy can lead to incorrect insulin dosing, increased episodes hypoglycemia, and further risk to health
- For professional use, identify sub-populations where BGMS may function differently
- All inpatients, by virtue of their hospitalization, may be considered “critically ill”. So, critically ill patients are not just those patients in the ICU
  - Consider the OR, ED, Trauma, Sepsis, and others
- CMS and FDA indicate that the definition of what constitutes “critically ill” must be defined by each institution.

Use of Glucose Meters for Critically Ill Patients

This white paper includes an overview of glucose meter limitations with practical advice for use of glucose meters in critically ill patients

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Options to Address CMS Changes

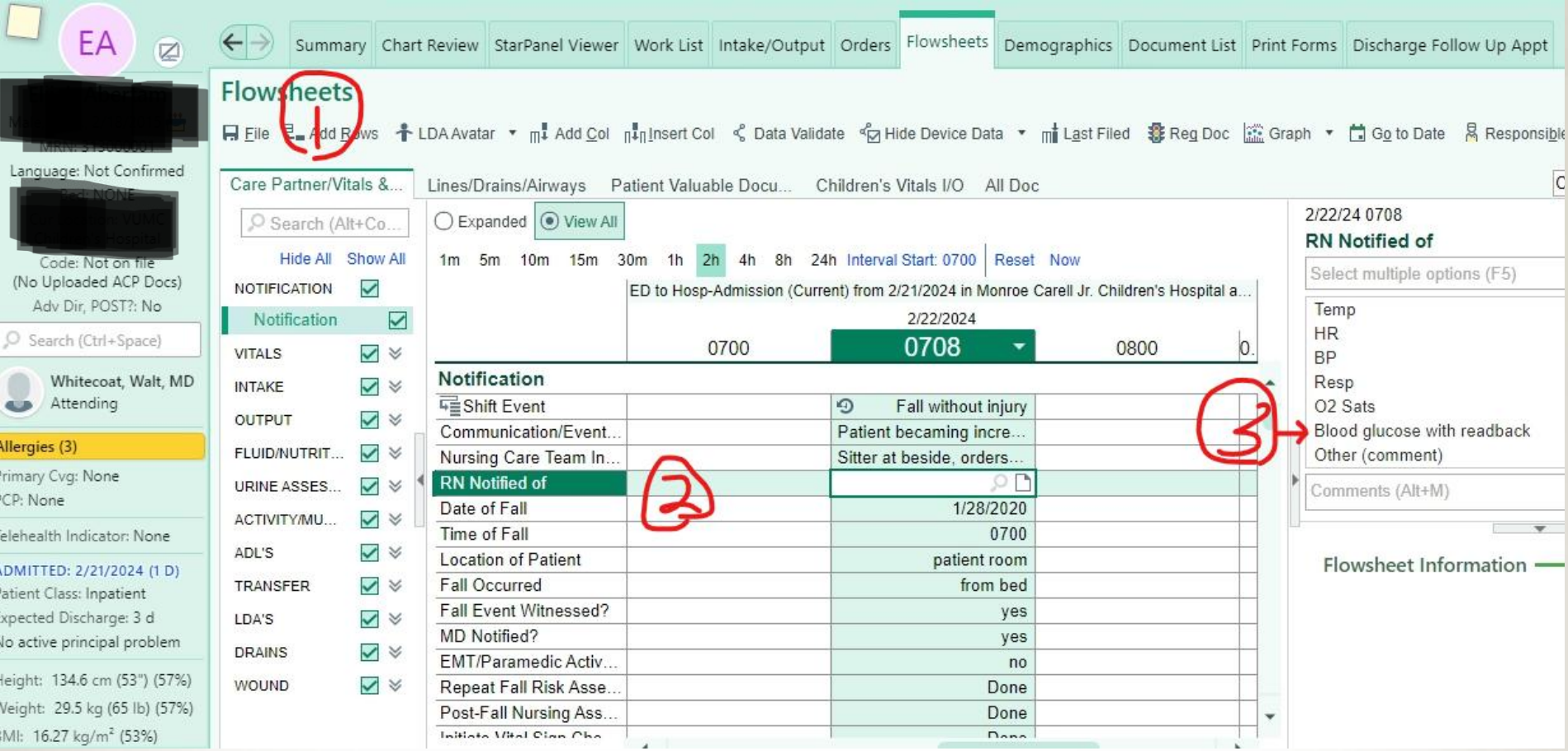
- Proposed Policy Change
  - Least disruptive
  - No change in practice, staff already trained and doing this
  - Meets letter of the regulatory change by defining what “critically ill” means for this device – the pkg insert limitations – so not testing under “off-label” uses
- Change to a meter cleared for “critically ill” use
  - Caution, no meter is cleared for use of capillary samples in critically ill patients!
- Stop using glucose meters for “critically ill” patients – use an “alternative” method
  - Require more costly Blood Gas testing
  - Core lab testing with delays in results that could impact care
- Use glucose meters “off-label”
  - CLIA high-complexity testing with required validation in critically ill patients
  - Consequences for staff educational background, licensure (med director), and ongoing documentation.

Care Partners and POCT

- Care Partners – high school diploma, no medical background and on the job training
- Historically conduct urine pregnancy and urine dipsticks in clinics
- Want to add Care Partners as operators for inpatient glucose meters
- Concerns:
  - Capillary fingersticks should not be conducted on patients with poor-peripheral circulation (severe dehydration (DKA), hypotension, shock, heart failure and peripheral vascular disease). But, Care Partners can't make medical/physical assessments of patient
  - Medications and conditions can interfere with glucose meters (hematocrit <10% or >65%, triglycerides >1800 mg/dL, galactose >15 mg/dL, IV ascorbic acid, IV N-acetylcysteine)
  - If poorly perfused, a venous or arterial sample can be obtained and analyzed on the glucose meter, but Care Partners do not perform phlebotomy

Care Partners and POCT

- Nurse is responsible for completing a physical assessment of patient to ensure patent circulation and no medication or condition that could interfere before delegating task of glucose testing to Care Partners.
- Possible signs and symptoms of impaired circulation could include:
  - Pigmentation, mottling, texture changes to skin, including peripheral cyanosis
  - Temperature changes in fingertips, specifically cold skin
  - Delayed capillary refill time (>3 seconds)
  - Diminished or absence of a pulse
  - Bilateral or unilateral edema
  - Sensation of touch decreased or lost, ie diabetic neuropathy
  - Pain, aching or throbbing
  - Clubbing of nail beds



- **Care Partner Assessment:**
  - RNs delegate blood glucose POCT to CPs at VUH.
  - CPs must report blood glucose values to the RN.
  - CPs must report and document that they notified the RN of critical POCT blood glucose values
  - (<40 and >500).
  - The option of 'Blood Glucose with Readback' will be added to the 'RN Notified of' flowsheet row.

Why is a Laboratorian Needed with POCT?

- To explain discrepancies
- To recommend specific POCT devices
- To advise which test to order for a patient – POCT or core laboratory
- To ensure the appropriate documentation and display of results after testing
- To assist in training and staff competency
- To ensure the quality of POCT

The Changing Role of the Laboratory

Traditional Lab

- Techs in the basement
- No windows
- Responsible for analytical workstation
- Sole interaction with physician by phone
- Little contact with patient care

The Changing Role of the Laboratory

POCT

- The lab as consultant
- The lab as educator
- Visible to clinical staff
- Part of the patient care team
- Valued for advice
- A key role as a resource in healthcare

POCT is an Opportunity!

- Once POCT is implemented, core laboratories have not seen their business disappear, rather volumes have increased due to
  - POCT device validations
  - Increased use of the lab as “reference” service
  - Follow-up of discrepant results
  - Quality Assurance activities
- POCT should not be viewed as a threat, but as an opportunity for the laboratory to take on new roles in healthcare
  - Laboratorian has skills as expert on test technical performance, appropriate test selection, test quality, and interpretation
  - Opportunity for increased visibility to patient care team

Teamwork

To succeed as a team

is to hold all of the members accountable for their expertise

Mitchell Caplan (CEO of E* Trade Group)

Nursing Roles

- Physical care
- Emotional care
- Spiritual care
- Lab Diagnostics?

Nursing and Technology

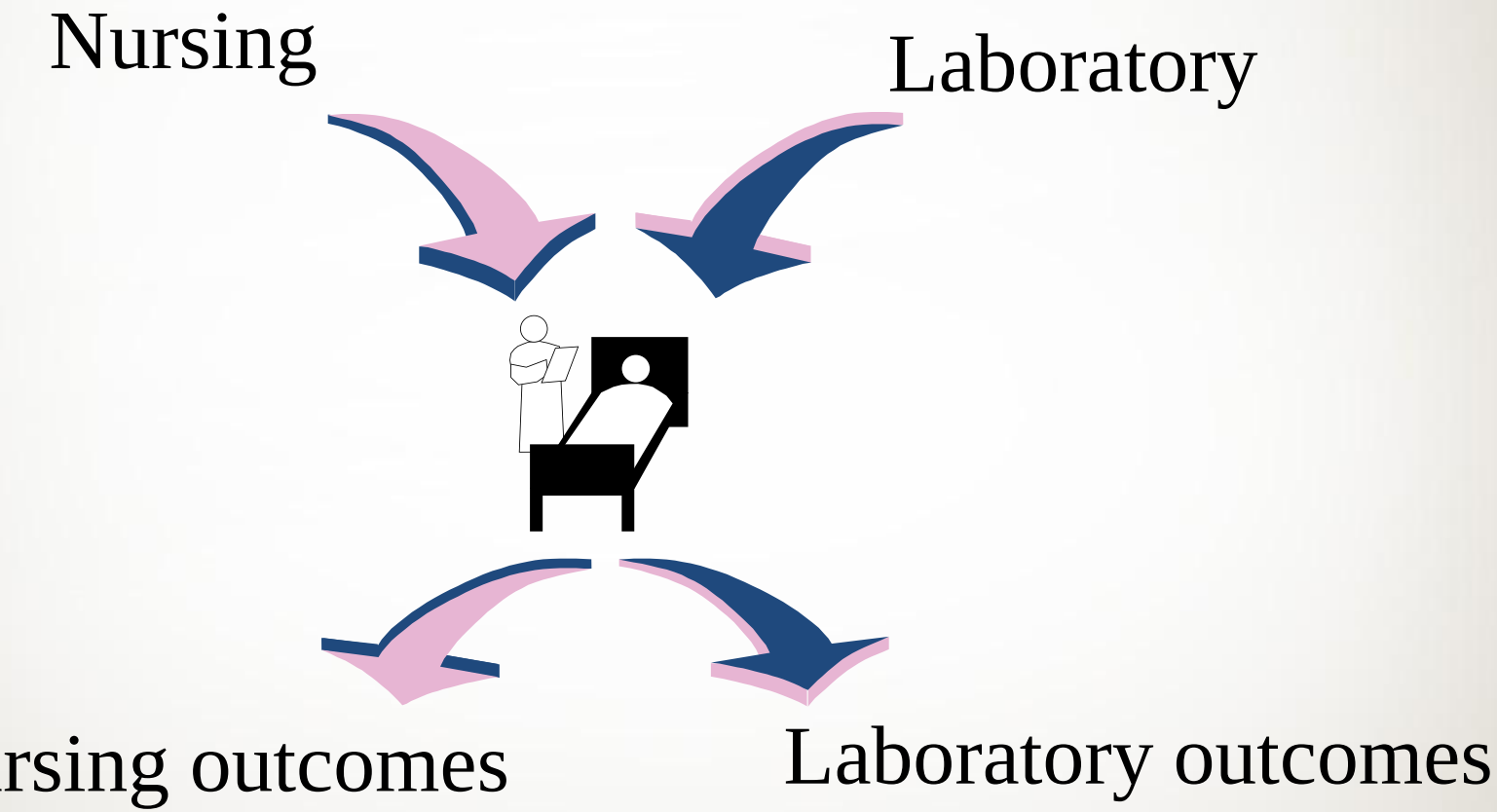
Optimism

- Easily assimilated into patient care
- More rapid clinical decision-making
- Decreased cost to patient

Cynicism

- Detracts from patient care
- Time- and labor-intensive for nursing
- Takes nurses away from the bedside
- Lab testing not viewed as traditional role for nursing

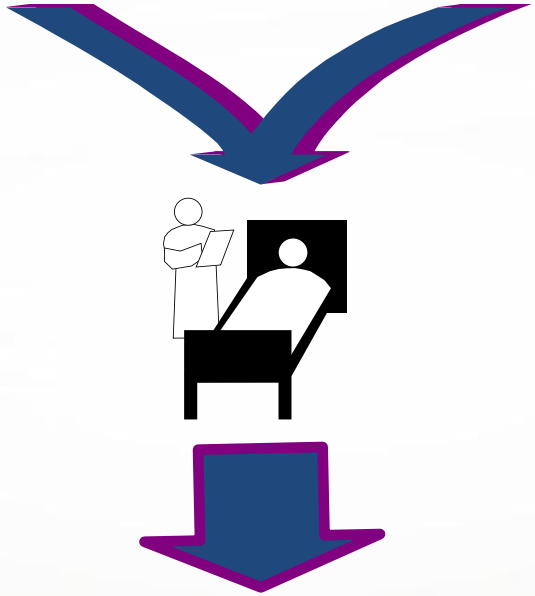
Multidisciplinary Teams and Point-of-Care Testing



Interdisciplinary Teams and Point-of-Care Testing

Nursing

Laboratory



Patient outcomes

Interdisciplinary Team Approach

- Committee CoChairs - Nursing/Laboratory
- Pathology role as a facilitator
  - Propose a draft policies and procedures
  - Nursing identifies problems
  - Mutually discuss solutions
  - Incorporate solutions into program
- Each member contributes expertise and separate point-of-view
  - Laboratory - technical and regulatory
  - Nursing - patient focused
- Laboratory as “Knowledge Resource” vs “Dictator of Practice”

Role of Laboratory Staff

- Evaluate technology
- Correlate methods
- Define normal ranges
- Write protocols
- Manage instruments
- Coordinate supplies
- Provide back-up
- Oversee and document training
- Review compliance
- Supervise quality assurance

Role of Nursing Staff

- Determination of clinical pertinence
- Training and documentation of continued competency
- Performance of quality control checks
- Surveillance of patient results and quality monitors
- Day-to-day maintenance and activities

Quality Control & Proficiency Testing: Nursing Perspectives

- Nurses familiar with pre- and post analytical steps of laboratory testing
  - Specimen collection
  - Taking action on results - instituting treatments
- Less accustomed to analytical steps
  - Quality control
  - Proficiency testing

Quality Control & Proficiency Testing: Nursing Perspectives

Laboratory

- Restricted tasks
- Large test runs: "factory environment"
- Process oriented
  - Calibration
  - Accuracy
  - Precision

Nursing

- Broader responsibilities
- Limited test runs: "boutique environment"
- Outcome oriented
  - Time spent with patient
  - Patient goal achievement

Role of Leadership in Point-of-Care Testing

- Create a vision for clinical staff of importance/proper use of quality control and proficiency testing (Focus on “Why QC should be done” not “Must do QC”)
- Streamline quality assurance requirements to achieve goals with minimal resource consumption and maximum result and patient quality
- Write policies and procedures in nursing language not laboratory technical lingo

POCT Policy

- Balance of all disciplines involved
- Remember CLIA'88 and accreditation agency regulations indicate what has to be done not how to do it
- Different nursing units have different workflow and operational aspects that can accommodate the regulations in different ways and still be compliant
- Institutional policies must allow nursing units to implement POCT in ways that fit their work, so policies and procedures must not be so restrictive as to lead to failure and noncompliance

Quality Control

- For many POCT devices, two levels of external liquid QC must be analyzed and documented every 24 hrs of patient testing
- Many ways this can be accomplished
  - Lab can send a MT to perform QC each day
  - Isn't compliant with spirit of law, shared responsibility
  - Units can schedule staff to rotate performance
  - Units can assign to one shift and rotate staff (periodically change shifts – 12 hour days easy to rotate requirement semi-annually)
  - Weekday outpatient clinics only need perform QC when open.
  - Other options possible provided nursing unit meets 2 levels every 24hr and rotates staff.
  - Newer option IQCP lowers QC to 1/month, who is assigned? Fewer QC events present more opportunity to forget, especially when staff rotate
- System change to devices with QC lockout features mandates the performance of QC at defined schedule and automatically document that QC was acceptable

Compliance

- When problems occur, often easier to blame an operator than the system for an error
- If we take note of the airline industry, most problems are not the cause of a person, but a weakness in the system that allowed the error to happen in the first place.
- Establish our POCT policies to prevent errors in the first place, and setup controls and monitors around weak steps that can't be engineered out of the testing process (like QC lockouts).

Patient Identification Errors

- POCT results are transmitted to the POCT manager when devices are downloaded
- The data manager orders and results the test in the LIS
- If the test does not match an active patient account the data manager holds the result for resolution
- Compliance problems as test cannot be billed, and worse - some results transmitted to incorrect patient record and inappropriate medical management

Operator Errors: Patient Identification

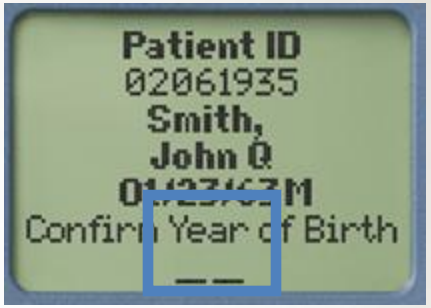
- Incorrect entry of patient identification can
  - Chart results to the wrong patient's medical record
  - Lead to inappropriate medical decisions and treatment
  - Improper billing and compliance
- Barcoded patient wristbands reduce the chance of misidentification, but patients can be banded with:
  - 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

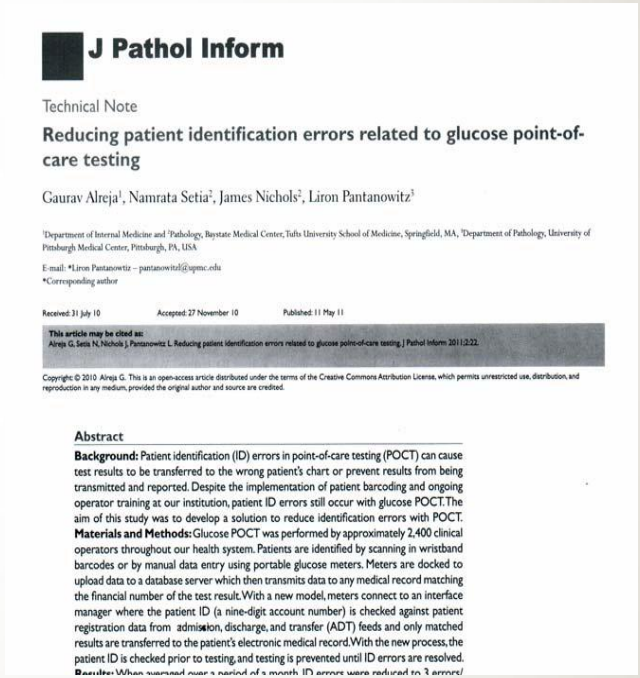
National Patient Safety Goals

- **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

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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/]

When to do POCT? Clinical Justification

- Turnaround Time
- Vascular entry
  - Fingerstick versus phlebotomy
- Required part of housestaff training
- Practice Trends
  - Increased inpatient acuity
- Efficiency of Patient Care
  - Physician refamiliarization with case

POCT: Operator Criteria

- The best performing device may not be acceptable to clinical staff - Institutions should consider:
  - Ease of use
  - Portability
  - Volume requirements
  - Automatic calibration
  - Reliability, maintenance
  - Infection control
  - Cost

Nichols, JH. Management of near-patient glucose testing. Endocrinology and Metabolism In-Service Training and Continuing Education 1994;12 (12):325-34.

Joint Commission/CAP

Improving Organization Performance

- **PLAN:** Form an Interdisciplinary POCT Team
- **DESIGN:** Standardized POCT QA program
- **MEASURE:** Performance monitors
- **ASSESS:** Trends noted
- **IMPROVE:** Modify program to improve trends
- **PLAN:** Implement program changes
- **DESIGN:** New performance monitors

Quality Improvement Compliance Indicators

- Documentation of daily maintenance
- Proficiency samples tested and results returned by due date
- Documentation of daily QC
- Meter coded correctly (strip code and plasma mode)
- Maintenance Log present
- In-date controls and strip vials
- Open date recorded on controls and strips
- Multiple vials of controls strips open at a time
- Meter cleanliness

Self-Management

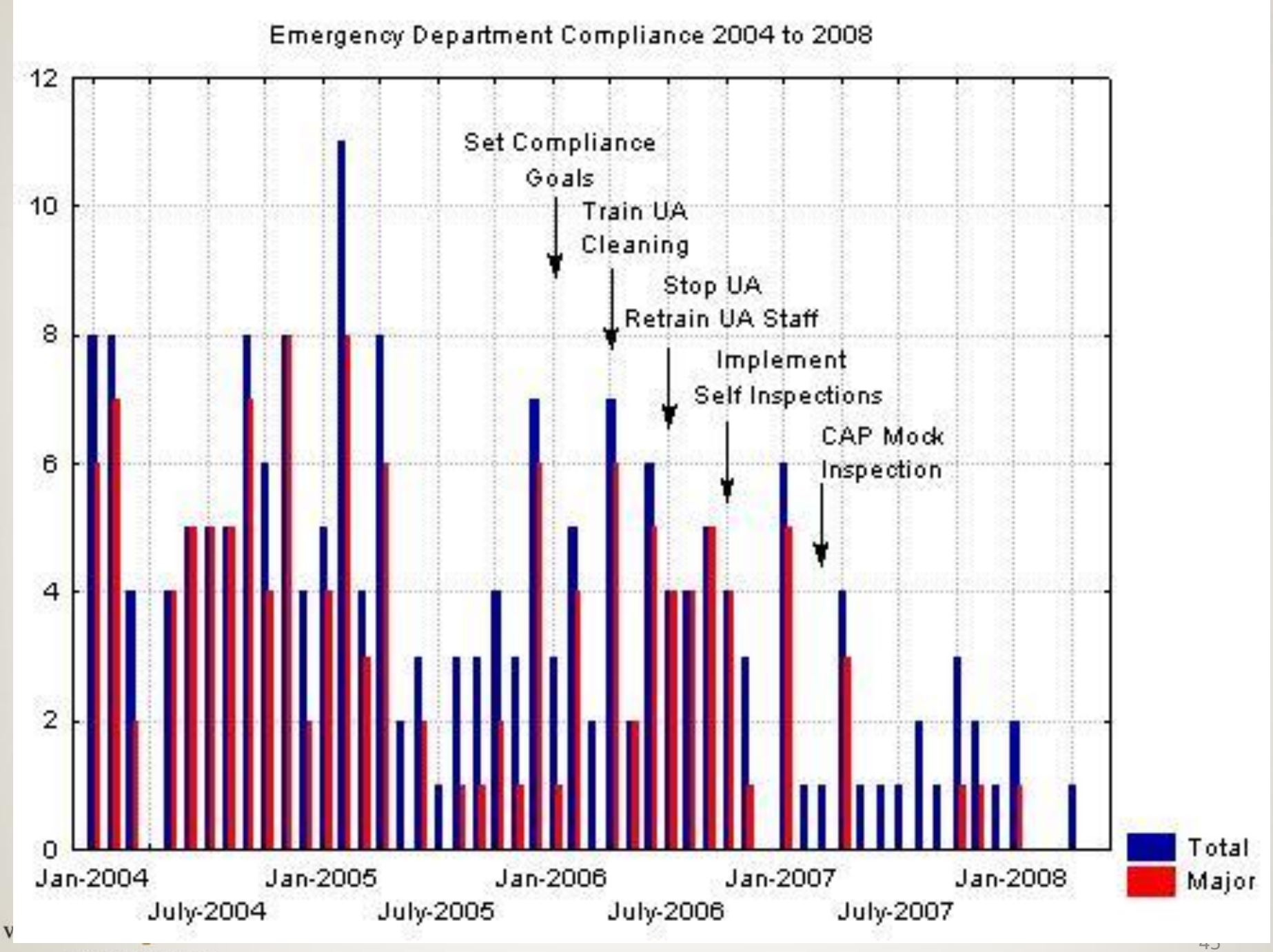
- While POCT is a partnership between lab and clinical services, inspectors hold the site performing the test and CLIA director responsible
- The lab can't hold an operator's hand 24 hrs a day, sites must take charge
- Institute a culture of self-management

Self-Management

- POCT website or electronic folder on common shared drive - provide all of the tools necessary to manage POCT
  - Policies and procedures
  - Training and compliance forms
  - Performance improvement/site compliance
  - Committee minutes and agendas
  - Progress on meeting POCT goals
  - Q & A forum
  - Government and regulatory updates
- POCT sites then have necessary resources, and have no one to blame but themselves for not succeeding
- Separates the lab from being responsible and in the middle of a nursing care process. Lab is available, nursing is responsible

Site Self-Inspection

- Key to self-management is site self-inspection
- Sites utilize same checklist that POC coordinators use to grade compliance
- Compliance tied directly to regulations
- Sites that regularly self-inspect show the most QA improvement


Emergency Department Compliance 2004 to 2008
12
10
8
6
4
2
0
Set Compliance Goals
Train UA Cleaning
Stop UA Retrain UA Staff
Implement Self Inspections
CAP Mock Inspection
Jan-2004
July-2004
Jan-2005
July-2005
Jan-2006
July-2006
Jan-2007
July-2007
Jan-2008
Total
Major

ED Challenges

- POCT staff monthly site inspections
- ED low compliance with key benchmarks
  - Frequent POCT identification errors
  - Missed days for temperature monitoring
  - Outdated reagents/controls
  - Failure to comment failed QC, out of range result communication, etc.
  - Poor follow-up and action plans
  - Leadership claims to be different than other units
- POCT not unique – similar nursing round results

The ED Environment

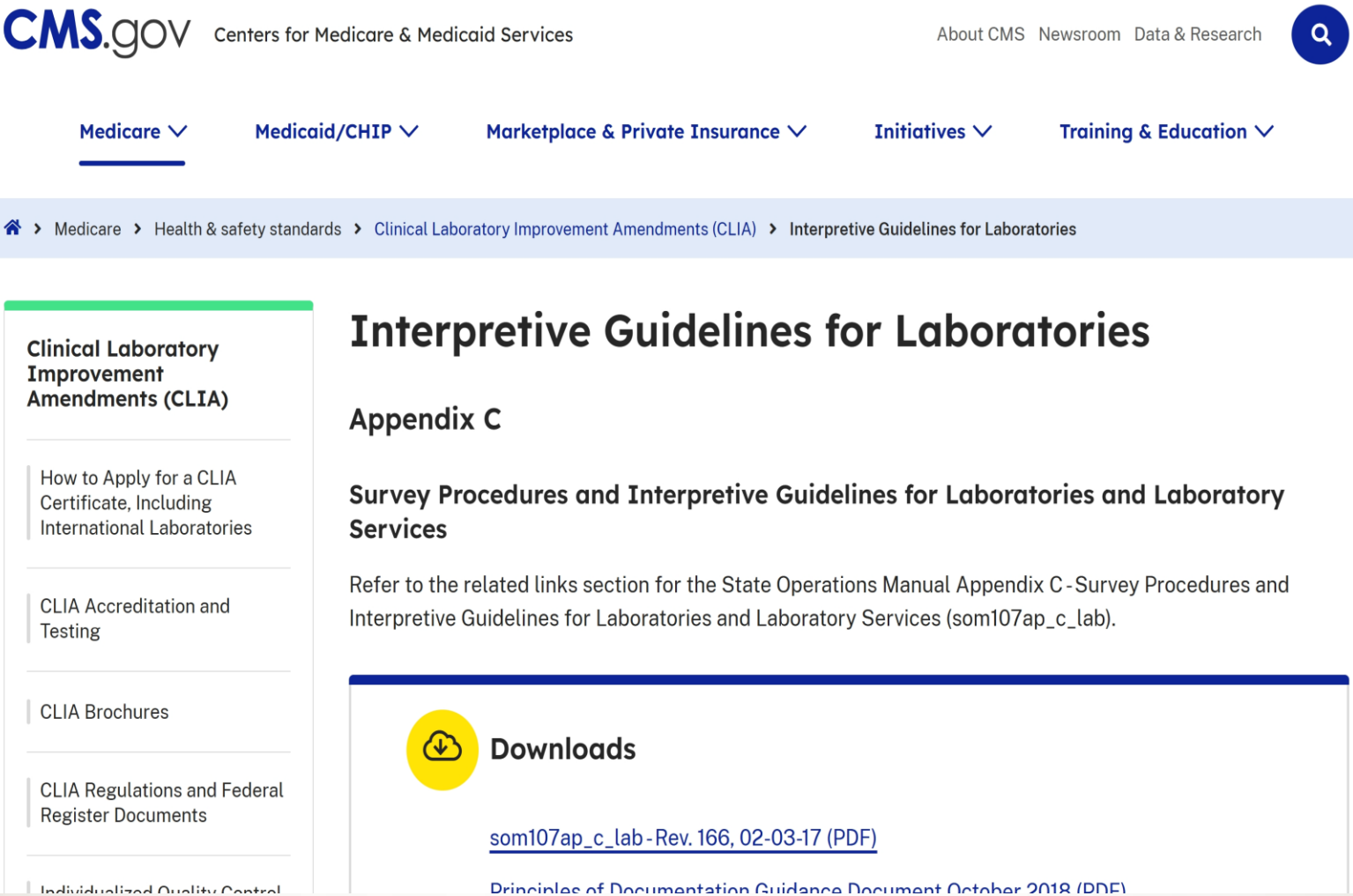
- Acute care – need for rapid response
- Level 1 trauma center
- High staff turnover and outside coverage
  - Lose administrative continuity
  - Frequent staff reeducation of basics
  - Less ownership than other hospital sites

ED Design Changes

- Two champions of POCT on unit helped motivate staff re: POCT challenges
- This staff provided visibility of POCT on unit and offered ongoing liaison for compliance
- Staff tired of same issues reoccurring month after month
- Collected a team of TA operators
- Redesigned the self-inspection form
  - Delegated tasks
  - Assigned POCT responsibilities to all shifts
  - 4 team leads all responsible wkly compliance

ED Outcomes

- Dramatic shift in compliance observed
- TA ownership of all staff
  - New self-inspection delineated responsibility
  - Defined ownership and job descriptions
  - Enhanced awareness of QC/exp dates/temp
- Staff turnover – planned for continuity
- Enhanced follow-up with action plans
- POCT ID errors down –
  - Staff weren't waiting for pt registration prior to POCT
  - Using downtime 999 codes w/o follow-up in 24hr
  - TA team worked with the ED reg staff to get pts registered and banded faster upon admission
  - Key – a process change led to enhanced outcomes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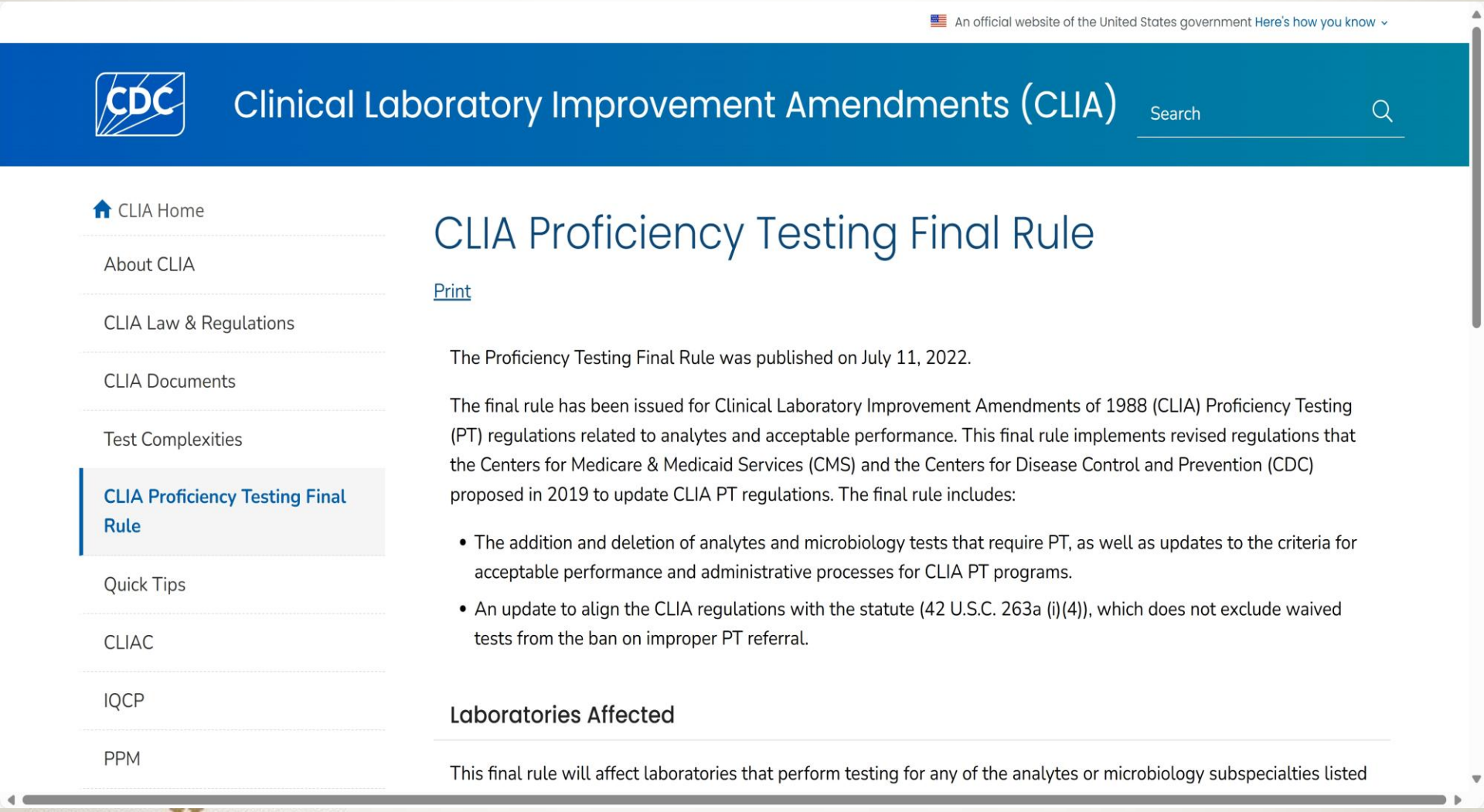
Clinical Laboratory Improvement Amendments (CLIA)
How to Apply for a CLIA Certificate, Including International Laboratories
CLIA Accreditation and Testing
CLIA Brochures
CLIA Regulations and Federal Register Documents
Interpretive Guidelines for Laboratories
Appendix C
Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services
Refer to the related links section for the State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (som107ap_c_lab).
Downloads
som107ap_c_lab - Rev. 166, 02-03-17 (PDF)

New CLIA PT Allowable Error Limits Effective July 11, 2024



Technical Supervisor Qualifications (GEN.53400)

NOTE 1: Individuals qualifying as a technical supervisor prior to December 28, 2024, may continue to fill this role if they have served continuously as a technical supervisor for high complexity testing in a CLIA-certified laboratory since then.
NOTE 2: Additional qualifications for technical supervisors in dermatopathology, ophthalmic pathology, and oral pathology may be found in CLIA regulation §493.1449 (f) and (g).

Diagnostic Immunology, Chemistry, Hematology, and Radiobioassay Technical Supervisor			
Educational Qualifications	**Board Certification Required**	**Training and experience**	**Additional Qualifications**
Bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution		Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty	
Bachelor's degree, other 42CFR493.1443(c)(5)(i)(B)		Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty	At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either: • 48 semester hours of medical laboratory science or medical laboratory technology courses; **OR**
			• 48 semester hours of science courses that include: ○ 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; ○ 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and ○ 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination

(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least 1 year directing or supervising nonwaived laboratory testing; and

(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; or

(3)

(i)

(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or

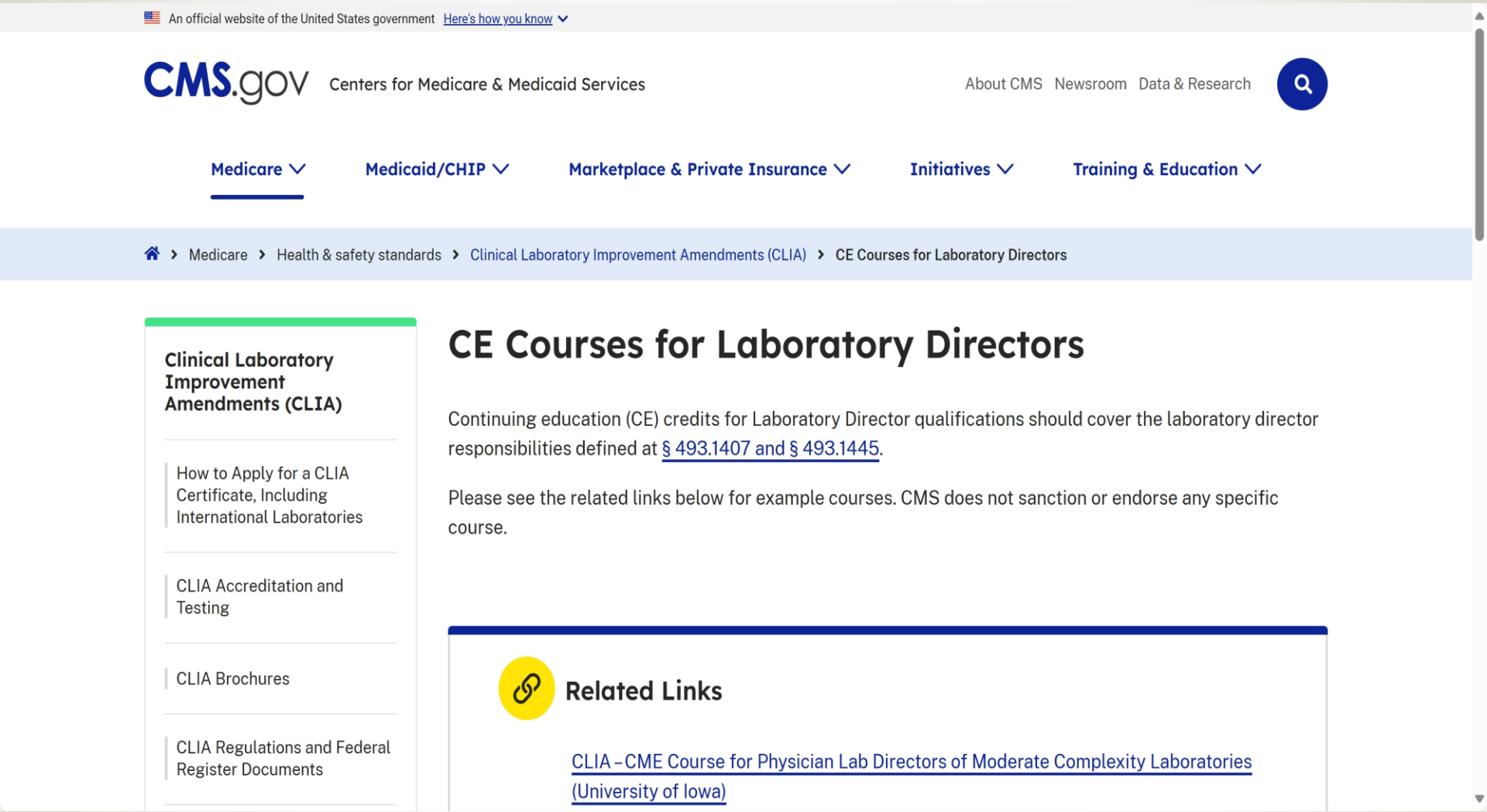
(B) Hold an earned doctoral degree; and

(*1*) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or

(*2*) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407; and

42 CFR 493.1405(b)(3)(ii) (enhanced display) **page 5 of 32**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Medicare Medicaid/CHIP Marketplace & Private Insurance Initiatives Training & Education
Medicare › Health & safety standards › Clinical Laboratory Improvement Amendments (CLIA) › CE Courses for Laboratory Directors
Clinical Laboratory Improvement Amendments (CLIA)
How to Apply for a CLIA Certificate, Including International Laboratories
CLIA Accreditation and Testing
CLIA Brochures
CLIA Regulations and Federal Register Documents
CE Courses for Laboratory Directors
Continuing education (CE) credits for Laboratory Director qualifications should cover the laboratory director responsibilities defined at § 493.1407 and § 493.1445.
Please see the related links below for example courses. CMS does not sanction or endorse any specific course.
Related Links
CLIA – CME Course for Physician Lab Directors of Moderate Complexity Laboratories (University of Iowa)

IQCP and Risk Management

- CMS allows Medical Directors to reduce the frequency of QC based on a risk management approach – develop and Individualized Quality Control Plan (IQCP)
- Latest ISO 15189 and ISO 22367 stress need for risk assessment in clinical laboratory quality
- Latest CAP checklists are adopting risk approach

GEN.NEW Risk Management Phase 0

The quality management system (QMS) uses a prospective risk management process that includes identification, control, and monitoring of risks throughout the laboratory. Potential sources of errors and non-conforming events are incorporated into the risk management process.

Note: Risk assessment includes a process to identify sources of potential failures and errors in the laboratory's systems related to patient testing. The process should evaluate the frequency and severity of potential failures and errors. Strategies for process modification to mitigate significant risks should be developed. Monitoring should continue until data demonstrates acceptable reduction of risk.

Proficiency testing (PT), quality control (QC) reviews, event occurrence management, recognizing patterns in data, and feedback from laboratorians/clients/patients are key ways to identify potential sources of error and non-conformances that could be included in the risk management process.

The risk management process should be proactive, it should focus on "what could go wrong." A laboratory culture of transparency, process orientation rather than personal blame, open communication, and strong leadership support is essential to a successful risk management process. Risk identification and mitigation should be incorporated into policies and procedures. Assessment of risk should be documented in development of new laboratory processes and test methods.

Evidence of compliance

Records of risk evaluation and risk mitigation **AND**
Records of investigation of complaints, and non-conformities includes assessment of future negative impact on process outcome and identification of mitigating actions **AND**
Description of risk identification, evaluation, mitigation and monitoring described in the Quality Plan

REFERENCES

ISO 15189:2022 Medical laboratories, Requirements for Quality and Competence. International Organization for Standardization. 2022.
ISO 22367:2020 Medical laboratories, Application of risk management to medical laboratories. International Organization for Standardization. 2020.
ISO 23824:2024 Medical laboratories, Guidance on application of ISO 15189 in anatomic pathology. International Organization for Standardization. 2024.
College of American Pathologists. Accreditation Resources - Quality Management. www.cap.org, e-LAB Solutions Suite (login required). Accessed 1/2/2025.

Concluding Thoughts

- POCT compliance reflects successful optimization of POCT quality
- Compliance requires policies that allow individual flexibility in implementation without being too stringent in enforcing a single view
- Some strategies to improve program compliance include:
  - Promoting self-management and role of each staff in patient care – POCT is patient care
  - Implementing system changes to compliance issues (rather than blaming the operator)
  - Communication of policies, program goals and expectations
  - Ongoing visibility on the nursing unit through lab visits and POCT contacts on the unit.