POCT Coordination: Managing Your Sanity as Your Program Expands Beyond the Horizon

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Objectives

- Identify POCT market trends
- Examine quality concerns with POCT
- Discuss the role of a POCT program in maintaining quality
- Offer tips for managing POCT

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POCT Definition

- Clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing).
- POCT refers to any testing performed outside of the traditional, core or central laboratory.
- Nichols JH (editor) National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: Evidence Based Practice for Point of Care Testing. AACC Press: 2007.

Point of Care Testing

- Advantages
  - Immediate results - no lab transportation
  - Small blood volume
  - Wide menu of tests available
  - Whole blood and other samples available
  - Works within clinical patient flow
- Disadvantages
  - More expensive than traditional laboratory tests
  - Quality is questionable as anyone can run the analysis
  - Difficulties with regulatory compliance and documentation
  - Lack of appreciation for preanalytic, analytic, postanalytic issues
  - Compliance issues with billing and charge capture

Projected POCT Market

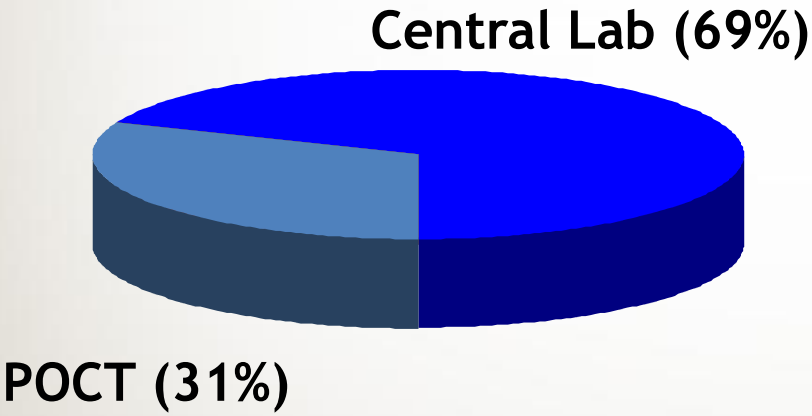
8.5% CAGR to $49 Billion by 2025

2008

US$ 13.1 Billion world-wide

Decreased glucose growth (managed care, price discounts)

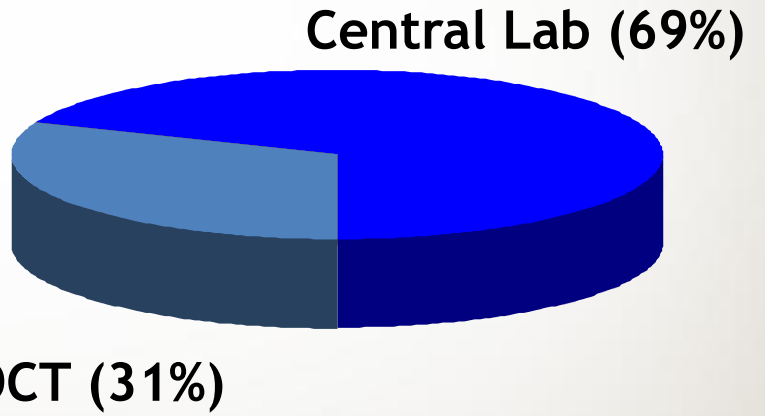
Increase IA and molecular POC 6% annual growth, glucose <5%



2015

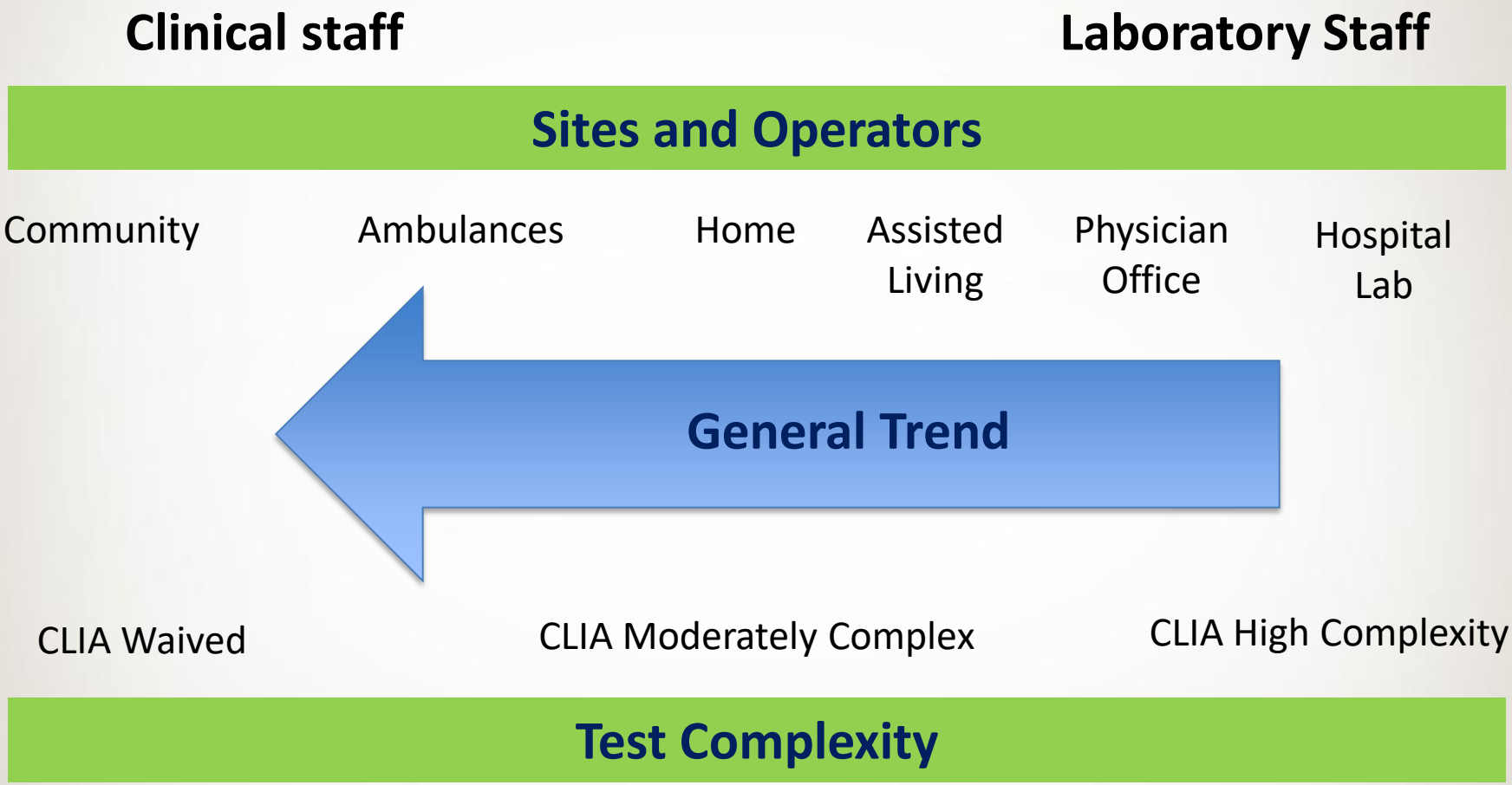
US$ 20.2 Billion world-wide

Central Lab growth in select areas of molecular, flow cytometry, AP keeps pace with POC growth



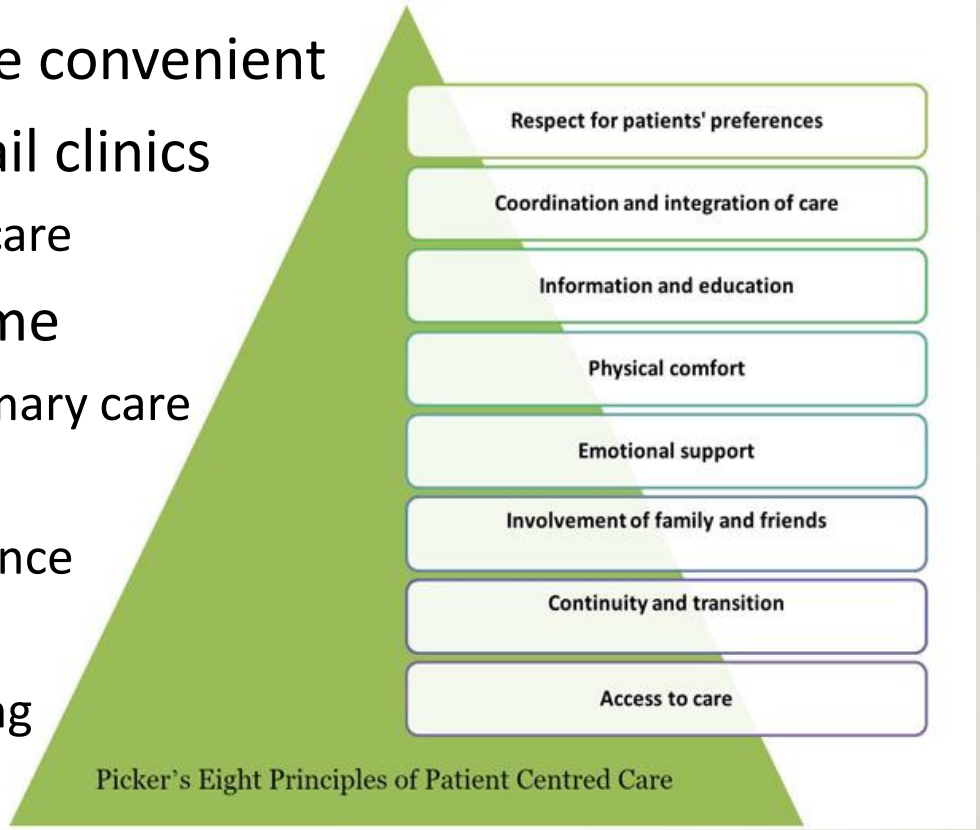
Emery Stephens, J POCT 2009;8(4):141-4.

Trends in Laboratory Testing



Key Drivers for POCT

- Patient-centered care and Healthcare Reform
- Lab brought to patient – more convenient
- Patient seeking POLs and retail clinics
  - Cost-effective, timely medical care
- Patient-centered medical home
  - Emphasis on patient's first/primary care
  - POCT improves access to care
  - POCT improves patient experience
  - POCT improves care quality
  - Enhances disease understanding and awareness by patient
- Patient satisfaction achieves meaningful use goals



Federal Oversight of Lab Quality

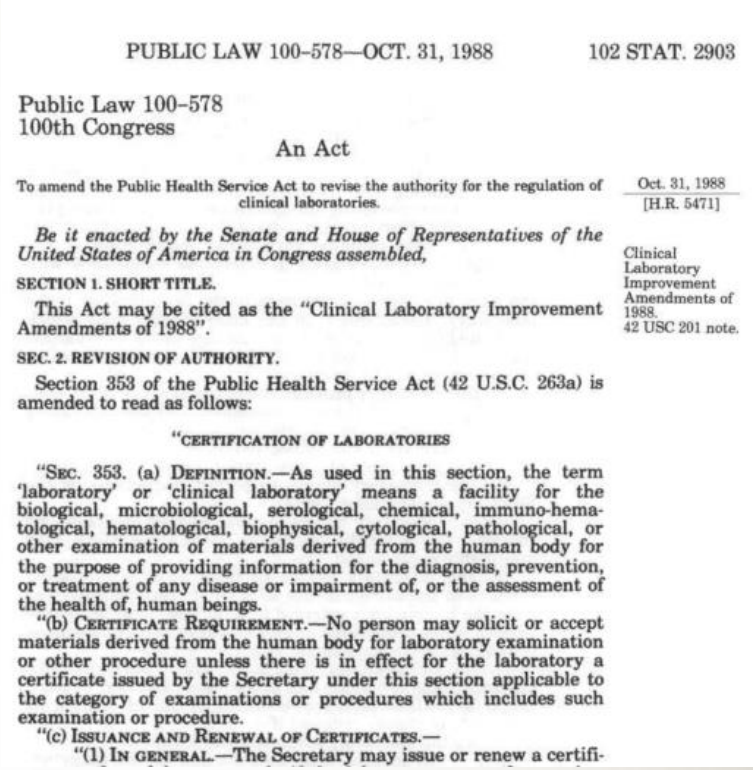
- Clinical Laboratory Improvement Amendments of 1988 (CLIA'88)
- Federal Regulatory Standards that apply to all clinical laboratory testing performed on humans in the United States
- Sets minimum guidelines for quality of "laboratory testing"
- Other state and accreditation agencies (Joint Commission and CAP) have additional requirements and standards

Test Categorization

- Waived Complexity – only 3 requirements
  - Pay biennial fee (every 2 yrs) for CLIA certificate renewal
  - Follow manufacturer's instructions for use
  - Allow the site to be inspected
- Moderate and High Complexity tests
  - Mandatory biennial lab inspection
  - Verify performance of test before use in patient care
  - Minimum education requirements, training/competency
  - Establish quality assurance, maintenance, calibration
  - Procedures including test order and report documentation

POCT Regulations

- Moderate complexity POCT
  - Medical director with lab background
  - Method validation, quality documentation
  - Mandatory inspections
- Need for infrastructure and lab involvement
- Waived testing easier to implement
  - Minimal regulations
- Challenge to switch methods in future



PUBLIC LAW 100-578—OCT. 31, 1988 102 STAT. 2903

Public Law 100-578
100th Congress

An Act

To amend the Public Health Service Act to revise the authority for the regulation of clinical laboratories.

Oct. 31, 1988
[H.R. 5471]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Clinical Laboratory Improvement Amendments of 1988.
42 USC 201 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Clinical Laboratory Improvement Amendments of 1988".

SEC. 2. REVISION OF AUTHORITY.

Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended to read as follows:

"CERTIFICATION OF LABORATORIES

"SEC. 353. (a) DEFINITION.—As used in this section, the term 'laboratory' or 'clinical laboratory' means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

"(b) CERTIFICATE REQUIREMENT.—No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

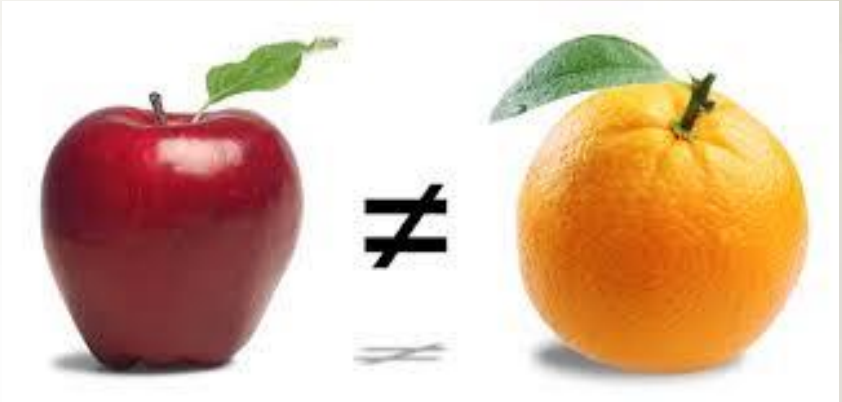
"(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

"(1) IN GENERAL.—The Secretary may issue or renew a certifi-

CLIA Laboratory Certificates January 2017 (255,170 Labs)

Total # Labs **Compliance (State)** **Waived** **Accreditation**	**255,170** **18,143 (7.1%)** **178,493 (69.9%)** **16,354 (6.4%)**
Total # POLs **Compliance (State)** **Waived** **Accreditation**	**121,973 (47.8% of labs)** **11,474 (9.4% of POLs)** **76,655 (62.8% of POLs)** **5,525 (4.5% of POLs)**

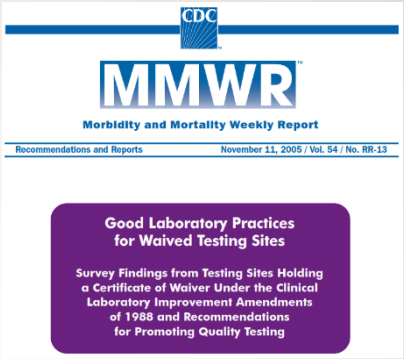
POCT results ≠ laboratory results



- POCT troponin and flu less sensitive than lab
- Rapid strep negative results require lab confirmation
- POCT creatinine biased to lab methods (can overcall patients with kidney impairment and lower chemo dose)
- Different glucose meter results don't match each other
- Physicians don't wait 5 min to develop occult blood tests
- POCT often gets reported with lab values in the eMR – can lead to diagnostic confusion!

Quality Concerns

- Quality concerns/risk of erroneous results
  - Lack of understanding/training of staff
  - Test limitations
  - Misuse
  - Exposure extreme environment conditions
- Call by GAO to strengthen lab oversight



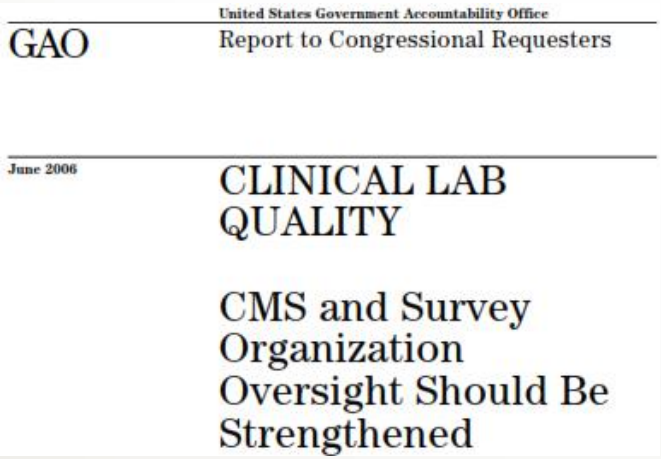


TABLE 5. Number and percentage of quality deficiencies related to following manufacturer's instructions and documentation in Certificate of Waiver sites, from the Centers for Medicare & Medicaid Services surveyed sites,* 2002–2004

Quality deficiencies	No. of sites	(% of sites)
Following manufacturer's instructions†		
The site did not		
Have current manufacturer's instructions	485	(12)
Routinely check new product inserts for changes§	701	(21)
Based on manufacturer's instructions, the site did not		
Perform quality control testing	866	(21)
Report test results with terminology or units described in package insert	744	(18)
Adhere to proper expiration dates	267	(6)
Perform required confirmatory tests	265	(6)
Perform function checks or calibration	195	(5)
Adhere to storage and handling instructions	135	(3)
Perform instrument maintenance	125	(3)
Use appropriate specimen for each test	81	(2)
Add required reagents in the prescribed order	24	(1)
Documentation¶		
The site did not		
Document the name, lot number, and expiration date for all tests performed§	1,493	(45)
Maintain a quality-control log§	1,151	(35)
Maintain a log of tests performed	1,318	(31)
Require test requisition (or patient chart) before performing a test§	304	(9)
Keep the test report in the patient's chart§	56	(2)
Check patient identification§	31	(1)

* N = 4,214 sites.
† Required for waived testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
§ 2003–2004 data only (n = 3,317).
¶ Not required for waived testing under CLIA.

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 overall quality of POCT
- To provide the resources to oversee POCT compliance

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

POCT is a Complex System

- Laboratory
  - One site
  - Limited instrumentation to perform bulk of testing
  - Limited staff, focused on same equipment daily
  - Staff trained in laboratory skills
- POCT
  - Dozens of sites, hundreds of devices and thousands of operators
  - Staff are clinically focused on patient not on equipment
  - Staff do not have laboratory training background
  - Testing delegated to lower level staff (TAs, MAs)

VANDERBILT POCT (2018)	Sites	Devices	Operators
Glucose	120	500	4096
Hemoglobin A1c	10	27	90
Blood Gas – GEM	18	34	1033
i-STAT	15	29	320
Heparin Management	1	3	8
ACT	7	35	174
PT/INR	19	24	105
AVOX	2	7	38
Occult Blood	35		1585
pH	5		100
Urinalysis	53	47	1029
Mono	20		156
Strep A	34		466
Influenza A & B	36	37	330
Pregnancy	60		910
Drug Testing	2		20
HIV	1		20

Develop a POCT Infrastructure

- The number of devices people and testing performed POCT in an institution requires an organization and management structure
- Clinicians want POCT in the clinics often miles from the central hospital
- Many institutions have a POC Coordinator (often a lab staff) and POCT Committee to oversee practice
- POCT Committee can depersonalize the review process for test approval, inspection preparation and actions to deficiencies.

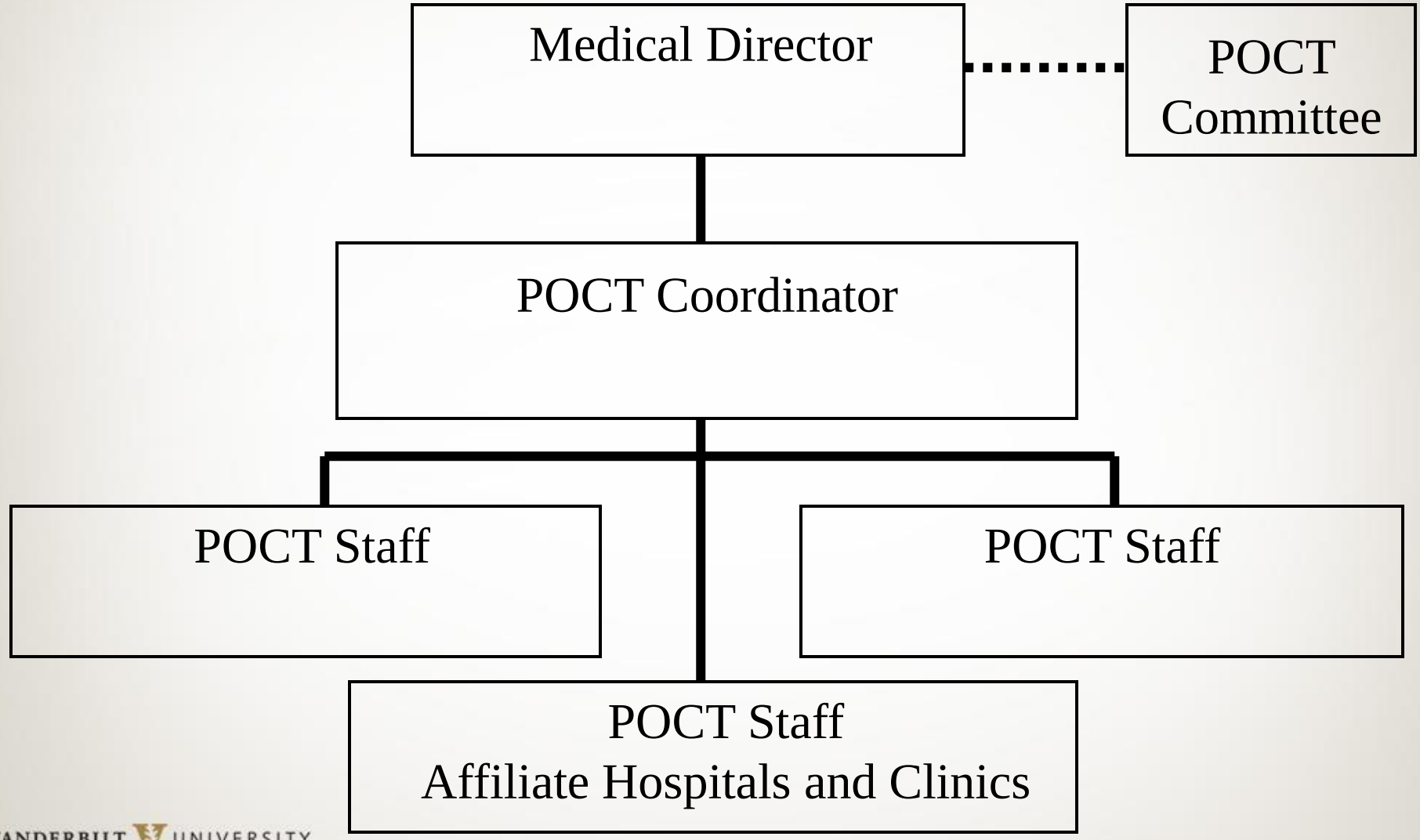
Why Do We Need a POCT Program?

- Organize the activities involving POCT
- Meet federal and accreditation regulations
- Identify what tests are conducted outside the formal core laboratory
- Approve/disapprove new test requests
- Determine who is performing POCT
- Document staff competency
- Manage POCT test results

POCT Committee

- Chair
- Lab – POC Coordinator
- Nursing – administration
- Purchasing
- Physician – user of POCT results
- Outpatient clinic representation
- Affiliate hospitals
- Other services involved – Pharmacy, Nutrition…

POCT Management



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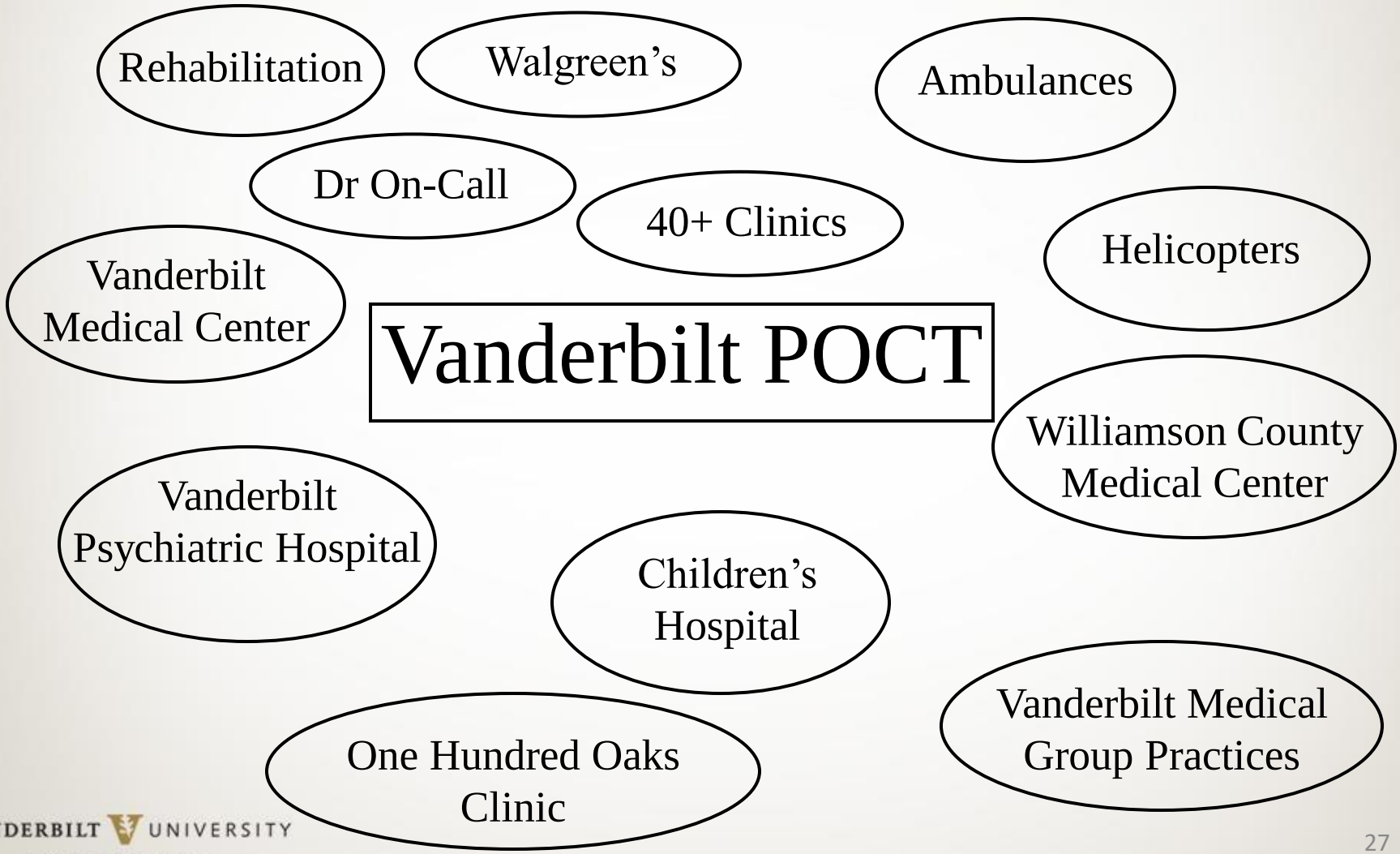
POCT Coordinator

- Staff manager of overall POCT program
- The most important person next to the Medical Director in the POCT Program
- Ensures documentation meets regulatory compliance
- Maintains records of sites and testing
- Coordinates IT services for data transfer of results to medical record
- Keeps policies and procedures up-to-date
- Troubleshoots testing problems

POCT Management
Vanderbilt Medical Center



Department / Area / Clinic	# [Certificates filed under cost center #]	Name of Accrediting/ Certifying Agency	Medical Director CAP Proficiency Au # (If applicable)	D. Trainer	PHONE	Address	Test Performed	Manager
1. FAMILY PRACTICE (First Floor)	20323XXXX	CLIA 44XXXX Exp.7/11/19	Dr. Warren MD	**Louis PC**	**555-1234**	, TN. 37067	Flu, strep, Clinitek Status, urine pregnancy, Sure Step glucose Hemocue, Hemocult, PPM KOH, wet preps,	Loretta Lynn
2. PEDIATRIC CLINIC (Second Floor)	20311XXXX	CLIA 44XXXX Exp. 2/14/18	Dr. Miller MD	**Kim Jones RN**	555-2121		Clinitek Status Urine, DCA HgBA1C Advantage Sure Step, Glucose, Flu, Strep, Hemocult	Ms. Price
3. INTERNAL MEDICINE (Third Floor)	20322XXXX	CLIA 44XXXX Exp. 7/10/19	Dr. Smith MD	**Ron Night**	**555-0102**	TN 37067	Flu, strep, Clinitek Status, urine pregnancy, Sure Step glucose, Hemocult PPM KOH, wet preps	Jackie Chan
GI CLINIC (third floor)	20326XXXX	GI I IM share lab CLIA	Dr. Jones MD	**POCT**	555-1212	Third Floor Franklin TN 37067	Hemocult	Lori Done

Simplify Regulatory Compliance

- Standardize instrumentation and methods across the health system
  - Minimizes number of different devices
  - One policy can be shared amongst sites
  - Central management system (ie oversight and data management)
  - Same methodology, clinical limitations
  - Share reference intervals (normal values)
  - Simplifies training and competency, float staff

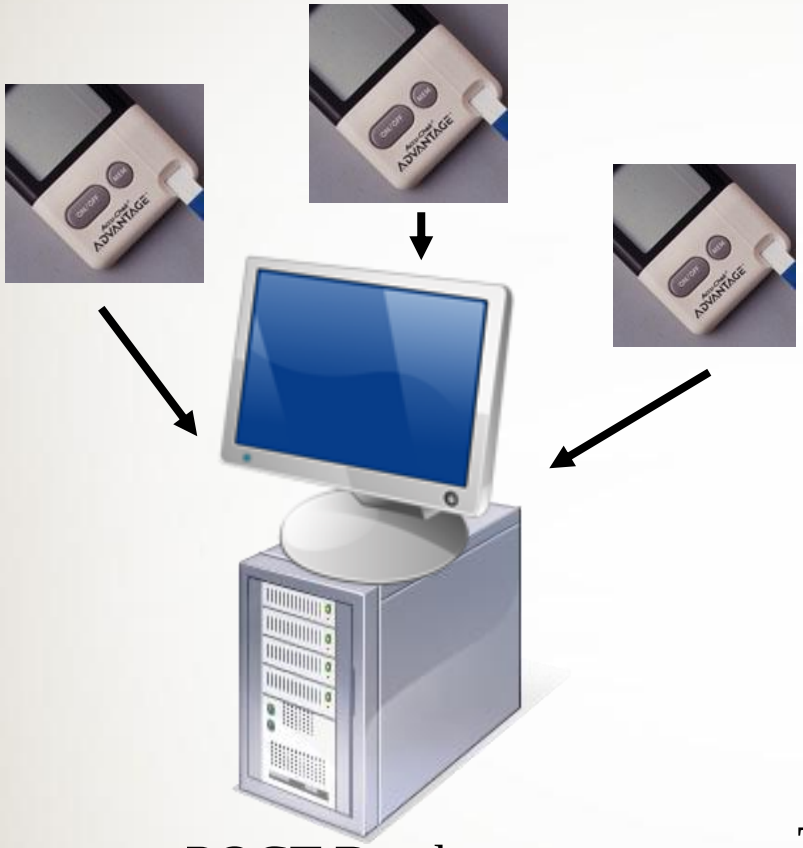
Sources of POCT Challenges

- Lack of experience:
  - Lower level staff w/ less training
  - More staff involved – less opportunity to test
- Unfamiliar with regulations:
  - Need for QC, training/competency, validation, documentation
- IT Integration and Data Management
  - Capturing results, separating POC in EMR, device lockouts
- Complex workflows:
  - Refrigerated storage vs room temp stability
  - Open vial stability (30 days v imprinted expiration)
  - Sample collection, transport, and test application

Staff Training and Competencies

- Copies of HS diploma or degree for mod complex operators
- Initial training and competency 6 mos and annually thereafter.
- 6 elements competency challenge with thousands operators
  - Direct observation of test performance (from patient prep to testing)
  - Monitoring reporting results, and critical values
  - Review worksheets, QC records, PT results, maintenance
  - Direct observation of maintenance and function checks
  - Assess performance of previously analyzed specimen or known sample
  - Evaluation of problem solving skills
- Some elements can be automated by online test, others require review and direct observation
- Make each staff responsible for own documentation!

Use Electronic Databases, Distribute Responsibilities, Reduce Paperwork



<u>POCT Database</u>

Quality Control Records

Operator Competency Dates

<u>Nursing Unit</u>

Employee Records

POCT Policies

<u>POCT Coordinator</u>

Device Validations

Lot checks and management

Training/Competency records

Nursing Unit Compliance Trends

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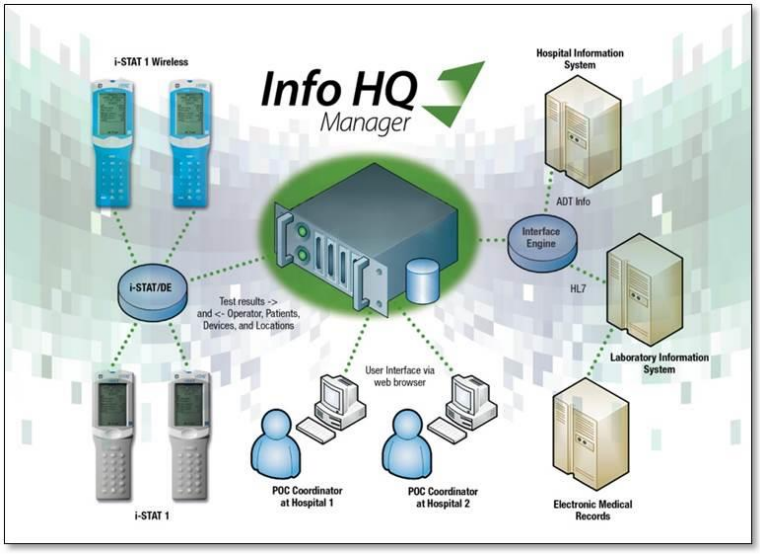
POCT Data Management

- Manual POCT results may not get recorded in patient's medical record,
- Computerized POCT devices automate the QA documentation (and billing) process by storing patient and operator identification with patient result, time and date, and serial number of device.
- Electronic POCT data can be transmitted to the medical record, hospital information systems or other databases.
- Computerized POCT devices mandate performance of QC and lockout if not performed successfully. Operator lockout ensures only trained and competent staff perform testing
- Electronic data streamlines the quality review of large amounts of data
- 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 automatically. (Need continuous wireless or operators may forget to push send button)

POCT Data Management

- Middleware
- Access from anywhere, home, office, POC
- Ensures quality testing and regulatory compliance
- Can access test result history and status of any analyzer
- Manage operators, set competency and lock-outs
- Review QC/corrective actions



POCT Operations

- POCT is portable, allows testing bedside
  - Cleaned between each use
  - Infection control of supplies

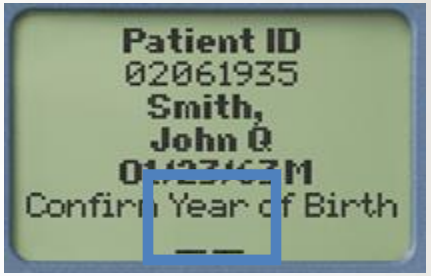
- POCT devices can be stationary
  - Samples must be transported to device
  - Potential for sample mix-up, requires labeling
  - Separates clinical staff from patient
- Each has unique challenges!

Issues with Patient Identification

- Incorrect entry of patient identification can
  - Chart results to the wrong patient's medical record
  - Lead to inappropriate medical decisions and treatment
- 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 goals – 2 patient 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

Gaurav Alreja[1], Namrata Setia[2], James Nichols[2], Liron Pantanowitz[2]

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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.

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/

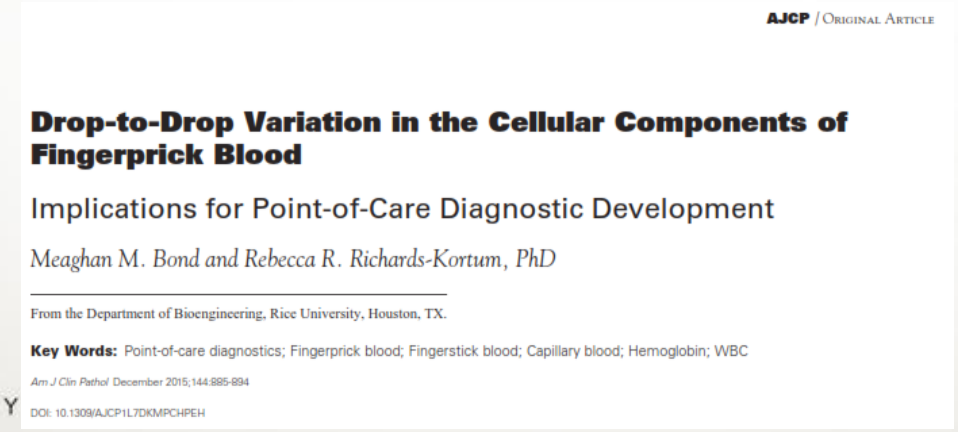
1. Alreja G, Setia N, Nichols J, Pantanowitz L. Reducing patient identification errors related to glucose point- of-care testing. J Pathol Inform 2011; 2: 22 [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3097526/]

Sample Collection

- Not all fingersticks are the same!
  - Easier than phlebotomy? For the nurse…
  - Variation in operator technique and potential for error
    - Apply directly to cartridge/test
    - Collect into a micro collection tube – transfer into test kit/analyzer
    - Collect into a capillary – transfer to test cartridge
    - Concern for blood gas exposure to environment

Capillary Sample Challenges

- Adequacy depends on depth and blood flow!
- Well known issue: operator technique, patient variation
- Safety and ability to mix with anticoagulant
- Capillary differs from venous in patients with poor circulation – source of FDA concerns over the use of glucose meters in critically ill patients



AJCP / Original Article

Drop-to-Drop Variation in the Cellular Components of Fingerprick Blood

Implications for Point-of-Care Diagnostic Development

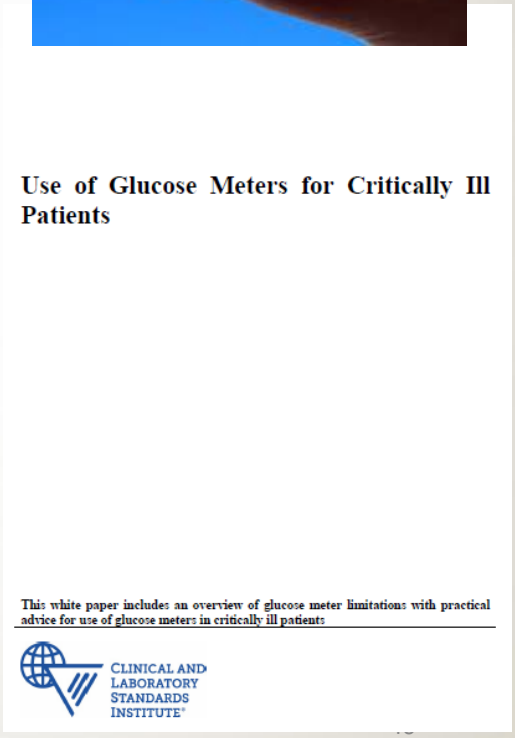
Meaghan M. Bond and Rebecca R. Richards-Kortum, PhD

From the Department of Bioengineering, Rice University, Houston, TX.

Key Words: Point-of-care diagnostics; Fingerprick blood; Fingerstick blood; Capillary blood; Hemoglobin; WBC

Am J Clin Pathol December 2015;144:885-894

DOI: 10.1309/AJCP1L7DKMPCHPEH



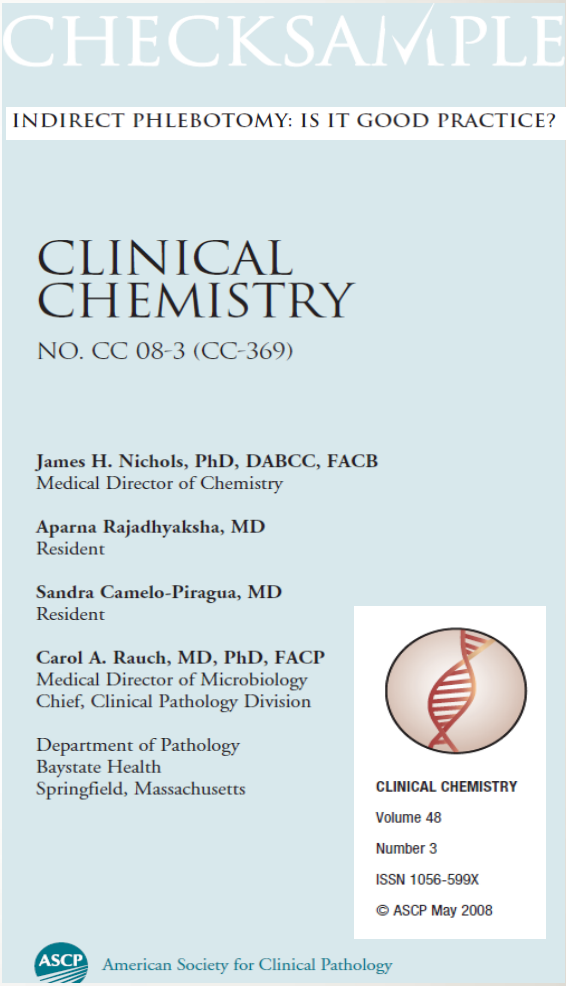
Use of Glucose Meters for Critically Ill Patients

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®

Indirect Phlebotomy (Line Draws)

- Potential to contaminate sample with line fluid
- Can dilute or elevate results depending on test and what is being infused through the line
- Collection through heparin lock – coagulation test results will be altered
- Not generally recommended – but a universal practice



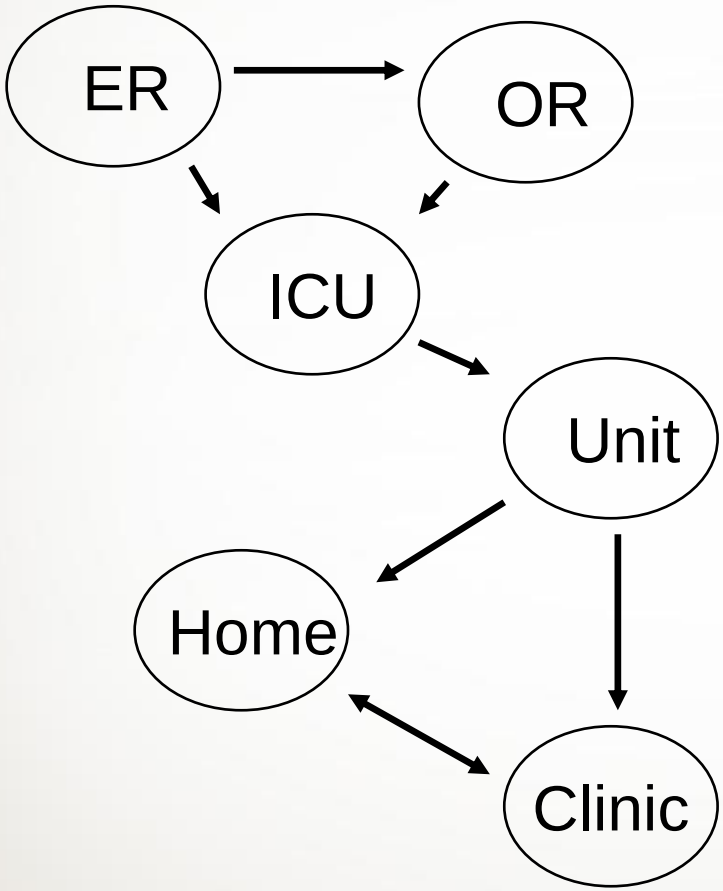
Manage Supplies

- POCT supplies (QC and kits) have varying storage temperature
  - Refrigerated must reach room temp to test
  - Room Temp storage easier to manage at multiple locations
- Manufacturer expiration dates change once bottles opened
- Operator must redate with new expiration upon opening
- Discard opened vials with no handwritten expiration
- Share purchasing across sites/clinics – single validation
- Talk with distribution to store refrigerated and RT supplies

Discarded strips due to no date[1]

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

Continuity of Care



POCT

Critical Care

Core Lab

POL - Clinic

Promote 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

Self-Management

- Develop a POCT website or use electronic document control to distribute policies and docs
- Provide all of the tools necessary to manage POCT
- POCT sites 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 Inspection

- Provide a checklist of top items to review
  - Open bottles dated/expired reagents
  - One lot in use at a time
  - Reagents stored as recommended
  - Temperature monitoring
  - QC performed as required
- Regularly visit sites
- Encourage site self-management to use checklists in the interim of POCT program visits
- Prepares sites for unannounced inspections
- Require follow-up within 30 days for any violations
- Track trends and provide performance scorecards

Review Sites for Efficiencies

- Our IQCP found helicopter transport sites acted like independent facilities despite under central management
- Each site ordered supplies, with required shipment check-ins, 6 mo linearities/cal verifications and monthly 2 level QC
- Intent was to QC the device rather than the reagents, but for i-Stats – the chemistry is in the cartridge, devices just readers
- Centralized ordering, one shipment check, distribute supplies to all sites. Sites then QC their cartridges monthly.
- For i-Stat QC same as some levels of cal ver set. If analyze 3 levels QC each month on every lot of cartridges, already performed a 6 mo linearity/cal verif. QC the reagent!
- Significant savings without compromising quality of POCT

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 i-stats = 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!

Summary

- POCT is an increasingly popular means of delivering laboratory testing closer to the site of patient care.
- A faster result isn't necessarily a better result
- Quality concerns require laboratory involvement and supervision of testing process
- A POCT program is a resource to clinical staff for policy, practice, education, troubleshooting and application of POCT results
- Simplify, Educate, and Be a Resource!