

# **Improving Your POC Program: An Upside Down Map**

**Sheila K. Coffman MT(ASCP)**

Presented at the Alabama Point of Care Coordinators Group Web Meeting

June 17, 2010

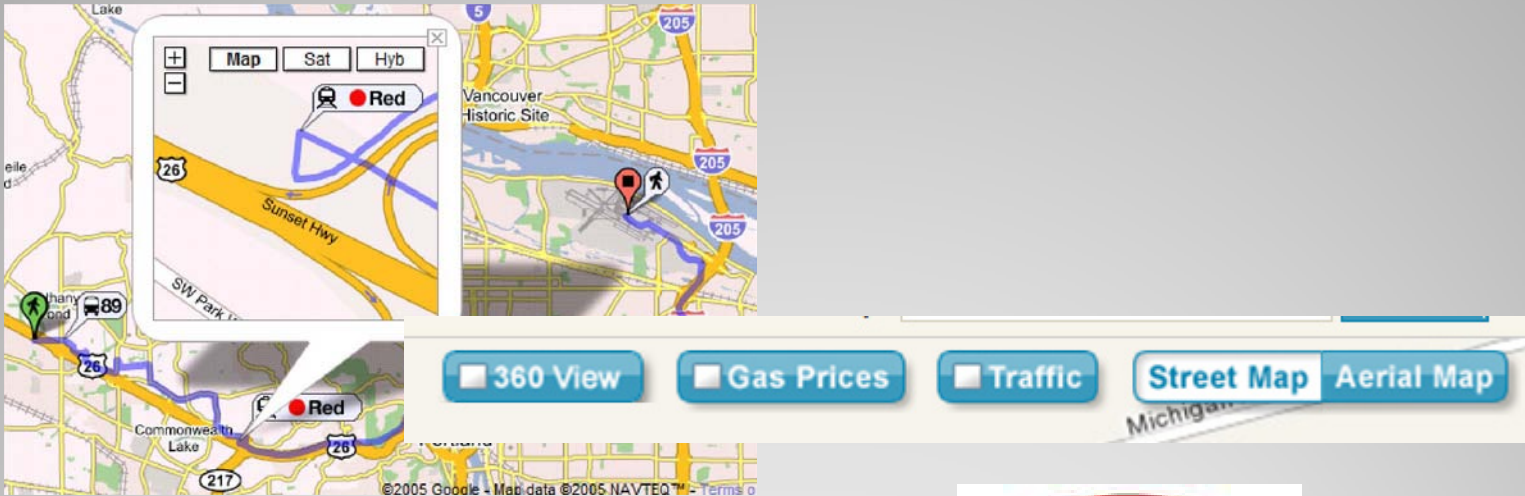
Produced by Whitehat Communications

If you have seen ONE Point of Care program...

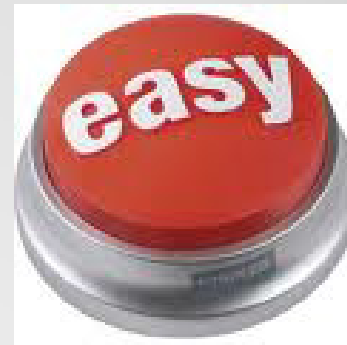


You have seen ONE Point of Care Program.

If only there was a MapQuest for POC...



Or an EASY Button...



# Key Players

## Organization of the POC Program

### Key Players?

Medical Director (pathologists, other?)

Lab Director

POCC- bench technologist, coordinator, manager?

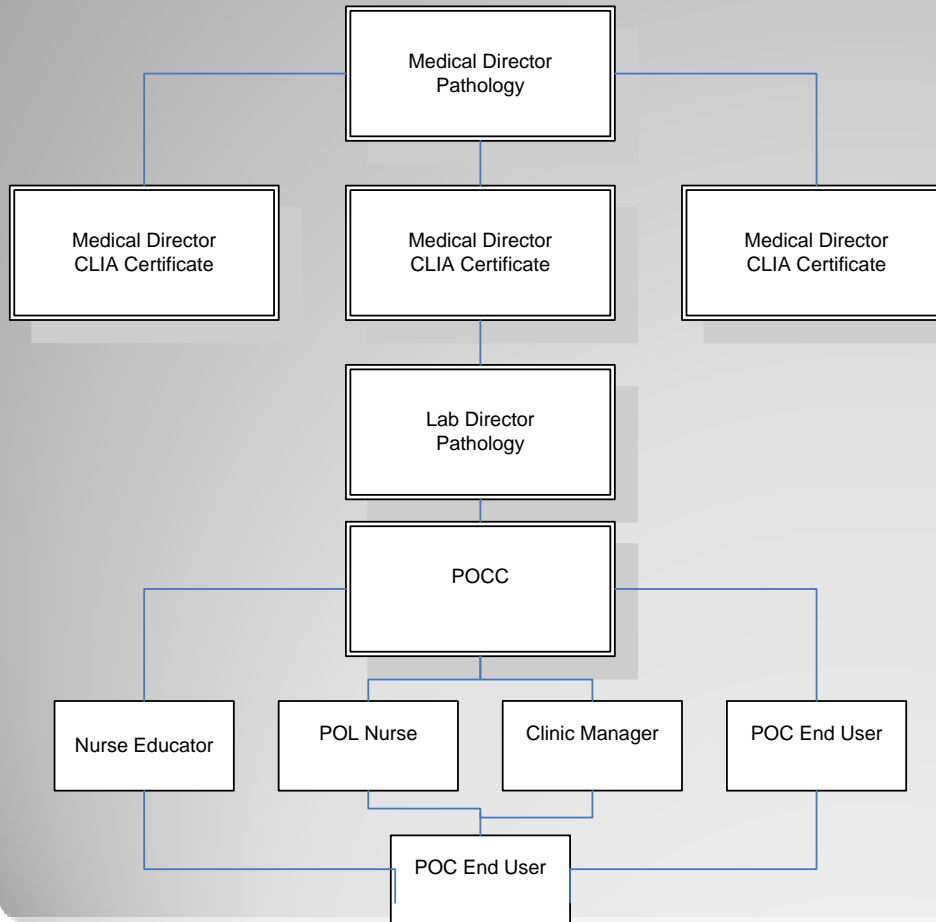
Nursing Key Leaders

POC Users

**Who are some other key POC personnel in your organization?**

# Administrative

## EXAMPLE



Do NOT forget to consider:

- Pharmacy
- Purchasing
- Information Services/Technology
- Risk Management
- Maintenance/Bio-Med

These folks play critical roles in a successful POC program.

# Administrative

- ❖ Define the roles of each of the key players
  - ❖ ID the responsibilities
  - ❖ ID the authority levels
  - ❖ ID the reporting structure
- ❖ An organizational chart should exist in the POC Manual
  - ❖ Needs to be kept current (use titles-not names)
- ❖ Create a Policy including the above information

# Administrative

## POC Committees

1. Choose the right participants/stakeholders (keep small and effective)
2. Issue an electronic invite-time, date and AGENDA
3. Agenda- include time allotments and assignments
4. Appoint a note keeper, time keeper
5. Finish on time with summary of completed items, action items and assignee for next meeting.

4 Ground Rules- participate, stay focused, maintain momentum, reach closure.

**MEET ONLY WHEN NECESSARY**

# Administrative

## Team Approach

- Clinicians define the medical situations where POCT is appropriate
- Laboratory focuses on good POCT results
- Nursing and other health professionals strive for good patient care



# Administrative

## Test Selection Criteria

### ❖ Test Information

- ❖ Name of test
- ❖ Location for use
- ❖ Already in use in POC Program?
- ❖ Name, manufacturer and methodology
- ❖ Cost analysis

# Administrative

## Test Selection Criteria

### ❖ Utilization Information

- ❖ Anticipated Indication
- ❖ Describe patient care benefits/outcomes and cost savings
- ❖ Current lab TAT
- ❖ Current volume of test
- ❖ Anticipated volume if POCT

CLSI POCT09

Selection Criteria for Point-of-Care Testing Devices

- To be published April 2010

# Administrative

## CLIA Certificates

Do you have the right type?

- Certificate of Waiver
- Certificate for Provider Performed Microscopy (PPM) Procedures
- Certificate of Registration and Certificate of Compliance
- Certificate of Accreditation

Do you have the right number?

Does your POC program combine any testing with the main laboratory?

# Policy and Procedure

**Policy**-The requirements may be mandated by regulatory or accrediting agencies (*i.e.*, TJC, CMS, CAP, COLA) or self-imposed to ensure safety, quality, or cost effectiveness. "thou shalt".

**Procedure (SOP)**-Provide the step-by-step instructions on how to achieve the activity, or task outlined in a process and should be written with the end user in mind.

**Job Aid**-Any tool used by an employee to carry out a procedure step. Examples-forms, checklists, decision trees (flow charts), reference guides, telephone lists, and signs.

# Policy and Procedure

## Improvement Opportunities

1. Read them with fresh eyes
2. Include all associated documents in the procedure

### EXAMPLE

#### Forms or Records:

- PT 212.A Patient Result Log
- PT 212.B HemoSense INRatio Quality Control Log
- PT 212.C HemoSense INRatio Reagent Log
- PT 212.D POCT Problem Log
- PT 212.E HemoSense Fingertick Collection Attachment
- PT 212.F HemoSense Error Guide for the INRatio Attachment
- PT 212.G HemoSense INRatio Competency

# Policy and Procedure

## Improvement Opportunities

3. Make sure the procedures reflect package insert changes.
4. Include Proficiency Testing Requirements and Ordering information (if applicable).
5. Make sure the P&P are in accordance with the appropriate agency (CAP, COLA, TJC, CMS,...) Get "in the know" on all changes to regulations.
6. Make them available electronically if at all possible maintaining a master hard copy.

# Training

## Competency Program

- ❖ Who provides the training?
- ❖ How does the POC operator receive it?
- ❖ What format is used?
- ❖ How is training documented?
- ❖ How is it retained for proof of completion?

# Training

Train the Trainer Program- "The Who"

Utilization of "Trainers" to go forth and train the masses.

- ❖ Nurse Educators
- ❖ Clinic Managers
- ❖ Lab liaisons
- ❖ Respiratory, Pharmacy, Anesthesia
- ❖ Key End Users

Who assists with training in your program?



# Training

**Outreach- How does the end user receive training?**

Orientation

Email

POC Educator

POC User

Intranet

Internet

Training Fairs

Connectivity Module

**Interactive Group Discussion**



# Online Training

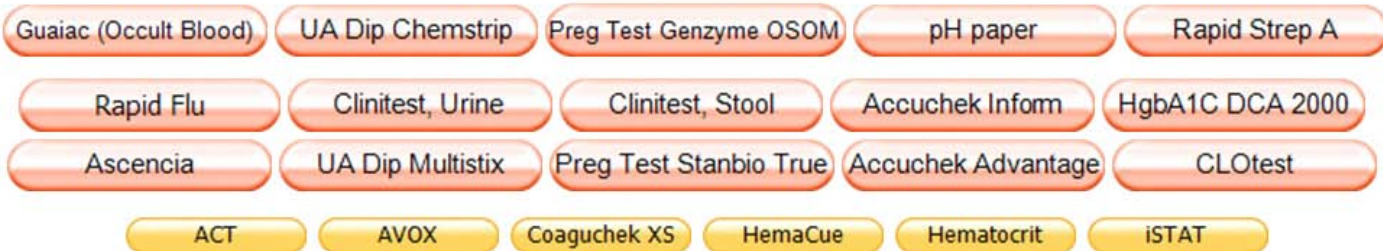
 **UTMB** The University of Texas Medical Branch

Point of Care Testing

## ONLINE COMPETENCY TESTS

Competency for waived testing is assessed using **at least two of the following methods** per person per test:

1. Performance of a test on a blind specimen (i.e. **check-offs**)
2. Periodic observation of routine work by the supervisor or qualified designee
3. Monitoring of each user's quality control performance (i.e. **validation tolls, Inform**)
4. Use of a written test specific to the test assessed (i.e. **online tests**)




**Note:** Test questions come from the respective [Policies and Procedures](#). In order for these tests to function properly, you **MUST** use the **Internet Explorer** browser. **DO NOT use NETSCAPE.**

# Training

## Connectivity Solution-Training Modules

http://www.rals.com/RALS-eQuiz.html



About MAS | MAS News | Home

April 14, 2008

Informatics Solutions for Point-of-Care Testing

RALS Workshops Benchmarking Security Support Contact Us

### RALS-eQuiz...

## Web-based Training and Re-certification of Point-of-Care Device Operators

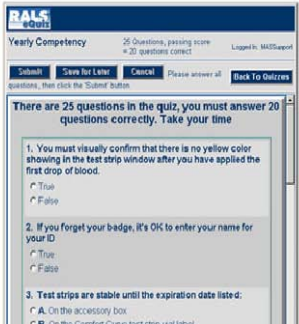
"RALS-eQuiz takes connectivity to yet another level....and assures that accreditation standards with regard to training and competency validation can be upheld and electronically tracked - thus enhancing maximal time management for the POC coordinator."

Deb Norkett, Point of Care Testing Coordinator  
Northeast Medical Center, Concord, NC

**On-line training quizzes available anywhere via the hospital intranet**

- RALS-eQuiz questions managed remotely, in real-time
- Multiple institutions can be managed remotely
- PC, tablet, wireless laptop—it's your choice
- 'Tool Tips' simplify navigation

**Easy to Implement and Access**



Yearly Competency 25 Questions, passing score = 20 questions correct Logout: MASupport

Submit Save for Later Cancel Please answer all Back to Outlines

There are 25 questions in the quiz, you must answer 20 questions correctly. Take your time

1. You must visually confirm that there is no yellow color showing in the test strip window after you have applied the first drop of blood.

True  
 False

2. If you forget your badge, it's OK to enter your name for your ID.

True  
 False

3. Test strips are stable until the expiration date listed:

A. On the accessory box  
 B. On the Companion Device both sides and label

# Quality Management

## Pre-Analytical/Examination

- Patient identification and preparation
- Specimen collection
- Specimen labeling
- Specimen handling



How can we improve (decrease) pre-analytical errors?

Brainstorm Session

# Quality Management

## Analytical/Examination

- Associated with actual specimen testing
- Identifies practices that ensure correct results
- Point-of-care testing allows provider near instant access to results
- Includes timely testing, instrumentation and methodology, quality control

# Quality Management

## Post Analytical/Examination

- Testing personnel should record results and identification of person performing the test in the patient's permanent medical record
- Reference ranges, reportable ranges, and critical values should also be reported for each test
- Whenever possible, permanent record of POC results should be transmitted electronically to the patient's electronic medical record

How can we improve (decrease) post-analytical errors?

LIS/HIS  
Connectivity



## Total Analytical Error Distribution

Error Source	Ross and Boone <sup>1</sup>	Plebani et al. <sup>2</sup>
Pre-analytical	46%	68%
Analytical	7%	13%
Post-analytical	47%	19%

1 – Ross and Boone, Inst. of Critical Issues in Health Lab Practices, DuPont Press, 1991

2 - Plebani and Carraro. Clin Chem 43:1348, 1997

# Quality Management

- Institute of Medicine\*
  - Medical errors cause 44,000 to 98,000 deaths each year

## Errors in perspective (per 10<sup>6</sup>)

- |   |                    |
|---|--------------------|
| ➤ Airline passenger fatalities                      | 0.2                |
| ➤ Deaths due to general anesthesia                  | 2-5                |
| ➤ Viral transmissions from blood transfusions       | 29                 |
| ➤ Deaths/accidents due to defective Firestone tires | 300                |
| ➤ Lost bags of airplane passengers                  | 5000               |
| ➤ <b>Lab errors</b>                                 | <b>10000-30000</b> |

\*To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press; 2000

\*\* Arch Pathol Lab Med 123:761, 1999



# Quality Management

## Major Compliance Concerns

- QC
  - Performance; remedial actions; documentation
- Operator certification
  - Authorized operators; recertification when required
- Lack of identification
  - Operator; patient
- Appropriate documentation in patient records
  - Patient results in a timely manner
  - Audit trail to link patient result with analyst, instrument, QC, time, date
- Documentation
  - Method verification, reagent validation, proficiency testing, etc.

<http://www.advanceforal.com/asp/spotanswer.asp>

# Quality Management

## Top Deficiencies (Cincinnati)

- Following manufacturer's instructions
- Documentation of patient results in patient record
- Patient identification
- Operator identification
- Failure to do QC
- Failure to respond to out-of-control situations
- Unauthorized tester
- Using outdated/expired reagents
- Failure to observe safety requirements
  - Barbara Goldsmith, 2001

# Connectivity

## Sneaker Net versus Connectivity Solution

Are you connected? 100% or less connectivity?

Some devices or all devices?

Uni-directional or bi-directional?

Manual/kit tests?

Do you still purchase POCT without connectivity options?

Do you have a policy that prohibits the purchase of POCT w/out connectivity?

# Connectivity

## What do you gain?

- Increased surveillance
  - Patient results, QC, QA, analyst
  - Alerts supervisor to problems
- Reduced data handling
  - Less chance for transcription errors
- Full data record for traceability
  - Links patient result, instrument, analyst, QC
  - Patient results in patient record
- Cost savings
  - Fewer repeats
  - Only authorized testing

# Connectivity

Features/Options:

Results (flagging, verification, ...)

QC (tracking, trending, lot numbers ...)

Report Functions (Levey-Jennings, Operator, Billing,...)

Training Solutions

Web Access

Tight Glycemic Protocol Monitoring

# Connectivity

## Who pays for connectivity?

POC Program (Pathology department)

POC Users (POL, Out Pt Facilities, Surgery Centers,...)

Manufacturer

# Regulatory

- Regulations
  - Accreditation
  - Standards
  - Guidelines
- Agencies ensure that labs comply with national Clinical Laboratory Improvement Act (CLIA) regulations
- Three major non-for-profit accrediting agencies in the US are:
  - College of American Pathologists (CAP)
  - The Joint Commission (TJC)
  - COLA

**Who accredits your program?**

# Regulatory

## CLIA

- 1967: US Congress passed CLIA
- Requires licensure of laboratories engaged in interstate commerce for human diagnosis, prevention, or treatment of disease
- Expanded to all laboratories, including physician's offices, with the Clinical Laboratory Improvement Amendments in 1988



# Regulatory

## TJC

- TJC accredits approximately 2,000 organizations providing laboratory services
- Represents approximately 3,200 CLIA-certified labs
- Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB)
- Accreditation process concentrates on operational systems critical to safety and quality of patient care
- After on-site survey, organization receives accreditation report

# Regulatory CAP

- CAP is a private not-for-profit accreditation organization
- More than 6,000 labs worldwide are CAP accredited
- Checklists are used to measure compliance with CAP standards
- Deviations can be cited as a deficiency or a recommendation

# Regulatory

## COLA

- Independent accreditation agency that originally focused on physician office labs; accredits more than 33,000 organizations
- Approved by CMS for laboratory accreditation in:
  - Chemistry/Urinalysis
  - Hematology
  - Microbiology
  - Immunology
  - Pathology
  - Cytology
  - Immunohematology

# Choosing an Accrediting Agency

## Certificate Requirements

- Certificate of Compliance
  - Requires an on-site inspection by CMS
- Certificate of Accreditation
  - Laboratory must name an agency to accredit their testing—TJC, CAP, COLA

# Choosing an Accrediting Agency

- CAP strictly regulates proficiency testing (PT) materials used by CAP-accredited labs
- COLA fees are typically lower than CAP or TJC
- Using a combination of agencies:
  - TJC for waived testing
  - CAP for non-waived testing

**Who uses both CAP and TJC? Why?**

# Proficiency Testing

- CLIA regulations require a laboratory to be enrolled in a CMS-approved PT program for all laboratory tests except waived and most PPM
- PT results must be monitored by the accrediting body

Where do you purchase your PT?

# Inspection Preparation

- Organize records for easy access
- Complete self-inspection program
- Knowledge of accreditation agency standards
- Continuous improvement

**How do you get prepared?**

# Inspection Preparation

- Do not volunteer more information than is requested
- Have current procedure manuals
- Obtain training documentation for all POC tests
- Possess up-to-date lists of trained operators
- Ensure documentation complies with retention policies



# Inspection Preparation

- Validation data for all instruments/methods available
- Examples of POC tests recorded in the patient record
- Performance improvement records available
- Verify compliance for reagent dating
- Observe standard precautions for all safety regulations

# Safety

Is your POC program SAFE?

OSHA

- PPE Training

- Hazardous Materials Training (MSDS)

Equipment Management

- New POCT evaluated for safety (replacing glass w/ plastic)

- Is it all on a maintenance schedule?

# Money

## Spending It

### Capital Budget

- ❖ Set up a “wish” list for each year for the next 3-5
  - ❖ Determine what needs to be bought and/or replaced
  - ❖ Include all things “needed” and “wanted”
- ❖ Include addition of new POC staff
- ❖ Prioritize list of need to want (use 1, 2,3 or A,B,C)
  - ❖ Do not let expense influence prioritizing

# Money

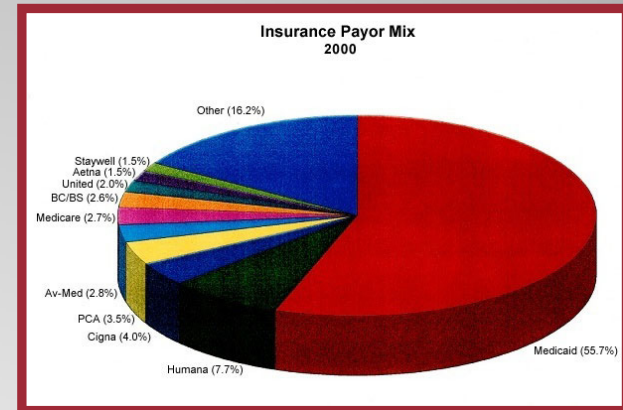
## Making It

Do you bill for POC tests?

What is needed?

- ✓ CLIA number
- ✓ MD order
- ✓ Medical necessity
- ✓ Information must be used to manage the patient
- ✓ Result relayed to physician promptly

Typical Payor Mix -> Medicare/Medicaid 45-60%, 20-40% managed care, 15-25% fee for service and 0-20% other.



# Money

## Connectivity

### Inpatients-

Most hospitals begin creating charges when the test order is created in the LIS.

Using the physician order, the proper billing codes are captured by the LIS and are held until the result is verified.

The time stamped result will then typically flow via an interface to the EMR and HIS which may have a component to collect all charges related to the patient stay.

# Money

Cont.

This billing component in the HIS may be part of your HIS or data may be interfaced to a third party system.

Charges are collected and checked for proper coding.

If the hospital is billing Medicare, the charges are grouped under a DRG (diagnostic related group) for the entire hospital stay. Hospitals will then upload the charges to Medicare and the billing system will create a cost report for the healthcare system.

# Money

Cont.

Medicare/Medicaid and Managed care contracts tend to make-up the majority of inpatient billing and these fall under DRGs, so you may think revenue from other payors might be exceedingly small, however, with the volume of point of care testing growing each year, hospitals stand to capture a significant number of dollars from fee for service payors if they can document and bill for these tests.

# POCC Development

## How to Improve a POCC?

- ❖ Boards
- ❖ List Servs
- ❖ Lecturing (Attend and Give)
- ❖ Publishing/Technical Writing (Journals, CLSI, ...)
- ❖ Get Certified (ASQ, POCTE,...)
- ❖ Seek CE (Microsoft Certification, Spanish, MLO, ...)
- ❖ Consulting (manufacturers, POL, ...)



- Who are some key personnel in your POC program that were not mentioned in the org chart?
- Does your POC program share the same type of instrumentation with the lab? If yes,
- Who does the training in your POC Program?
- Do you have ideas for improving pre-analytical errors in POC? What has worked in your program?
- Do you feel all devices should have connectivity? Will you bring in new devices without connectivity?
- Who has a split program for accreditation (Cap and TJC) and is willing to discuss their reasoning and success?
- Where do you purchase your PT materials and why?
- What are some fun or original ideas for preparing for inspection?

## Questions and Answers

# Questions and Answers

Thank You

**Sheila K. Coffman MT(ASCP)**

**Abbott Point of Care**

**[sheila.coffman@abbott.com](mailto:sheila.coffman@abbott.com)**

**(407) 430-8520**