Improving Your POC Program: An Upside Down Map

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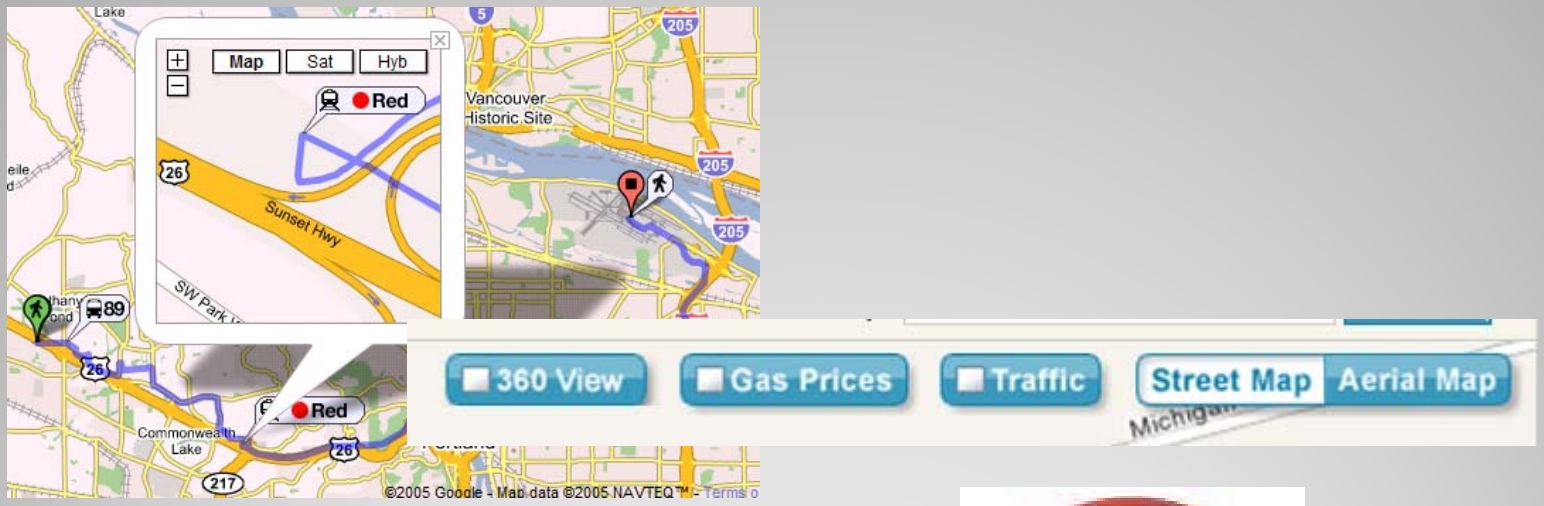
If you have seen ONE Point of Care program…

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

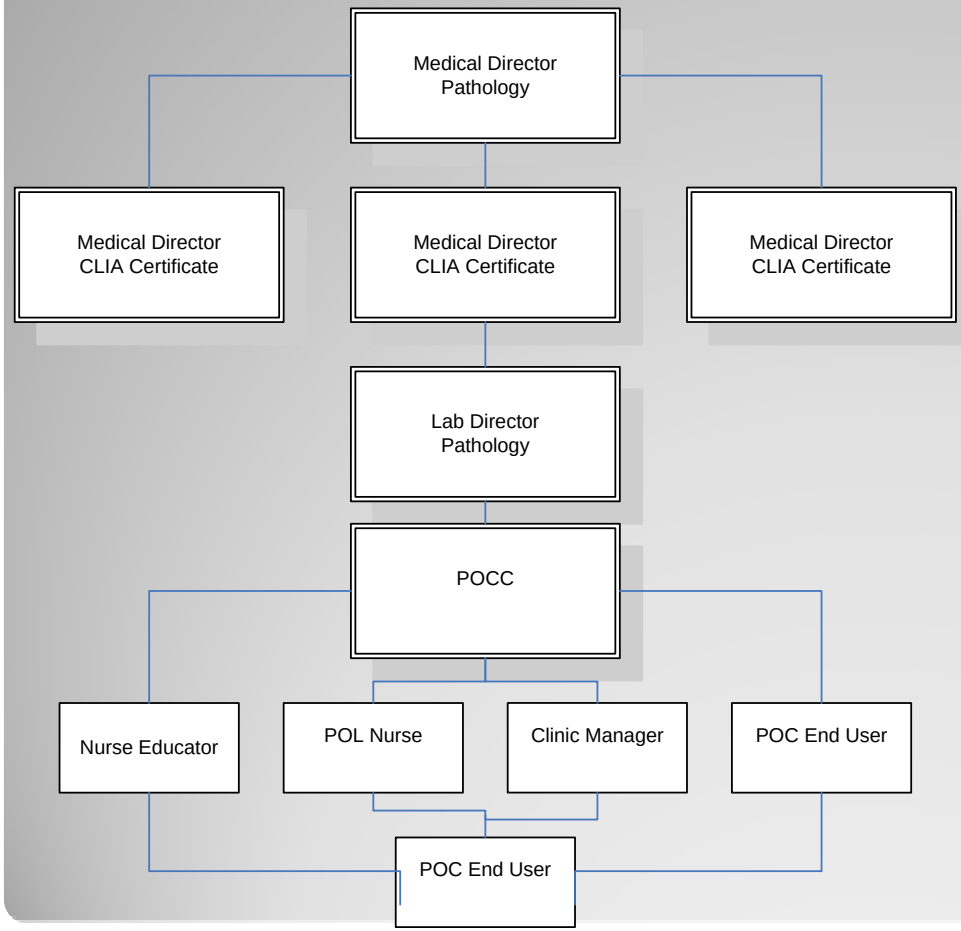
Key Players?

- 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 Fingerstick 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)

Guaiac (Occult Blood) | UA Dip Chemstrip | Preg Test Genzyme OSOM | pH paper | Rapid Strep A

Rapid Flu | Clinitest, Urine | Clinitest, Stool | Accuchek Inform | HgbA1C DCA 2000

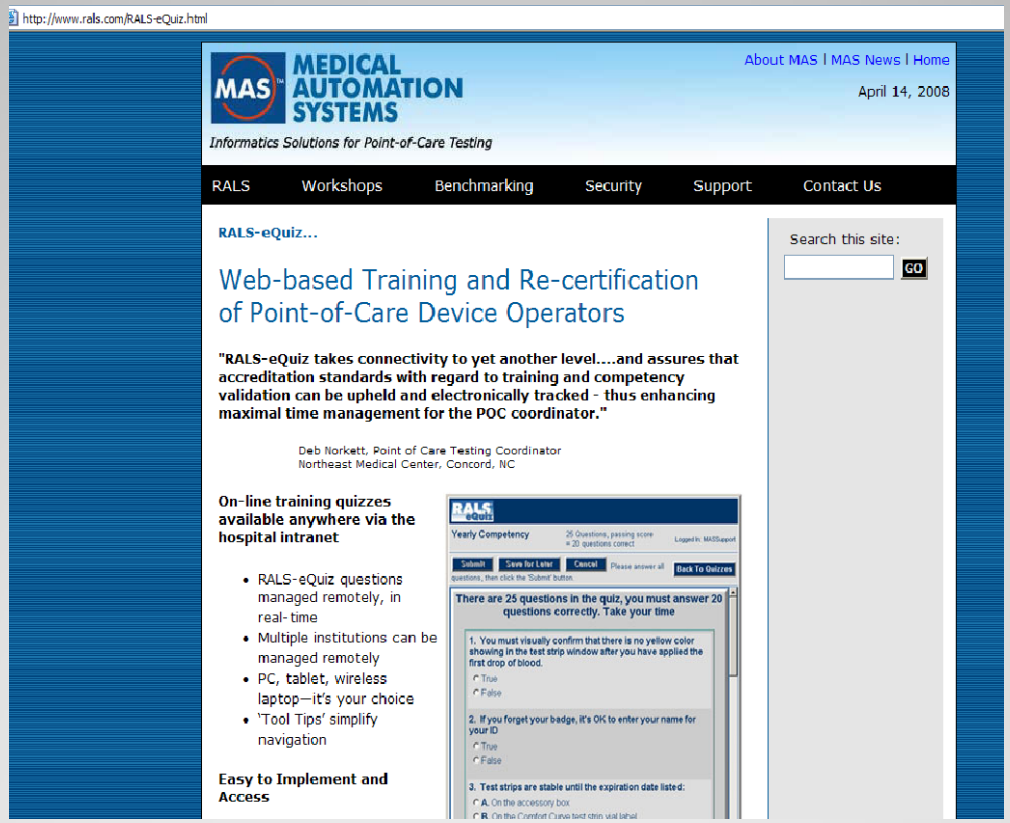
Ascencia | UA Dip Multistix | Preg Test Stanbio True | Accuchek Advantage | CLOtest

ACT | AVOX | Coaguchek XS | HemaCue | Hematocrit | iSTAT

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



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

MAS™ MEDICAL AUTOMATION SYSTEMS
Informatics Solutions for Point-of-Care Testing

TELCOR

Total Analytical Error Distribution

Error Source	Ross and Boone[1]	Plebani et al.[2]
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 10^6)

- 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
- **Lab errors** **10000-30000**

*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

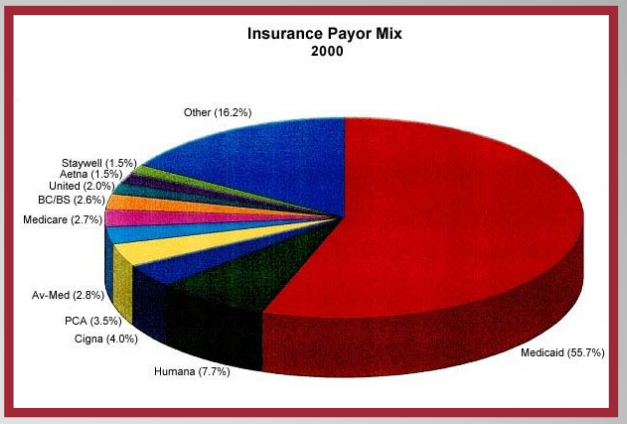
Capital Budget

- 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

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