Point of Care Testing Compliance

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Learning Objectives

- Identify common compliance issues with POCT programs
- Discuss strategies to improve POCT compliance
- Describe one way to develop a POCT website using Microsoft Word



POCT Management is Complex

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



Baystate Health





Baystate Health

- Leading provider of healthcare services in Western MA
- Baystate Medical Center tertiary care
- Hybrid Academic/Private Practice >1400 physicians
- 653 beds; 3rd largest acute care in NE
 - 115,000 emergency visits (Level One Trauma Center)
- Western Campus Tufts School of Medicine 240 faculty
- Franklin Medical Center (90 beds) > 4700 admissions
- Mary Lane Hospital (31 beds) >1600 admissions annually
- Baystate Reference Laboratory >6 million tests annually



Baystate Health System POCT

METHOD	<u>SITES</u>	DEVICES	OPERATORS
Abbott PCx	46	220	2200
UriSys 1100	5	4	100
Pyloritek	2		15
Quidel Pregnancy	14		80
Quidel Strep	9		50
Hemoccult	2		50
Nitrazine pH	9		50
HIV	2		20
i-Stat-1	10	130	800
CA2000/Afinion	2	2	10
ITC Signature Elite ACT	7	15	80
ITC ProTime PT	8	20	75
PPM	8		10



POCT Programs

- Set policy for QA/QC strategies to minimize risk of errors
- Establish quality goals
- Monitor compliance with POCT policies
- Document performance improvement



Performance Indicators

• Successful QC

- QC documentation
- Number of errors where wrong QC analyzed
- QC statistics compared to hospital statistics
- Percent of QC that fail
- QC outliers with comment
- Failed QC with appropriate action (patients not tested)
- Utilization (number of tests/site or device)
 - Tests billed vs tests purchased
 - Single lots of test and QC in use at any time
- Compliance
 - Untrained operators
 - Clerical errors or data entry errors
 - Medical record entry with reference ranges
 - Expired reagents
 - Refrigerator temperature monitored
 - Proficiency testing successful
 - Action plan response to site compliance deficiencies



ES Transitional Unit	1 QC outlier without a comment code. (See BMC QC Compliance report (enc.) for note).
ES Urgent Care	Ok.
Flex/Float	Ok.
Hem/Onc Lab - Center for Cancer Care 3350 Main	Ok.
Hyperbaric - Wesson Ground Wound Care	Ok.
ICU	Ok.
LDRP	1 QC outlier without a comment code.
NICU/CCN	Temperature out of range.
OR/Anesthesia	Ok
PACU	2 QC outliers without comment codes
Baystate Health Springfield, MA 01199 SZ	Ok. Copies of Pyloritek training needed for POCT records. See site inspection form (enc.) for names.

Common Compliance Issues

- ID errors the patient ID entered into the glucose meter or other POCT device doesn't match active patient or matches wrong patient on download
- Daily refrigerator monitoring
- Performance and documentation of QC or QC exceptions and corrective actions
- Expired reagents of controls
- Site action plans and follow-up to compliance issues



Improving Compliance

- Self-management
- System Changes
- Communication
- Visibility and POCT representation on unit



Self-Management

- Every person plays a role and has responsibility in patient outcome
- POCT is part of patient care not an ancillary service
- Those involved in patient care have responsibility to perform and maintain POCT
- Promotes mutual respect and individual responsibility
- Philosophy sets lab as resource not dictator



Self-Management

- Lab can't hold everyone's hand, 24 hours a day
- Lab is a resource in setting hospital policy (together with nursing, physicians, etc)
- Lab knows the CLIA requirements and what needs to be done
- Nursing/Clinicians know how the test will be used in patient management
- Mutual trust that this policy will be fulfilled, it is a role of the employee's job
- Nursing not the lab is responsible for discipline when actions not followed.



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 24 hr and rotates staff.
- System change to devices with QC lockout features mandate 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).



Critical Values

- CLIA and regulatory requirement to contact the ordering physician or clinician who can take action ASAP after critical result
- Some POCT require staff to repeat test or send confirmation to the lab – setup for noncompliance
- Our policy only indicates the various options for staff
 - Repeat the test on same/different device OR
 - Send a confirmatory venous sample to lab OR
 - Treat clinically as result matches clinical symptoms
- Communication doesn't need to be documented IF operator is ordering physician or if nurse who can take action
- All nursing TA's must document critical results like ALL POCT results using the electronic nursing notes in the EMR.
- System integrates critical results into routine operation



Clerical ID Errors

- ID errors the patient ID entered into the glucose meter or other POCT device doesn't match active patient or matches wrong patient on download Clerical ID entry errors monitored
- Initial goal 8 years ago was <5% errors, lowered 5 years ago to < 3%
- Blood gas analyzers set up for duplicate data entry to help with clerical errors
- CAP recommended zero tolerance
- Attempted implementing operator 3 strike rule



Clerical ID Errors

- Problem was a system problem
- We were requiring a 5 digit operator ID and 9 digit patient account number with every test
- Manual entry of 14 digits is source of errors
 Only means of achieving zero errors barcoding



Patient ID Errors

- Barcoding patients reduced frequency of errors, but didn't reach zero errors:
 - Moved to thermal barcoded wristbands (durability)
 - Curved barcodes sometimes not readable
 - Continued manual entry of ID with errors
 - Wrong financial number outpatient vs inpatient
 - Wrong patient wristbanded with wrong ID
 - Unreadable wristbands from other hospitals
 - 911 testing unregistered patients without follow-up
- Led to continued ID errors (50 100 a month)



Scanner Angle



Scanner Distance



23

Scanner Depth of Field

i-Stat 1 Barcode Scanner Depth of Field z=-8.571+35.043*x-0.043*y-2.855*x*x+0.02*x*y-0.005*y*y



Baystate 🚮

Scanner Depth of Field

Abbott PCx Glucose Meter Barcode Scanner Depth of Field z=42.042+24.86*x+0.12*y-2.215*x*x-0.071*x*y-0.012*y*y



Springfield, MA 01199

Bar Code Bands are HERE!!

Tips:

1. Scan 6 inches away.

2. Keep your fingers out of the scan area.



3. When your patients bar code has been accepted the machine will show the # briefly then you will see this screen:







Glucose Meter Identification Errors



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Date

Patient ID Errors

- Joint Commission and CAP patient safety require at least 2 unique patient identifiers with each test
- Implemented glucose meter with positive patient ID
- Meter captures patient identifiers from Admissions/Discharge Transfers data
- Active confirmation of barcode scanned financial # by displaying patient name and requiring operator to enter birthdate year
- Positive patient ID has addressed our residual ID errors
 - No more wrong financial #, episode #, wrong pt wristbands or bands from other hospitals
 - Continue to have issues with 911 testing of unregistered patients without follow-up (1 or 2 a month from ED only)



Baystate Communication

- POCT website developed with 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



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Welcome to the Point-of-Care Testing (POCT) website. This site is designed to provide you the tools to manage your POCT program. Staff will find current policies and procedures, training forms, quality improvement scores for individual sites and guidance to manage their POCT program. Unit POCT contacts, nurse managers and directors are encouraged to visit this site frequently to keep up-to-date with the latest developments affecting their POCT.

Mission

100%

Trusted sites

Building a POCT Website

- Many ways to accomplish
- Use IT resources to design to specification (most institutions don't have staff availability)
- Recruit Lab Information Services staff to build the website (particularly if lab policies and procedures going paperless)
- Build it yourself



Website Tools

- Website software
 - Website Studio 4.0
 - Adobe Dreamweaver CS4
 - Photon FX Easy Website Pro
 - EZGenerator
 - Web Page Maker
 - Site Spinner
 - WebEasy Professional
 - Flash Website Builder
- Facebook, Twitter, Blogs



POCT Website 101

- I, like most medical professionals have no web experience nor available staff resources from IT to build a site for me
- POCT could budget for resources, but the wait time is long for IT projects and expensive even if we could get budget to build a site
- Build it myself using existing software (Word)



Building a POCT Website

- .html is the universal webpage file extension
- Microsoft word has templates and can walk you through a short tutorial. Once done save the file as an .html rather than .doc
 - Open Microsoft word
 - Load a template
 - Fill in the page content
 - Save the file as .html








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Building a POCT Website

- Basic pages with a few links are easy to build and manage
- As links grow, number of files to manage becomes a challenge
- Updating one page, can lose links tied to that page, so need to check all links on a page after each revision
- This is where the task of maintaining a website becomes resource intensive
- Recommend to keep all files with associated links, pictures, etc. in a separate folder on your hard-drive, the back-up, working copy
- Simple task to copy this folder to the "live" website server



POCT DYI Website

- Obviously, this is not as professional nor does the website have as many features as a professionally developed site
- Website can be built in a few hours from existing files and educational materials
- Only requires IT assistance to provide space on hospital server and a link to your POCT content









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N Nursing Manuals Nutrition Care Manual Nutrition Care Manual Addendum			
O OB Policy Manual Operations Manual [BMLH]			
P Patient Privacy [HIPAA] Policies Perioperative Services Physician Billing Office Point of Care Testing			
R Radionuclide Radiation Safety Policies Respiratory Protocols Risk Management Principals for Clinics and Office Practices			
S Stroke Packet for tPA Administration			
T tPA for Ischemic Stroke Transfusion Manual			
W WETU			
X X-Ray Radiation Safety Policies			
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Mission

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100%

Trusted sites

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Point of Care Testing <u>POCT Home</u>	Policies and Procedures Last Updated: December 10, 2010			
Policies and Procedures Training	These are the current Policies and Procedures for POCT with the latest revision date. Hard copies can be printed to update the medical unit POCT Procedure Manuals at least annually.			
Quality Improvement	HemaPrompt (Fecal Occult Blood) [reviewed 8/10/2010] Hemochron Signature Elite (ACT-LR/ACT+) [revised 10/19/2010]			
POCT Committee CAP Inspections POCT Contacts	<u>i-Stat 1 Testing Procedure [revised 10/19/2010]</u> <u>i-Stat 1 Glucose Fact Sheet [updated 1/29/2010]</u> <u>i-Stat 1 Cartridge or PCx Plus Strip: Which Glucose is Right for My Patient?</u> [updated 1/2010]			
Back to BHS Intranet	Macroscopic Urinalysis Dipstick Chemstrip 10MD [reviewed 8/10/2010]			
	Macroscopic Urinalysis (UriSys 1100) Chemstrip 10MD [reviewed 8/10/2010]			
Macroscopic Urinalysis Visual Dipstick [reviewed 8/10/2010]				
pH Paper/Nitrazine Paper [reviewed 8/10/2010] pH Paper QC Log [updated 1/2/2003]				
	Pregnancy (Quidel QuickVue) Urine hCG Test [reviewed 8/10/2010]			
	Proficiency Testing (POCT) [reviewed 8/10/2010]			
	Provider Performed Microscopy Training and Competency [reviewed 8/10/2010]			
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The F-STAT T analyzer is intended for use with F-STAT cartridges for in vitro quantification of various analytes in whole blood and with the Abbott MediSense® Precision PCx^{TM} Blood Glucose Test Strip for the in vitro quantification of glucose in whole blood. The system incorporates a comprehensive group of components to perform blood analysis at the point of care. A portable hand-held analyzer, a cartridge with required tests and up to 95 µL of blood will provide quantitative test results for blood gas and chemistry tests within 2 minutes. Glucose results are available from the Precision PCx Blood Glucose Test Strip in as little as 20 seconds on the hand-held analyzer.

II. Principle

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a. i-STAT Test Cartridges

Sodium, potassium, chloride, ionized calcium, pH and pCO₂ are measured by direct ion-selective electrode potentiometry. In the calculation of results for sodium, potassium, chloride and urea, concentration is related to potential through the Nernst equation.

100%

POCT Website Afterthoughts

- Protect your content
 - Use .pdf versions or copy protected word docs
 - Only allow access behind your institutional firewalls
 - Get IS involved in serving your content
 - Becomes important with separate physician offices/hospitals under separate CLIA just adopting your policies



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



Baystate Health Systems/Emergency Department POCT Site Inspection Report

Signature:	Date:			
Glucose	Review OK	Comments or Actions		
QC marked with Exp. Date				
The QC bottles are good until manufacturers outdate or for 90 days once opened. There should be one set opened and in the plastic box in the lab room.				
Urinalysis	Review OK	Comments or Actions		
Reagents dated and not expired?				
Caps tight on the multistix bottles?				
Correct QC on log?				
Correct QC ranges noted on log?				
QC performed each day on all open bottles?				
QC performed when a new bottle is opened?				
QC failures repeated with remedial action plan?				
Daily and weekly maintenance performed on Clinitek 50?				
Temperature chart complete with action taken when out of range?				
Patient results logged? MR # and initials on tape?				
Patient results charted with reference ranges?				
Urine controls are to be kept in the refrigerator. They are good until manufacturers outdate. They are good at room temperature for 30 days. Each open bottle must have QC done. Multistix bottles are to be dated and initialed when opened. They are good until manufacturers outdate unless the cap is left too loose or off.				



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



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
 - 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.



POCT as Technology

For a list of all the ways that technology has failed to improve the quality of life, please press three... Alice Kahn

