Life Cycle of A New Point of Care Test Request
Managing the Chaos
Speaker Introductions

Jeanne Mumford, MT(ASCP)
Manager, Point of Care Testing
Johns Hopkins Medicine

jmumfor3@jhmi.edu

• Quality Oversight of 2 Academic Hospitals and 3 Community Hospitals and 50+ Physician Office Laboratories
• 9 Full Time Point of Care Coordinators
  ➢ Standardizing Workflows and Managing Quality Oversight
Jeanne Mumford Disclosures

- Nonfinancial - Member of Board of Directors, COLA Resources, Inc, President, KEYPOCC Keystone Point of Care Coordinators; receives no financial compensation
- Financial – Honorarium – Speaker- AACC, KEYPOCC
## List of Current POCT

**Interfaced Devices:**
- ACT-LR, ACT Plus
- Creatinine
- INR
- Hgb
- Urinalysis
- HBA1c
- Glucose, whole blood
- O2 Saturation
- Blood Gases

**Tests Available:**
- pH
- Strep A
- Rapid HIV 1/2 Antibody
- Rapid HCV
- Urine Drug Screen
- PPM
- Tear Osmolality
- Fecal Occult Blood
- Specific Gravity
- Urine HCG
Point of Care Coordinators
Objectives

At the end of the session, participants will be able to:

• Identify key components in developing a formal approval structure for new test requests
• Recognize and overcome common IT issues when interfacing point of care devices
• Learn how to integrate new tests into your point of care program
Definitions

• Enterprise – the university, all 5 hospitals and all ambulatory sites
• Facility – single hospital
• POCC – point of care coordinator
• JHH – The Johns Hopkins Hospital
• JHM – Johns Hopkins Medicine: Hospitals, University and Ambulatory
A. Test site location(s): Emergency Room
   [x] Inpatients only  [ ] Outpatients only  [ ] Inpatients and Outpatients  [ ] Research Study

B. Hours of operation: 24/7  Frequency of test performance: approx. 1-2 a month

C. CLIA Test Complexity:  [ ] Waived  [ ] Moderately Complex  [ ] Highly Complex  [ ] PPM

D. Is this service currently available through the central laboratory?  [x] Yes  [ ] No

E. What is the desired turnaround time for this test if performed in the central laboratory?
   Immediate: 1-2 minutes

F. Briefly explain why the current central laboratory services do not fulfill your needs?
   We require a quicker turnaround time for our patients on warfarin who are presenting with symptoms concerning for acute stroke that require an INR to determine eligibility for IV TPA

G. If this test were made available at the point-of-care, how soon would the results be utilized for clinical decision making?
   Immediately

H. Would patient treatment/management decisions be based solely on the point-of-care test results?  [x] Yes  [ ]
   No. Explain: 

I. Estimate the number of point-of-care tests to be performed: ____/day  ____/week  2___/month

J. What level(s) of staff would be performing this test and how many would need to be trained?

RN’s, already familiar with POC testing for glucose

K. Briefly describe what the patient care benefits/outcomes and potential cost savings would be with implementing this point-of-care test. (Please provide evidence, preferably peer-reviewed, of the test’s clinical utility)

This would include ONLY patients on warfarin presenting for consideration of acute stroke treatment. All patients would get INRs sent to the lab as per current protocol; HOWEVER immediately available POC testing would reduce wait time in eligible patients from nearly 45 minutes to only 4-5. Evidence shows that neurons die every minute therapy is delayed so this has significant potential impact on morbidity and mortality.
L. Are funds approved to support the costs associated with this new test request?  [ ] Yes  [ ] No
(Some costs associated with bringing in POCT include quality control, reagents, test validation, training/competency assessment, proficiency testing, oversight, etc.)

M. Please provide cost center/budget number designated for POCT costs: ____________________________

N. Signatures Required:

Medical Director Signature/Date: ___________________________________________________________

PRINT NAME: _________________________________________________________________________

Finance Administrator’s Signature/Date: ______________________________________________________

PRINT NAME: _________________________________________________________________________

Testing Personnel Manager’s Signature/Date: _________________________________________________

PRINT NAME: _________________________________________________________________________
Who is a Part of the Decision Process?

POC Committee (Enterprise-wide)

• 6-8 key members
  – Lab Directors from each facility (5)
  – Medical Director over POCT at JHM (Chairman)

• Overall goals and visions of this committee:
  – Global vision to standardize test devices across facilities.
  – More educated, insightful decision process with SME’s in the latest technologies.
POCT vs. Central Lab

“Medical professionals considering POCT need to balance POCT’s rapid turnaround and positive effect on patient care with the more robust results available through lab-based testing” (David, 2016).

- Many factors to consider before implementing POCT:
  - Pre-analytical, analytical and post-analytical errors (proper collection technique per device, application of sample, documenting results)
  - Manufacturer’s instructions (ex. off-label use)
  - Good communication

How the Decision is Made

- Decision is based off of information provided on the new test request form, as well as central laboratory reports, if needed.

- The POC Committee may want to meet with the requestor to go over this information and determine the best course of action.
Brand new POC device to facility:

- Contact vendor for price quote (device, QC, reagents, linearity kit).
- Perform meter validation/check-in based on good laboratory practices.
- Perform correlation studies between new device and central laboratory, if available.
- Create procedure and competency assessment tools for training.
- POCC trains unit trainer(s), then unit trainer trains the staff.
Current device already in use at facility

- Contact vendor for price quote (device only).
- Perform meter validation/check-in based on good laboratory practices.
- Use current procedure and competency assessment tools for training.
- POCC trains unit trainer(s), then unit trainer trains the staff on their unit.
Vendors

• Use vendors and your training and QA program to actually train testing personnel.
• Vendor and industry support is important.
Trainer Sessions

- POCC trains unit trainers.
- Train the trainer sessions held annually.
- Go over any updates to policies and procedures.
- Ensure proper technique is being used to train new hires.
POC Advisory Meeting

• Includes unit trainers, patient care managers, Epic interface rep., clinical engineering, regulatory rep., nurse educators and POCC.
• Meetings are held monthly.
• Send out info frequently, but sometimes doesn’t get communicated.
Work Together

- Use resources from other facilities to implement the new test.
- Experienced POCC’s that have used the device.
- Nurse educators.
- Vendor reps.
Timeframe

• May take several months to implement a new POC device.

• Dependent on:
  – Size of facility
  – Number of POCC’s
  – Complexity of test
  – Workload
Balancing Act

New Test Requests
- Prioritize by request date
- Set realistic timeframe

Everyday Activities
- Ensure completion of tasks
- Prioritize activities
Example 1: Hemoglobin in Renal Clinic (Outpatient)

- Need for immediate hemoglobin result in order to administer erythropoietin within clinic visit.
- This minimizes delay in patient care and having to schedule a subsequent appointment for treatment.
Example 2: Creatinine in Imaging (Inpatient/Outpatient)

- Need for immediate creatinine result in order to administer media contrast for imaging studies.
- Reduced procedure cancellations and need to reschedule appointments.
Example 3: BUN, Creatinine, Na, K, Mg in Cardiac Clinic (Outpatient)

- Need faster TAT for lab results to not delay treatment.
- Can cut visit time by 30%.
- Central lab had no complaints from clinic other than many samples were hemolyzed.
- Importance in communicating with central lab.
Challenges

• Clinical staff expecting implementation within an unrealistic timeframe.

• Communication between the requestor of the test and end-users.

What Aids in a Successful Implementation?

- Responsive and dedicated vendor reps.
- Teamwork
- Effective communication

Enterprise Interface Infrastructure: Past

- Within our Health System, we had nothing in common
- Unable to troubleshoot and support POCCs
Johns Hopkins Hospital: Past

• Manually recording results in patient charts
• By “sneakernet” system, we would download instruments once a month to keep data
• Transcription errors
Enterprise Interface Infrastructure
Present

- JHH
- BMC
- POC Middleware
- HC
- SH
- SM
- LIS
- EMR
**Interface Infrastructure**

- Glucose
- Creatinine
- Hgb
- Hgb A1C
- INR
- ACTs
- Urinalysis
- Blood gases

**Vendor Middleware**

- POC middleware

**LIS**

**EMR**

Aimee Craft
TELCOR, Project Team Leader
Point of Care Testing Solutions
POC Connectivity

• Today, your POCT program efficiency will depend on the instrument’s rapid TAT combined with the fast access of the accurately integrated results.

• Example: Blood gas instrument in an ICU setting

Connectivity Advantages

• Helps ensure that all care teams have access to patient results in a timely manner
• Monitor POC program from a centralized location
• Operator certifications are more manageable
• More control over large number of instruments
• QC and calibration documentation
• QA monitoring/ troubleshooting in real time
• You are not alone!
Pathways: Instrument to EMR

1. Operator runs a test
2. Result is sent to the POC middleware
3. Result is sent to LIS
4. LIS creates order
5. Result is posted to EMR

If ADT sent to instrument, Patient Information is displayed.
Instrument Connectivity

How does this happen?
Who is Your Team

- Point of Care Coordinators
- Hospital IT representative – multiple groups depending on connection types
- Vendor- including an IT expert
- LIS representative
- EMR representative
- Operator/nursing
- Billings representative
Vendor Support and Importance

- Need to be able to provide support for IT and POCCs
- Understand instrument connection capabilities
- Understand what type of barcodes instrument can handle, what type of information is accepted
Questions to get started:
- How are you connecting the instrument?
- Do you need data jacks installed/ activated?
- What steps are involved to send results?
  Extra steps for operators?
Interface: Connections

Connection Type/Requirements:

**Wired connection:**
- Are network jacks available/ need new installation
- Are they active
- Does your Hospital IT have special requirements

**Wireless connection:**
- Is there a certificate required
- Any expiration dates
- Do you need dedicated IPs

Get your Hospital IT involved
Besides instrument validation, the interface set up needs to be tested, including:

- Reporting units
- Reference ranges
- Critical action values
- Instrument comments
- Any calculated values
- EMR result posting
- Billing validation

*It is a CAP requirement to check proper performance for an instrument interface when installed and after any modifications*
## Interface: Training

<table>
<thead>
<tr>
<th>POCCs</th>
<th>Instrument Operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middleware functions</td>
<td>What steps are needed for the instrument to connect</td>
</tr>
<tr>
<td>Operator certifications</td>
<td>Basic connection troubleshooting</td>
</tr>
<tr>
<td>Reagents set up</td>
<td>Where to find results (Lab section)</td>
</tr>
<tr>
<td>Corrections</td>
<td></td>
</tr>
</tbody>
</table>
Interface: Challenges

- To meet expectations (i.e., transmission timing, location of results)
- Instrument date/time must be accurate
- Human factor, for instruments not automatically uploading
- Wireless dead spots
- Depending on institution’s size, IP addresses availability: wireless traffic
- Different IT regulations per site
Interface: Successes, Tips and Tricks

- Learn from experiences
- When testing, try to “break” the system
- Knowing your Team
- Having a POCC with IT knowledge
Enterprise Infrastructure: Future

- Vendors become up to date with IT requirements (network security)

- IT Harmonization

- We embrace new technology and connectivity
Point of Care Testing

JHM operates six academic and community hospitals.

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Beds</th>
<th>Glucose Operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johns Hospital</td>
<td>1,059</td>
<td>4,313</td>
</tr>
<tr>
<td>Bayview</td>
<td>545</td>
<td>1,300</td>
</tr>
<tr>
<td>Howard County</td>
<td>267</td>
<td>1,466</td>
</tr>
<tr>
<td>Sibley</td>
<td>318</td>
<td>800</td>
</tr>
<tr>
<td>Suburban</td>
<td>229</td>
<td>1,343</td>
</tr>
</tbody>
</table>

- Johns Hopkins Community Physicians – 39+ sites, 400+ providers, 1,600 glucose operators (primary and specialty care)
Integrating the System

- Whose procedures do we use?
- Whose POCT devices?
- Whose workflows are the Best Practices?
Best Practices

• Steps to standardizing and harmonizing procedures, workflows and processes
• Now what? How to keep in touch and how to run this as one big complicated program?
Ongoing Monitoring

• Mock inspections and intracycle monitors
  – Follow regulatory body checklist
• Enroll in a CLIA approved Proficiency Testing Program
• Perform semi-annual patient correlations
• Patient Safety Net (PSN) which allows for staff to submit lab issues and other patient safety concerns
• Safety Officers program
  – Safety officers are engaged in the unit practices. Safety Officers include nurses, medical assistants, unit managers, providers
Ongoing Monitoring

• Schedule internal audits or inspections to each unit
  – Inspect all storage areas where POC supplies are kept
  – Look for open and expiration dates on all POC containers and/or test kit/devices
• Observe testing and sample collection techniques
• Review all Quality control and patient documents
• Inspect devices/instruments
  – Look for QC liquid on device surfaces
  – Ensure that back up batteries are charging
  – Ensure that docking stations are properly plugged in and charging devices
Ongoing Monitoring

- Host a monthly meeting with the major lab vendors such as Quest, Lab Corp and Johns Hopkins Medical Lab
  - Review cancellation reports
    - Trends in cancel reasons
    - Education
    - Supplies
    - Courier schedules
    - New Test Codes
    - New Specimen Collection Devices
Communication? Maybe?

Attention:
Toilet
ONLY
For
Disabled
Elderly
Pregnant
Children
Communication Cycle

Sender

Feedback

Message

Receiver

Channel
The Message
Suggestions from Hopkins

• Monthly Meetings
  – Testing Personnel
  – Unit Managers
  – Trainers

• Standards of Care (Monthly, as Needed)
  – Nursing Representation from every Discipline
Have You Considered?

- Host a monthly meeting with the major lab vendors such as Quest, Lab Corp and Johns Hopkins Medical Lab
  - Review cancellation reports
    - Trends in cancel reasons
    - Education
    - Supplies
    - Courier schedules
    - New Test Codes
    - New Specimen Collection Devices
Vendor Support/Training

• Utilizing Vendor Reps for support in training
• Vendor reps are brought into sites to perform on site training with our competency checklist
• Vendor reps have a great report with sites and reach out several times a year for support
More Tools

- Quarterly Flyers Published by Nurse Educations
- Screen Savers on Computers Across Hospital Campus
- Attending Team Huddles and Staff Meetings
Less Is More

• Nurse Educators can help POCC’s learn how to trim down their message in order to have meaningful exchange of information
  – Nurses and clinical care teams techniques
  – Balancing clinical demands with laboratory regulation demands
Empathy In Communication

• Understanding someone else’s perspective
  – How does it impact the nurse or tech if they have to troubleshoot QC on a meter when a patient is crashing and needs an urgent glucose result?
Empathy In Communication

• Let the nurse or tech state their point of view
  – While meeting regulatory requirements, you may still work with clinical teams to meet their needs

• Take the time to check regularly that the message is still meaningful
Good Communication Is Key For Patient Safety

“Poor communication is reported as the root cause in 70% of hospital sentinel events and in 40% of malpractice cases due to medical errors.”

Keynote Session, Safety, Quality and Patient-Centered Care
Peter Pronovost, MD, PhD, FCCM
Sr. Vice President for Patient Safety and Quality
Director of the Armstrong Institute for Patient Safety and Quality Johns Hopkins Medicine
Summary

The single biggest problem in communication is the illusion that it has taken place.

George Bernard Shaw
Our Accomplishments So Far

- Standardized IT platform for Point of Care tests across 5 Hospitals and Ambulatory Medicine
  - Will allow for quality indicators across the enterprise
  - Will allow for centralized reporting and oversight
- Standardized electronic medical record
  - One Patient, One Record
- Standardized laboratory information system
  - Harmonized test panels
- Standardized testing platforms
  - Chemistry and Hematology lines
  - One Patient, One Test Result
Future Goals

• Electronic Audit/Rounding Tool
  – Real time grading and feedback on tablets
• Networking Events for all POCC’s
• No New POCT Devices Without Interface Capabilities
• Managing Non-laboratory Devices Through Middleware (i.e., transcutaneous bili)
Jeanne Mumford, MT(ASCP)
Pathology Manager, Point of Care Testing
jmumfor3@jhmi.edu
Johns Hopkins Hospital