Life Cycle of A New Point of Care Test Request

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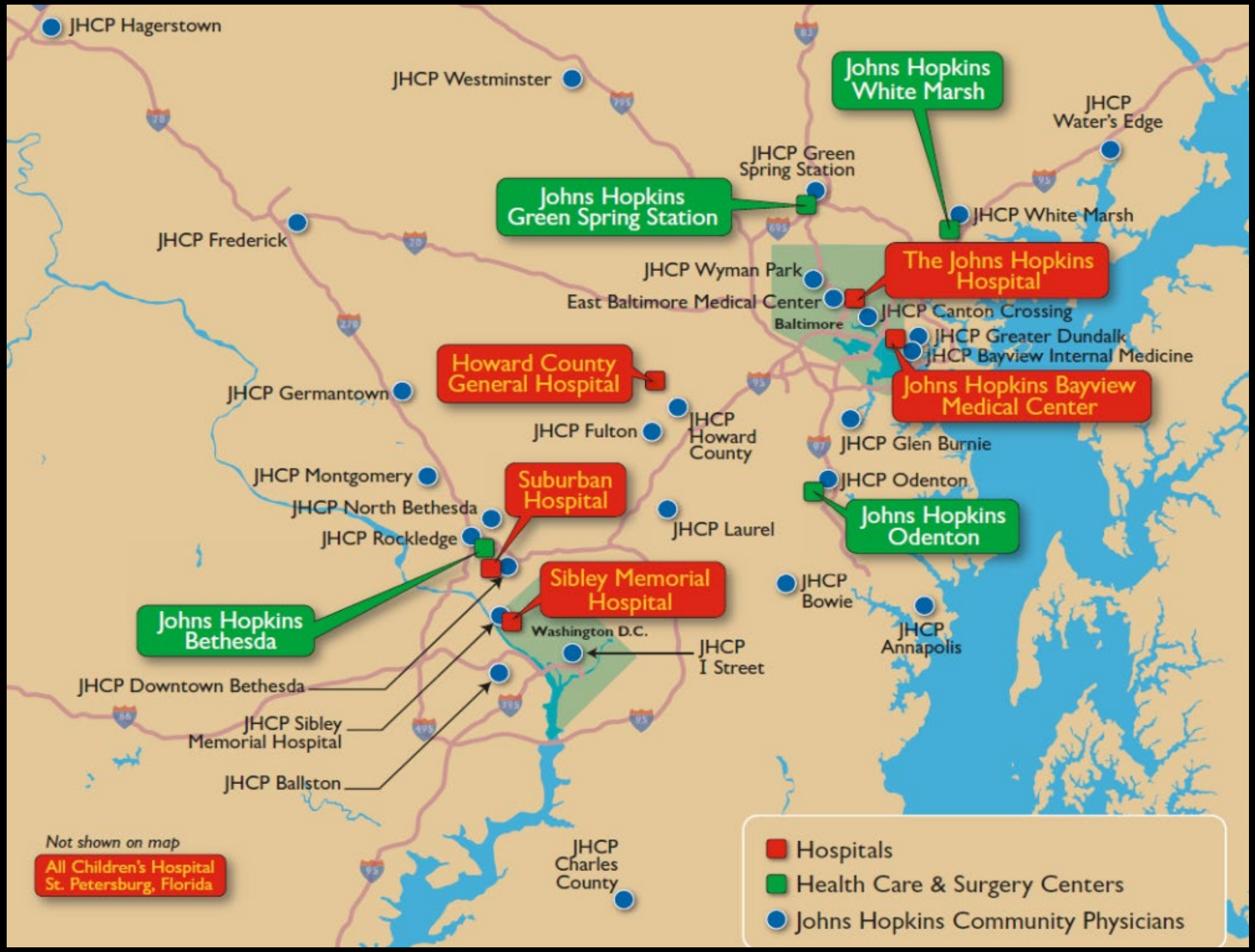
Disclosures

- Honorarium, Expenses: Cepheid Speaker Bureau, bioMerieux, ADLM

Happy Lab Week


JHCP Hagerstown
JHCP Westminster
Johns Hopkins White Marsh
JHCP Water's Edge
JHCP Green Spring Station
Johns Hopkins Green Spring Station
JHCP White Marsh
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JHCP Annapolis
JHCP I Street
JHCP Downtown Bethesda
JHCP Sibley Memorial Hospital
JHCP Ballston
Not shown on map
All Children's Hospital St. Petersburg, Florida
JHCP Charles County
Hospitals
Health Care & Surgery Centers
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List of Current POCT

Interfaced Devices:

- ✓ ACT-LR, ACT Plus
- ✓ Creatinine
- ✓ INR
- ✓ Hgb
- ✓ Urinalysis
- ✓ HBA1c
- ✓ Urine HCG
- ✓ Glucose, whole blood
- ✓ O2 Saturation
- ✓ Blood Gases
- ✓ SARS-CoV-2 Only and 4PLEX Molecular

Non-Interfaced Tests/Devices:

- ✓ pH
- ✓ Strep A
- ✓ Rapid HIV 1/2 Antibody
- ✓ Rapid HCV
- ✓ Urine Drug Screen
- ✓ PPM (multiple)
- ✓ Tear Osmolality
- ✓ Fecal Occult Blood
- ✓ Specific Gravity
- ✓ Urine HCG
- ✓ SARS AG
- ✓ SARS-CoV-2 PCR

Department of Pathology

Point of Care Testing

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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

Point-of-Care Testing Breakdown

Hospital	Beds	Glucose Operators	POCT TYPES	# of POCC's
Johns Hospital	1,146	8,000	32	5
Bayview	468	1,300	20	1.5
All Children's	259	900	12	3
Howard County	244	1,466	3	1
Sibley	288	800	9	1
Suburban	226	1,343	9	1
JHCP Sites	50+ Sites	1,600	15	2

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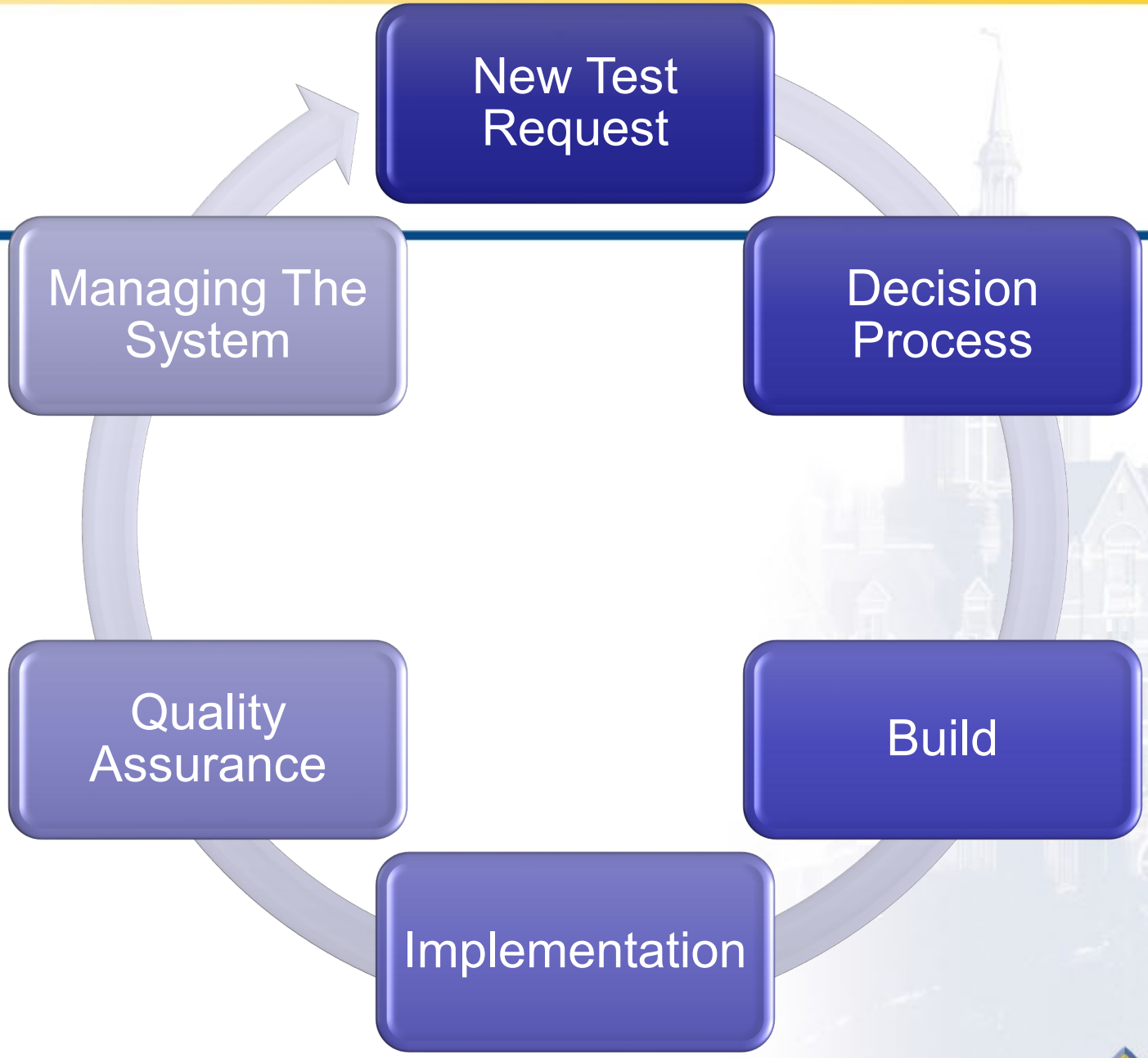

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New test request

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TEST PROCEDURE:

Instrument/Kit Name: _____ Manufacturer: _____

A. Test site location(s): _____ (Building, Floor, Room Number)

☐ Inpatients only ☐ Outpatients only ☐ Inpatients and Outpatients ☐ Research Study

B. Hours of operation : _____ Frequency of test performance: _____

C. CLIA Test Complexity: ☐ Waived ☐ Moderately Complex ☐ Highly Complex ☐ PPM

D. Is this service currently available through the central laboratory? ☐ Yes ☐ No

E. What is the desired turnaround time for this test if performed in the central laboratory?

_____

F. Briefly explain why the current central laboratory services do not fulfill your needs?

_____

_____

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

_____

H. Would patient treatment/management decisions be based solely on the point-of-care test results? ☐ Yes ☐ No

Explain: _____

_____

_____

Johns Hopkins Medical Laboratories
Baltimore, Maryland

Point-of-Care Testing
New Test Request Form

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

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

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)

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 Point-of-Care Testing 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: _____

Date POCT Received: _____

_____ **Date:** _____ ☐ **Approve** ☐ **Disapprove**

Director, POCT Program

Revision: 1/24/2018 **Date Submitted to CQI for Billing/Licensing:** _____ **Needs Telcor: Yes $**_____ **or NO** ☐

Decision process

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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.
- Case-by-Case

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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.

The Build

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You said, “Yes”, Now What?: New Device to Facility

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.

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You said, “Yes”, Now What?: Current Device

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.

Implementation: Training

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Training

Training

- Trainers or Superusers
- Vendors
- Team Work
- Communication
- Challenges

Interface/Connectivity

- IT structure
- IT Team
- Advantages
- Challenges
- Step by Step

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Vendors

- Use vendors, your training documents and procedures to train testing personnel.
- Vendor and industry support is important.

Trainer Sessions

- POCC/Vendor 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.

Slide credit: Serafina Brea, CLS(ASCP)

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.

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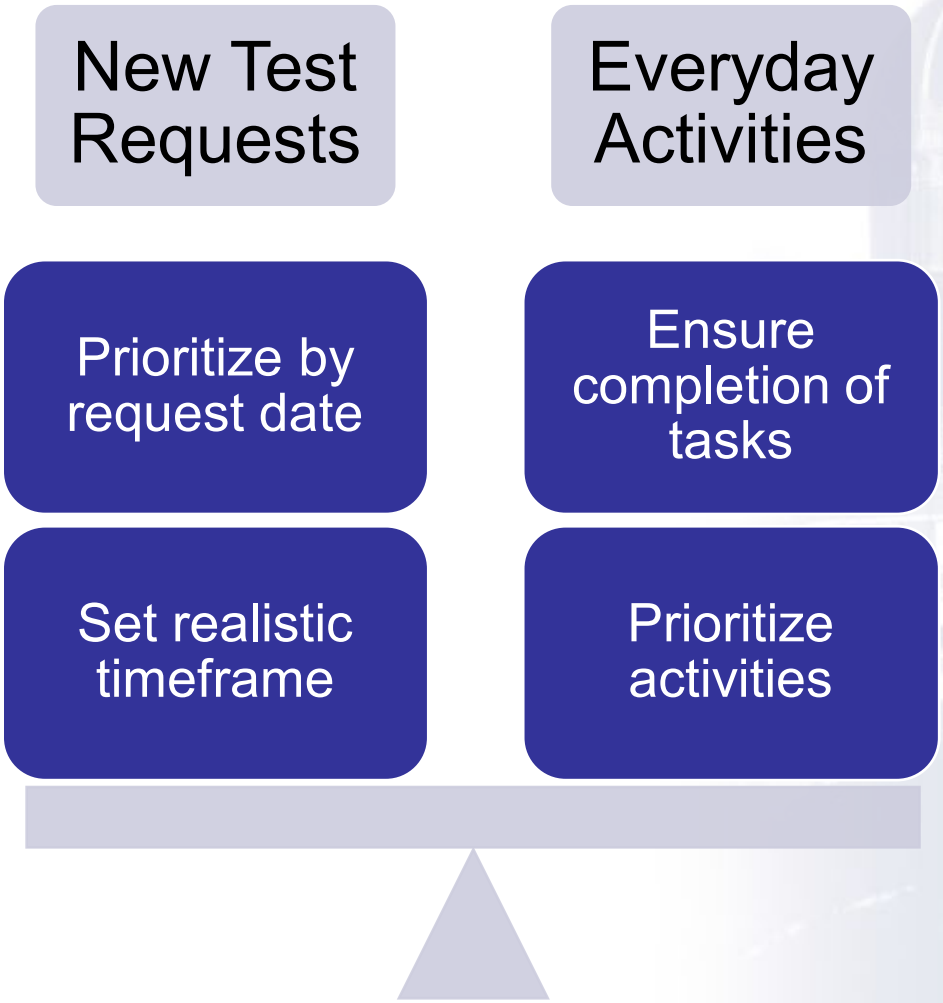
Timeframe

- May take several months to implement a new POC device.
- Dependent on:
  - Size of facility
  - Current workload
  - Number of POCC's
  - Complexity of test
  - Number of testing personnel
  - New test, or previously established test

Balancing Act



Example 1: Blood gases and electrolytes for inpatient, pediatric

- Need for smaller sample size for test
- Need for immediate results for treatment
- Difficult venipuncture patients, prefer capillary sticks
- This minimizes delay in patient care

Example 2: Glucose and Hemoglobin PEDS OR

- Need faster TAT for lab results to not delay treatment – life saving
- Small Sample Size preferred
- Ability to expand test menu with additional procedures
- POCT approved, Peds OR budget not approved

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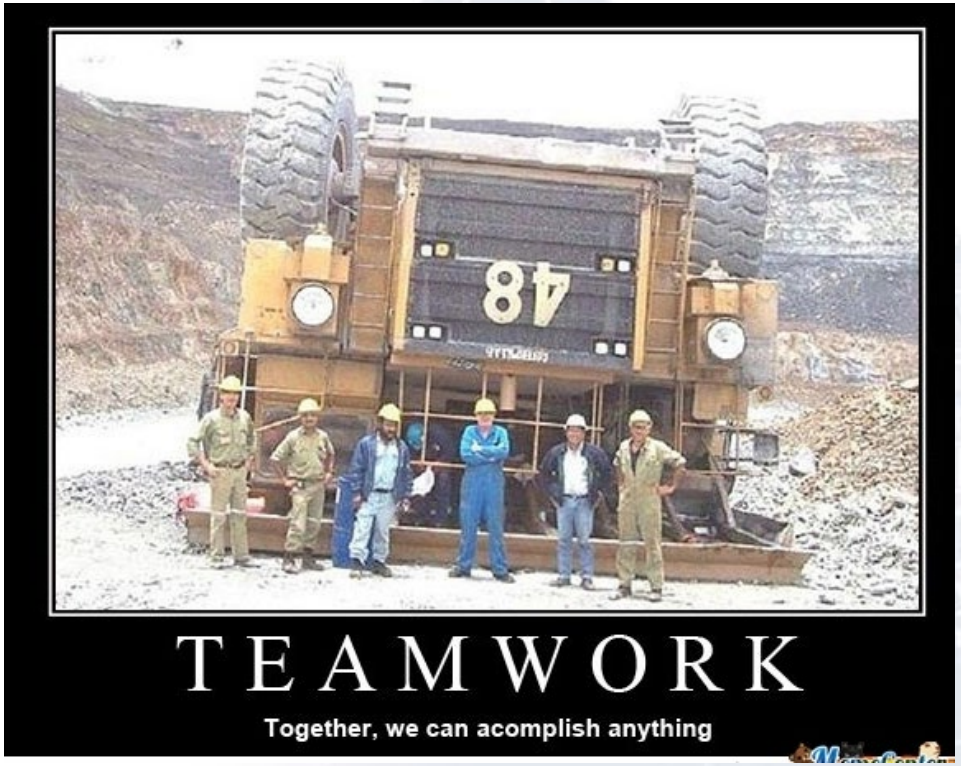
Challenges

- Clinical staff expecting implementation within an unrealistic timeframe.
- Communication between the requestor of the test and end-users.



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What Aids in a Successful Implementation?

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

Retrieved from http://www.practicalsoftwaresolutions.com/implementation-methodology.html

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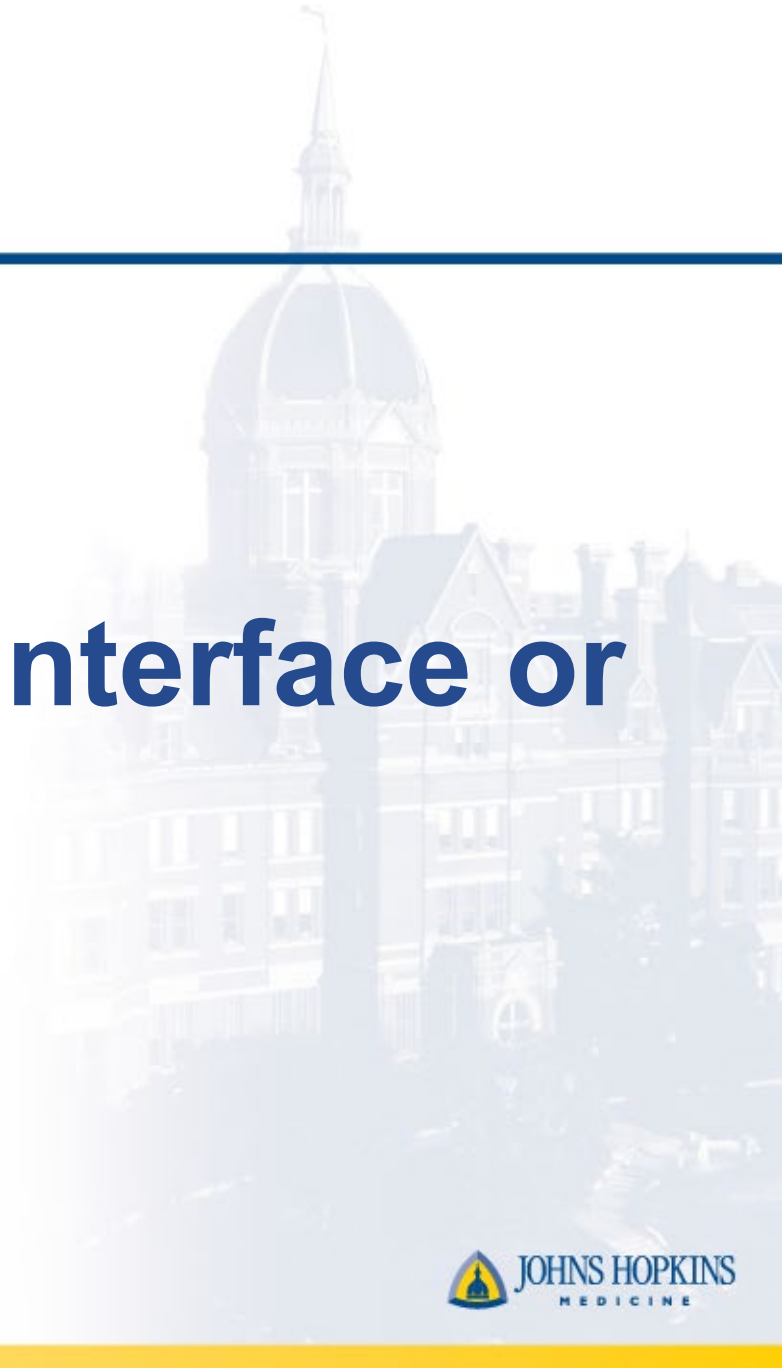
Implementation: Interface or Manual



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Enterprise Interface Infrastructure: Past

- Within our Health System, we had nothing in common
- Unable to troubleshoot and support POCCs
- Worked in Silos

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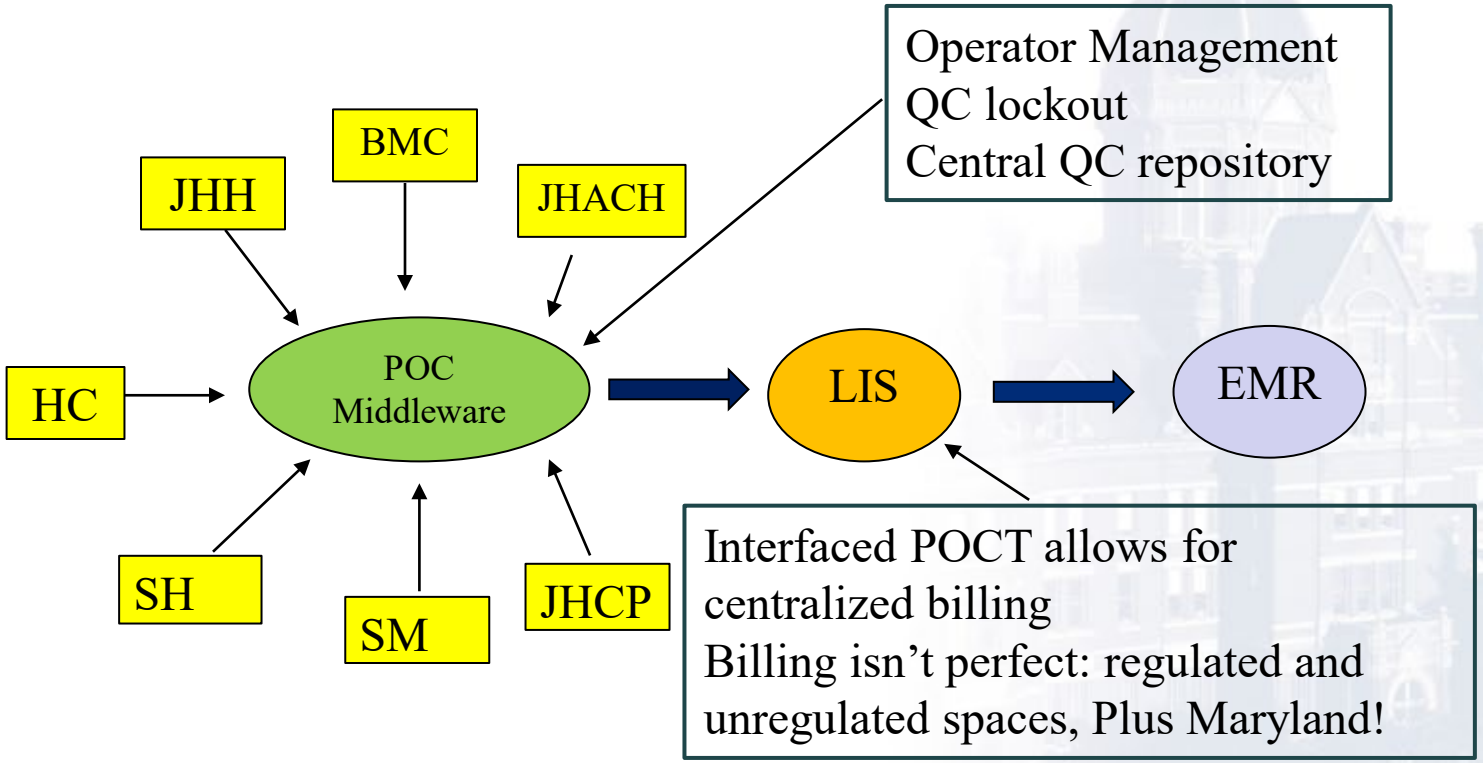
Past – Little to No Interface

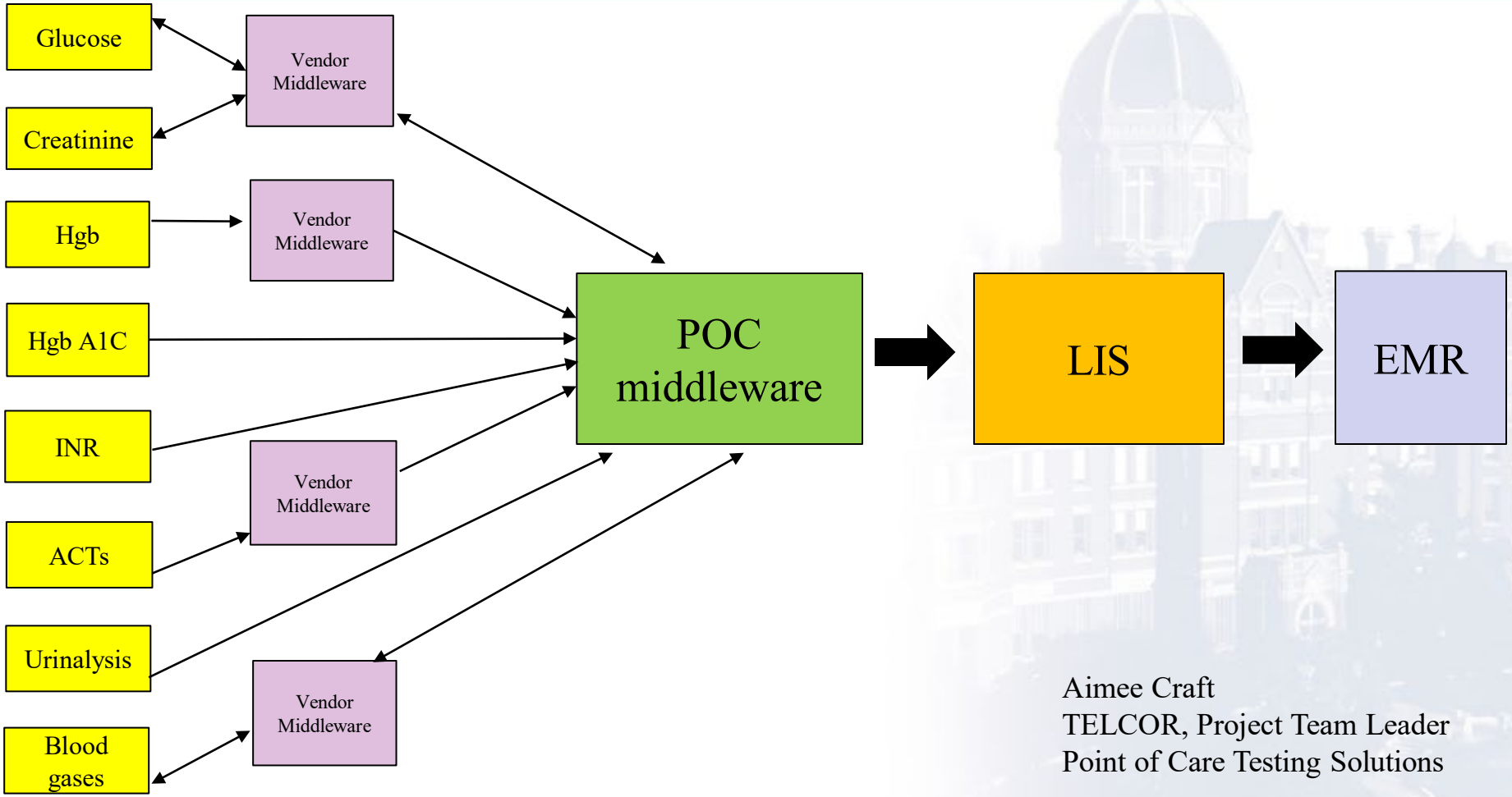
- Manually recording results in patient charts
- By “sneakernet” system, we would download instruments once a month to keep data
- Transcription errors

Present – Single Interface



Slide credit: Leandra Soto, CLS(ASCP)

Enterprise Interface Infrastructure



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

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POCT 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

Futrell, K. (2016, September). *Point of Care Testing: The Great Boom Ahead*.

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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!

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Instrument Connectivity

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Your Connectivity 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

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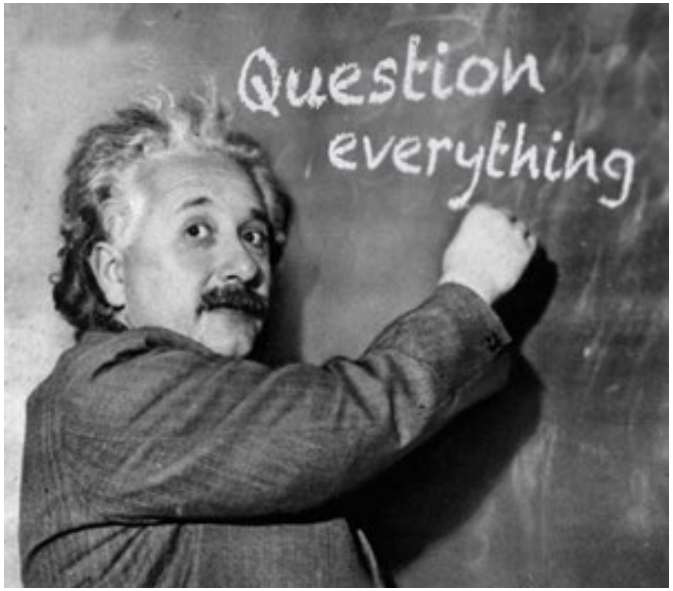
Importance of Vendor Support

- 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



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Interface: Step by Step

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?

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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

Slide credit: Leandra Soto, CLS(ASCP)

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Interface: Instrument Testing

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

POCCs	Instrument Operators
Middleware functions	What steps are needed for the instrument to connect
Operator certifications	Basic connection troubleshooting
Reagents set up	Where to find results (Patient Medical Record)
Corrections	Corrections

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
- You are not alone! Network with fellow POCC’s

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Quality assurance

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Standardizing Practices

- Standard and harmonize policies and procedures
- Standardize computer based learning modules used for competency assessment
- Evaluate workflow for testing, can these be standardized?

Internal Audits and Mock Inspections

- Mock inspections and intracycle monitors
  - Follow regulatory agency checklist and/or standards
- 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

When Auditing Units/Sites

- 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

Safety and Quality

- Enroll in a CLIA approved Proficiency Testing Program
- Perform semi-annual patient correlations
- Safety event reporting system 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

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
- They are the subject matter experts on their products and services

Additional Considerations

- Quarterly Flyers Published by Nurse Educations
- Screen Savers on Computers Across Hospital Campus
- Attending Team Huddles and Staff Meetings
- Visibility on units and clinical areas

Summary

- The use of a standardized New Test Request form and process can help streamline the implementation of new POCT.
- Including subject matter experts in the decision making for new POCT's can help your team make informed choices.
- Remembering to enroll in PT, and/or offer continuing quality assurance on all POCT will help your program offer the highest quality patient results.
- Ask for help from colleagues and experts!

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Questions

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