# Standardizing Point of Care Testing and Harmonizing Workflows Between Hospitals and Ambulatory Locations

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# Disclosures

- Nonfinancial: President, KEYPOCC Keystone Point-of-Care Coordinators
- Financial – Honorarium/Speaker: AACC; Cepheid Speaker Bureau; Whitehat Communications

# Objectives

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

- Establish open communication and identify key players in standardization of point of care tests
- Discuss tools and strategies for multidisciplinary collaboration
- Identify POCT clinical considerations and managerial challenges

# Point of Care Coordinators

Department of Pathology

Point of Care Testing

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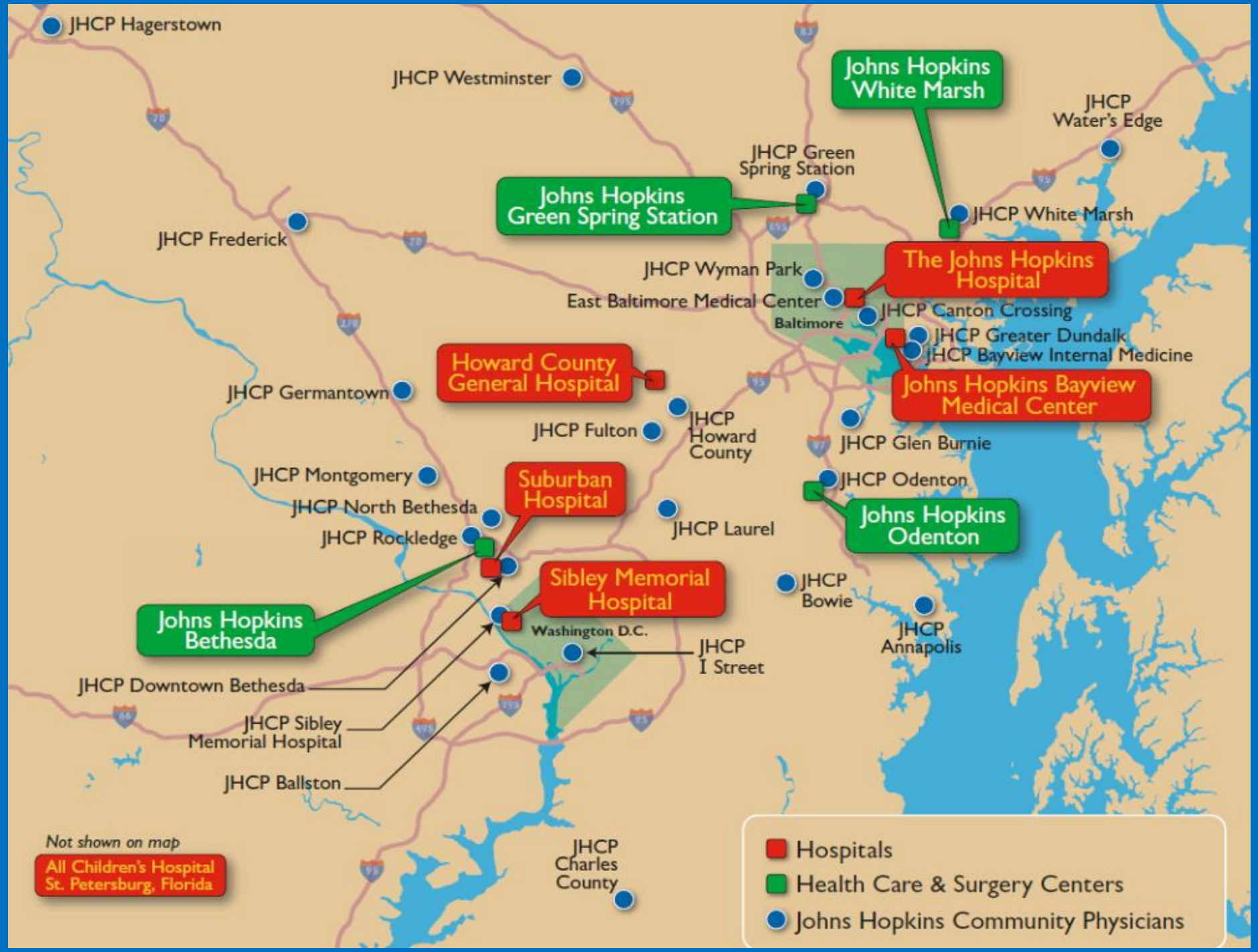
JHCP Hagerstown
JHCP Westminster
Johns Hopkins White Marsh
JHCP Water's Edge
JHCP Green Spring Station
Johns Hopkins Green Spring Station
JHCP White Marsh
JHCP Frederick
JHCP Wyman Park
The Johns Hopkins Hospital
East Baltimore Medical Center
JHCP Canton Crossing
Baltimore
JHCP Greater Dundalk
JHCP Bayview Internal Medicine
Johns Hopkins Bayview Medical Center
Howard County General Hospital
JHCP Germantown
JHCP Howard County
JHCP Fulton
JHCP Glen Burnie
JHCP Montgomery
Suburban Hospital
JHCP Odenton
JHCP North Bethesda
JHCP Laurel
Johns Hopkins Odenton
JHCP Rockledge
Sibley Memorial Hospital
JHCP Bowie
Johns Hopkins Bethesda
Washington D.C.
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
Johns Hopkins Community Physicians

# 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

# Point of Care Testing Breakdown

| Hospital | Beds | Glucose Operators | POCT TYPES | # of POCC's |
|---|---|---|---|---|
| **Johns Hospital** | 1,059 | 4,313 | 29 | 4 |
| **Bayview** | 545 | 1,300 | 19 | 1 |
| **All Children's** | 259 | 900 | 12 | 3 |
| **Howard County** | 267 | 1,466 | 3 | 1 |
| **Sibley** | 318 | 800 | 9 | 1 |
| **Suburban** | 229 | 1,343 | 9 | 1 |
| **JHCP Sites** | 40+ Sites | 1,600 | 15 | 2 |

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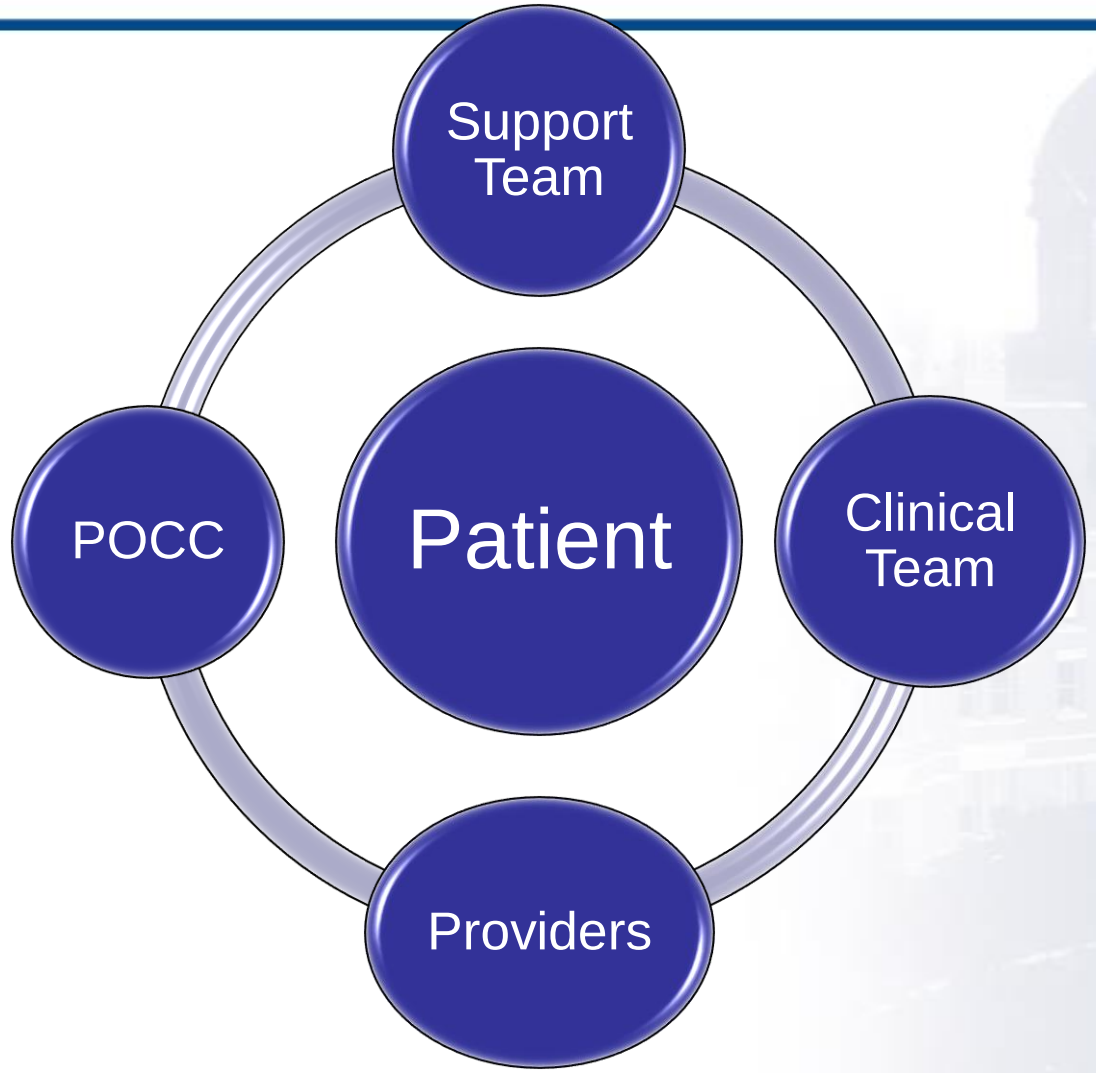
# Why Standardize?

- What does it matter?
- Is it work the effort, money, or time?
- What benefits gained?
- Does it increase quality and safety?

# What Role Does POCT Play in Patient Care?

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# POCT's Role in ECMO

http://www.peytonmanningch.org/critical-care/ecmo/

https://www.hopkinsmedicine.org/news/articles/an-ecmo-record

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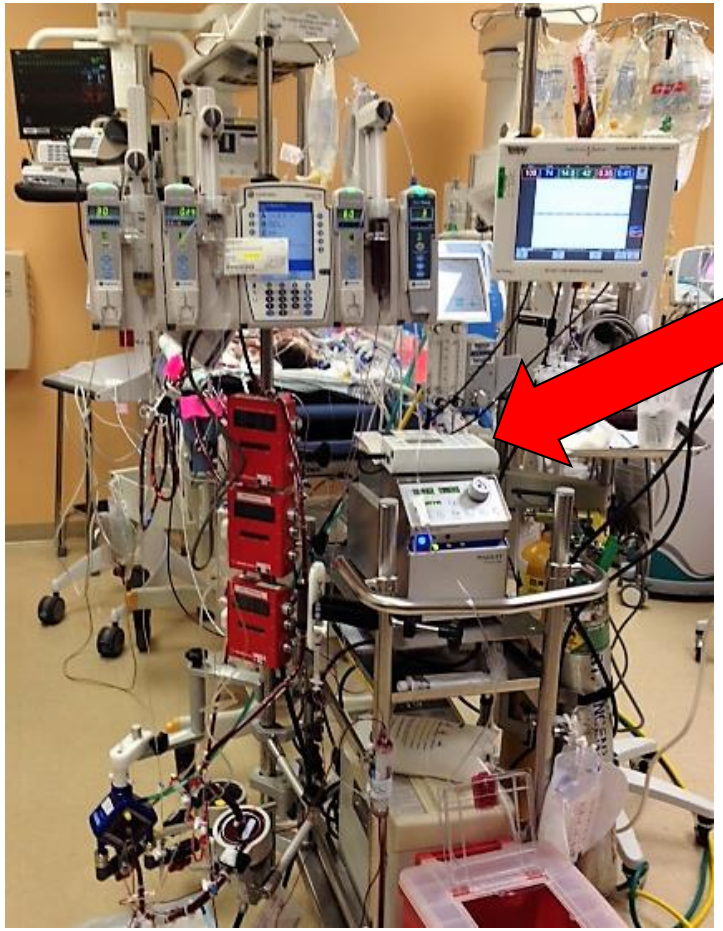
# POCT Activated Clotting Time in ECMO

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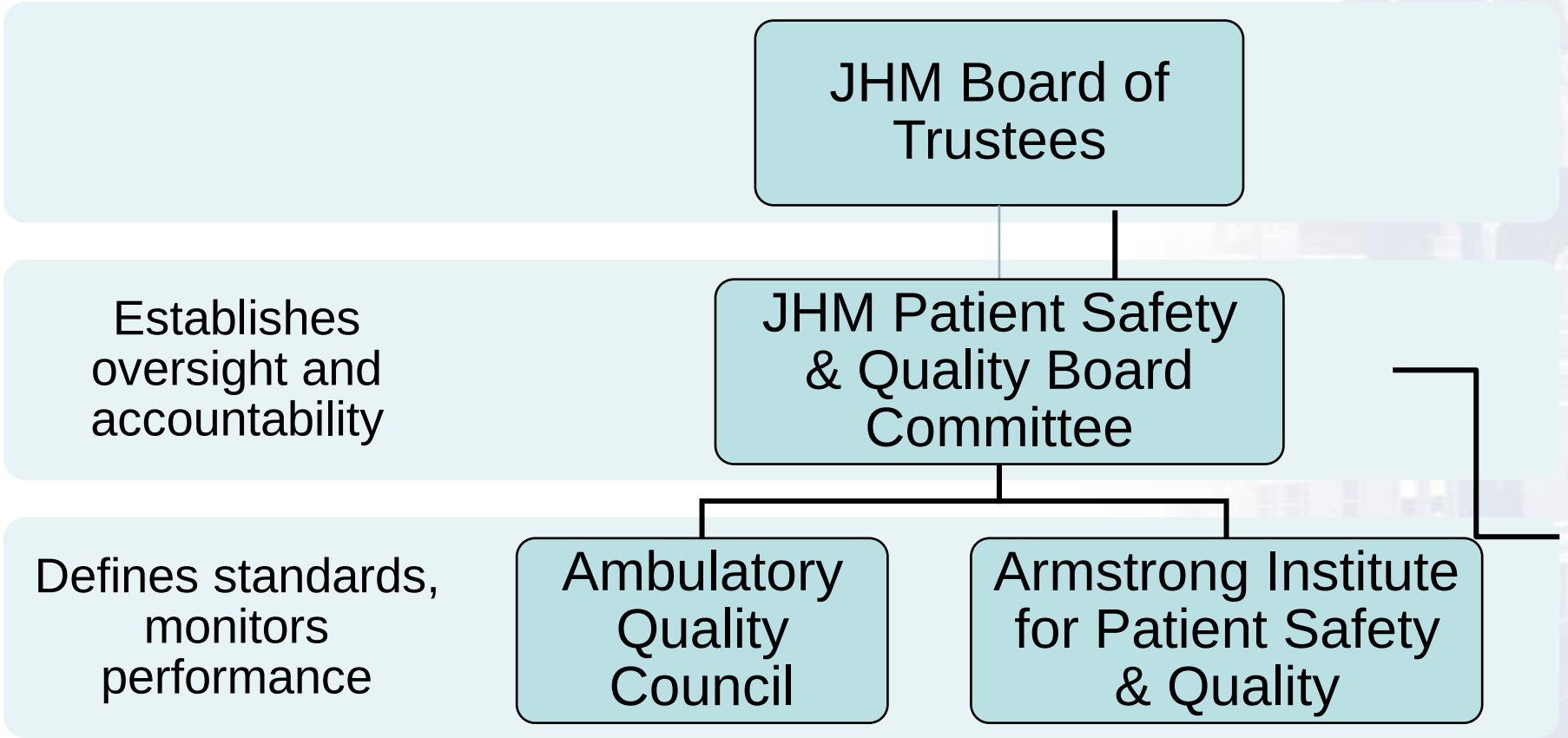
# Our POCT Structure

- Single Medical Director of JHM POCT
- JHM Manager
- Local Lab Directors and POCC at each Hospital
- JHCP: Single Medical Director and Two POCC's

# Quality Structure Across JHM

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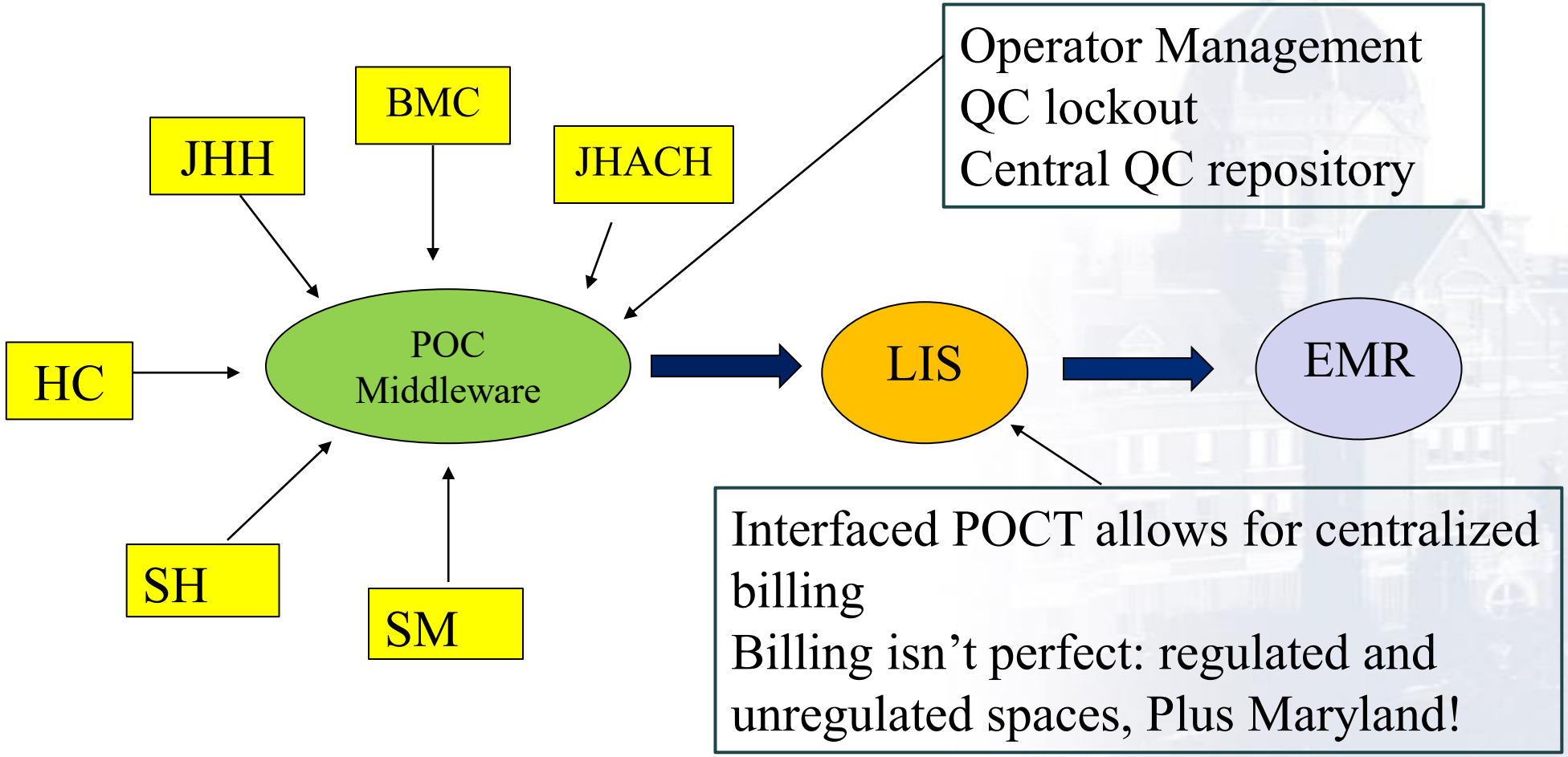
# Integrating the System

- Which POCT devices?
- Which policies and procedures?
- Where do we start?

# Enterprise Interface Infrastructure




Slide credit: Leandra Soto, MT(ASCP)

# POCT Devices

- Single device and single analyte
- Single device with multiple analytes
- There is no such thing as one size fits all for POCT
- Purchasing power, single contract, better pricing

# Challenges to standardizing

- Global manufacturing limits
- Global shipping challenges
- Supply allocation
- Limited internal resources across enterprise

*Likely related to pandemic, but, what if?

# Implementation of POCT COVID-19 Testing using a Mesa Biomedical SARS-CoV-2 Testing Platform in a Labor and Delivery Department

Johns Hopkins Hospital, Baltimore, MD 21287

M. M. Karikari, J. Mumford, W. A. Clarke

## Background

In the spring of 2020, a global pandemic for Coronavirus disease 2019 (COVID-19) was declared by the World Health Organization (WHO). As patient care adjustments were made in The Johns Hopkins Hospital (JHH), the need for a rapid COVID-19 test result was identified in the Labor and Delivery (L&D) unit. Several methodologies and platforms for COVID-19 Point-of-Care Testing (POCT) were evaluated early in the pandemic, including antibody, antigen, and molecular platforms.

The Accula™ SARS-CoV-2 Test, a molecular point of care (POC) test, fit the needs of the L&D unit based on the time to results and ease of use. The goal of this project was to decrease turn-around times - measured from Order Time to Result, and improve the quality and safety of patient care.

## Methods

The Accula™ SARS-CoV-2 Test was utilized to assess nasal swab specimens collected from pregnant women being admitted to the L&D unit at JHH for the presence of SARS-CoV-2 viral RNA.

All L&D RNs received extensive training from a POC Coordinator and/or an approved unit trainer prior to independently performing specimen collection and patient testing. In the POC workflow, an RN collects a single nasal swab from both patient nostrils, then places the swab into a labeled Accula™ SARS-CoV-2 Buffer extraction solution for transport to the POCT Laboratory for testing. Additional steps were completed once in the POCT laboratory, including visual interpretation of the results.

All results were documented on a paper patient result log, which was then used to document results in the Electronic Medical Record. In this workflow design, a single RN was responsible for the entire process, which, in turn, led to quicker result availability and rooming of patients in the proper location with applicable ventilation and PPE requirements to assist in the provision of high quality, safe care.

Quality oversight activities performed by the POCT Office included monitoring of positivity rates, regular audits of all logs (QC, patient result, and maintenance), and swipe testing to check for the presence of SARS-CoV-2 viral RNA on the testing surface and Accula™ Docks.

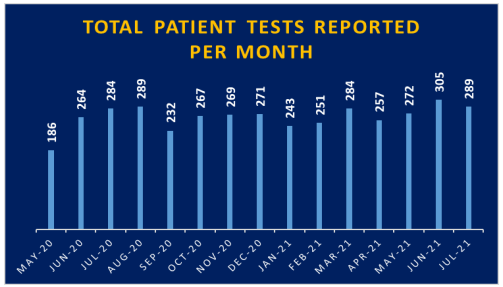
## Discussion/Barriers

**Discussion**

- Use Case Scenario: All patients being admitted to L&D, regardless of symptomology, were tested using the Accula™ SARS-CoV-2 Test, with consent.
- Due to scarce resources, and in response to the pandemic, L&D converted 2 of 6 triage rooms, and 1 of 3 operating rooms to negative pressure/Biomode initially. Additionally, four rooms that were previously antepartum were converted to create a negative pressure/Biomode unit.
- At the start of the pandemic, hospital staff were reassigned and deployed as runners for specific floors. This resulted in TATs of multiple hours (>120 minutes) on average for Core Lab SARS-CoV-2 testing.
- Prior to POCT implementation, L&D Leadership sought approval to have all SARS-CoV-2 tests classified as Stat, improving TAT to approximately 60-90 minutes.
- Few patients declined the test; those who did were treated as PUI.
- Ultimately, POCT implementation allowed for both proper rooming of patients in a timely manner and for conservation of resources.

**Barriers**

- Accula is not the most cost-effective platform on the market.
- Clinical staff, while comfortable collecting samples, did not want to perform this lab test at the point-of-care.
- Sample collection and testing were performed in two different rooms. Staff were expected to don and doff multiple times, causing concerns about the rate of scare resource usage (PPE).
- The Accula Dock does not allow for operator lockout, which led to at least one instance, noted during QA review, of individual(s) performing testing without completing training and competency requirements.
- Result interpretation is visual and required within a specific timeframe following completion of the dock processing step.
- Lack of instrument interface causes some delays and a higher level of QA review, as all results are documented manually on the patient's EMR.
- Although the Invalid rate has remained within the manufacturer's acceptable limit (<5%), the rate of Invalid test results was costly, caused great frustration with the clinical staff, and potentially resulted in some patients being treated as PUI in the absence of a timely POCT result.




**Patient Tests resulted in EMR (05/11/2020 through 07/31/2021):**

**3,963**

**Average Monthly Patient Test Total (05/11/2020 through 07/31/2021):**

**264**

## Results

Prior to the implementation of point-of-care COVID-19 testing, delays of greater than two hours between specimen collection and result availability were commonplace as hospital operations adjusted in the early months of the pandemic.

The availability of two Accula™ Docks at the point of care allowed for an expedited process of specimen collection, testing, and resulting for women being admitted to the L&D Unit. The POCT method go-live occurred on 5/11/2020; through the month of June 2020, the average turnaround time was 48 minutes. Comparatively, in the month of February 2021, a decrease in the average TAT down to 35 minutes was noted.

## Conclusions

The Accula™ SARS-CoV-2 Test provided a viable solution for the needs of the Labor and Delivery Unit at JHH, with improvements noted in turnaround times and in the quality and safety of patient care.

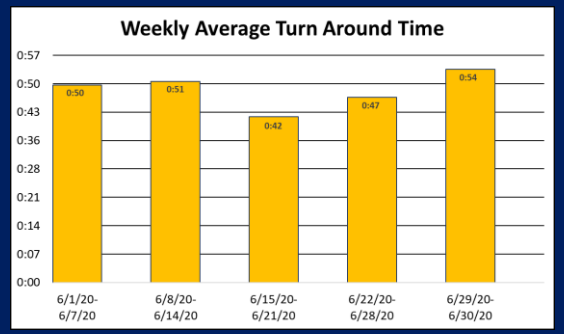
This project led to identification of the following best practices:

- Swipe Testing, implemented at go-live, remains a regular QA activity that creates accountability for compliance with decontamination procedures, and is an added safety measure.
- Identifying a POCT advocate who is willing to be a primary contact and trainer is key. In this project, the Assistant Nurse Manager took on this role; issues are now first routed through her, with the POCT Office contacted for assistance as needed.
- Quality Assurance activities for this test can be time consuming; quickly identifying common sources of error and key metrics to evaluate helped streamline review.

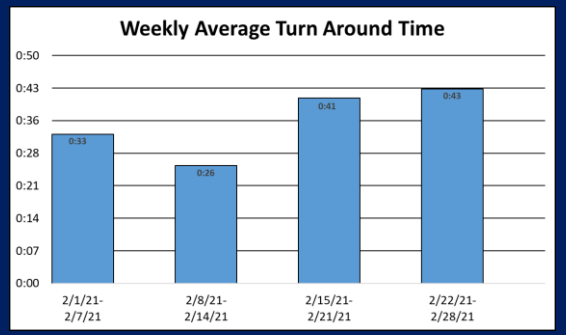
Even with an easy-to-use platform, however, robust quality oversight is key in ensuring success in the implementation and maintenance of COVID-19 testing at the Point-of-Care.

## *Comparison of Average TATs in First Full Month and 11 Months Post Go-Live*

**June 2020**




**February 2021**

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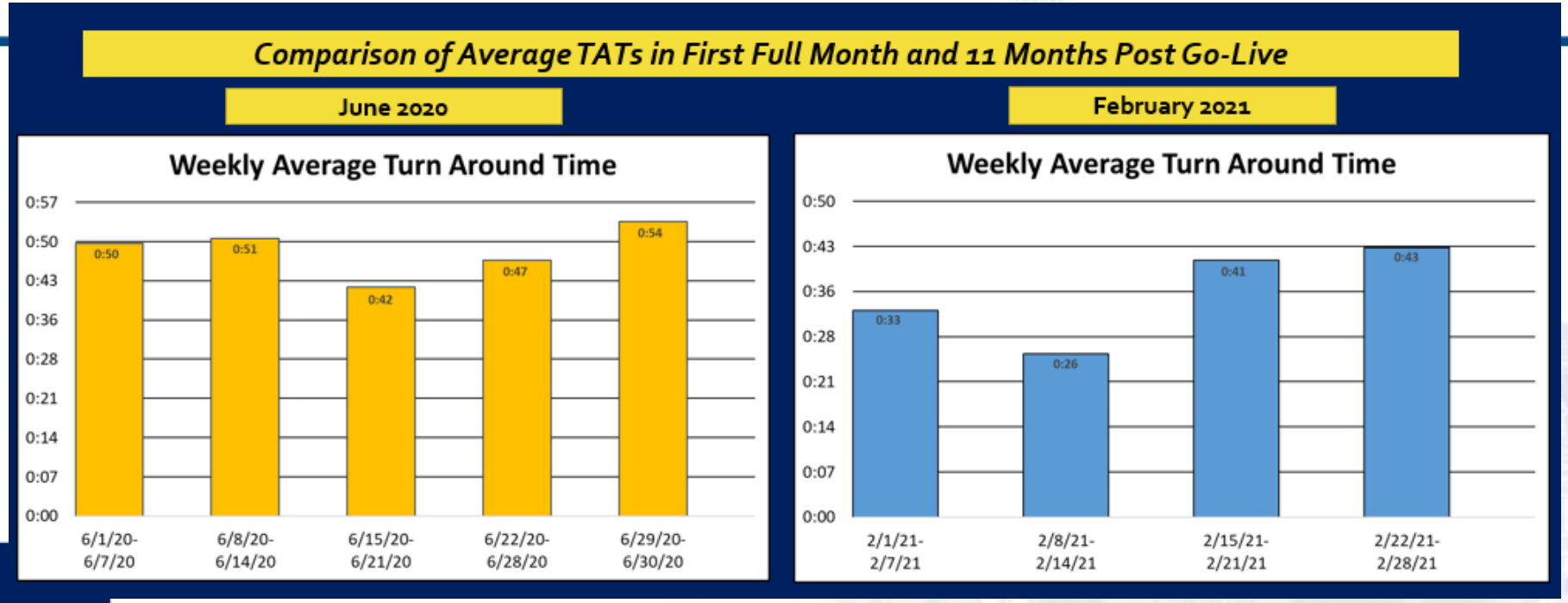
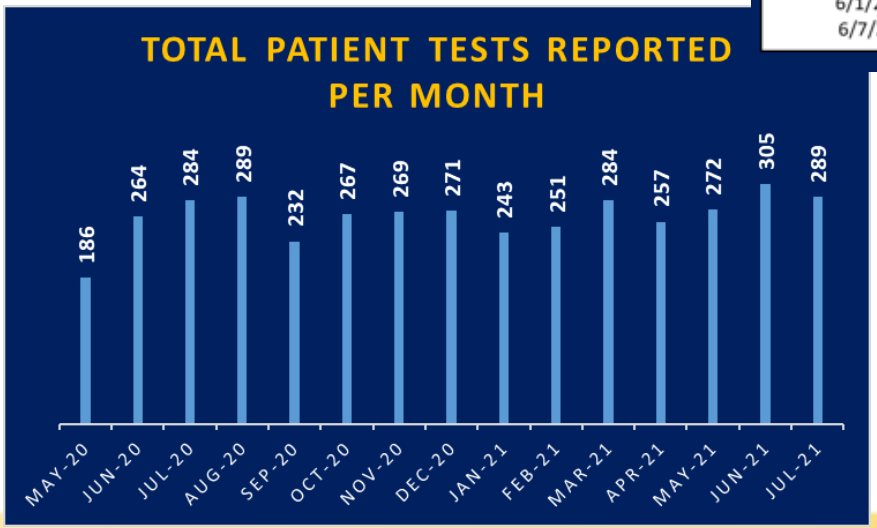
# Labor and Delivery TAT Improvement

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# Implementation of POCT SARS-CoV-2/Flu A & B/RSV Testing using the Cepheid GeneXpert Xpress Testing Platform in a Tertiary Care Adult and Pediatric Emergency Department

Johns Hopkins Hospital, Baltimore, MD 21287

M. M. Karikari, J. Mumford, R. E. Rothman, M. O. Saheed, K. J. Fenstermacher, T. C. Colburn, L. M. Sauer, H. M. Gardner, B. A. Maliszewski, G. Cole, W. A. Clarke

## Background

In the spring of 2020, a global pandemic for Coronavirus disease 2019 (COVID-19) was declared by the World Health Organization (WHO). As adjustments were made to patient care in The Johns Hopkins Hospital (JHH), the need for a rapid COVID-19 test result was identified as immediate in the Adult and Pediatric Emergency Departments (EDs).

The Cepheid GeneXpert Xpress was identified as fitting the needs of the Adult and Pediatric EDs due to throughput capacity, availability of the SARS-CoV-2/Flu A + B/RSV test cartridge, time to results, interfacing capabilities, and ease of use. The goal of this project was to increase the percentage of SARS-CoV-2 results available within 3 hours of patient arrival, improve turnaround times for STAT SARS-CoV-2 results, and improve the quality and safety of patient care for symptomatic patients presenting to either Emergency Department with influenza-like illness.

## Methods

The implementation of the Cepheid GeneXpert Xpress SARS-CoV-2 instruments in the adult ED was expedited with a goal of less than six week timeline, from conception to implementation.

Testing was set up in a newly built ED point-of-care laboratory staffed by Certified Nursing Assistants (C.NAs) working 4-hour shifts. The ED laboratory was created specifically for this project and is staffed 12 hours a day, 7 days a week, and processes 75% of the daily SARS-CoV-2 samples for both EDs.

All testing personnel received extensive training from a Point-of-Care Coordinator prior to independently operating the Xpert Xpress analyzers. The operator responsibilities include documenting results on a patient result log, which is then transcribed onto the Electronic Medical Record.

Quality oversight activities performed by the Point of Care Testing Office include supply management due to extreme allocation limitations initially, monitoring of positivity rates, daily audits of all logs (QC, patient result, and maintenance), and swipe testing to check for the presence of viral material on the testing surface and GeneXpert Xpress Systems, among others.

## Discussion/Barriers

**Discussion**

- Use Case Scenario: All symptomatic patients from both the Adult and Pediatric EDs were tested using a Cepheid Xpert Xpress Test.
- In response to the pandemic, symptomatic patients were routed to negative pressure/Biomode area(s) as applicable.
- Early in the pandemic, staff were hired for the specific task of continuously running SARS-CoV-2 samples from the EDs to the Microbiology Lab for testing. TAT goals at this time were 60% under 3 hours.

Pre-Interface, Manual Entry Only

- Due to the expedited project timeline, it was decided testing would go-live on 12/08/2020 *without* the interface. This required manual entry of all patient results in the EMRs, and documentation on paper logs.
- Testing at this time was solely using the 4Plex cartridges (SARS-CoV-2/Flu A&B/RSV).

Post-Interface

- Five months post initial go-live, the interface went live. This allowed for patient results to post automatically to their EMRs.
- Both types of cartridges (4Plex and SARS-CoV-2 only) will be used with the interface, depending on the presence or absence of flu season.

**Barriers**

- C.NAs were comfortable collecting samples, but did not want to perform this lab test at the point-of-care initially.
- At least one instance of testing personnel performing testing without first completing hands-on training was reported.
- Initially, there was some instability in resource allocation.
- Manufacturer switched from 4Plex to SARS-CoV-2 only cartridges, and is expected to switch back to 4Plex again. The switch corresponded with the cold and flu season.

Pre-Interface, Manual Entry Only

- In the absence of the interface, multiple hours had to be dedicated weekly to QA review and follow-up to address identified issues.
- There were several instances of patient testing performed without an order being placed. Demographic labels were used on patient specimens, and did not require placement of an order first.

Post-Interface

- Use of a lab collect workflow has resulted in delivery of specimens to the wrong testing location. When a Microbiology specimen is ran in the POCT Lab, the wrong Specimen ID is used. This in turn leads to delays in patient results posting.

***Patient Tests Reported***

| December 2020 | January 2021 | February 2021 | March 2021 | April 2021 | May 2021 | June 2021 | July 2021 | Total Tests | Average Monthly Tests |
|---|---|---|---|---|---|---|---|---|---|
| 1096 | 1617 | 1376 | 1643 | 1722 | 1584 | 1376 | 1461 | 11,875 | 1484 |

## Results

The benchmark turnaround time for STAT tests performed from symptomatic patients via the Microbiology laboratory was at least 60% of test results available ≤3 hours of patient arrival in the ED. In the month of November 2020, prior to POCT implementation, an average of 66 tests were resulted per day, with 63.7% meeting the benchmark in the Adult ED.

By comparison, in the 3-month timespan following the December 2020 go-live with the POCT method, the following improvements in statistics were noted:

- From the Adult ED, an average of 39 tests were resulted per day, with a mean 87.3% of results being made available within 3 hours of patient arrival.
- Using median arrival to result time calculations for the time period of 12/8/2020 through 3/8/2021, the average turnaround time utilizing the POCT methodology was 98 minutes, improved from 160 minutes.
- The Pediatric ED saw a 93.4% rate benchmark in the same time period.

Original POCT Lab Layout, as of 12/08/2020.

## Conclusions

The Cepheid SARS-CoV-2 Test at the point-of-care provided a viable and effective solution for the Adult and Pediatric EDs, with improvements noted in turnaround times of results.

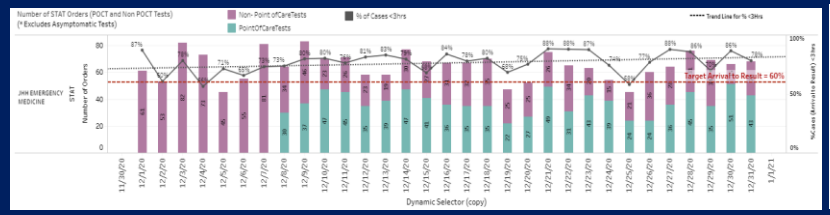
The following best practices were identified:

- Given the option, this project would not have gone live until the interface piece was finalized due to time intensive QA requirements in its absence.
- Swipe Testing is a regular QA activity that creates accountability for adherence to decontamination procedures, and is an added safety measure.

Even with an easy-to-use platform, however, robust quality oversight is key in ensuring success in the implementation and maintenance of COVID-19 testing at the Point-of-Care.

## *Supportive Data for Sample Result Turn-Around Time: Comparing Lab to POCT Workflows*

### December 2020



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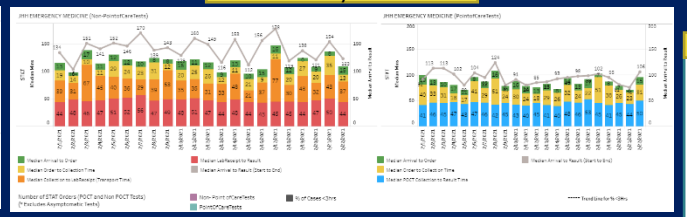
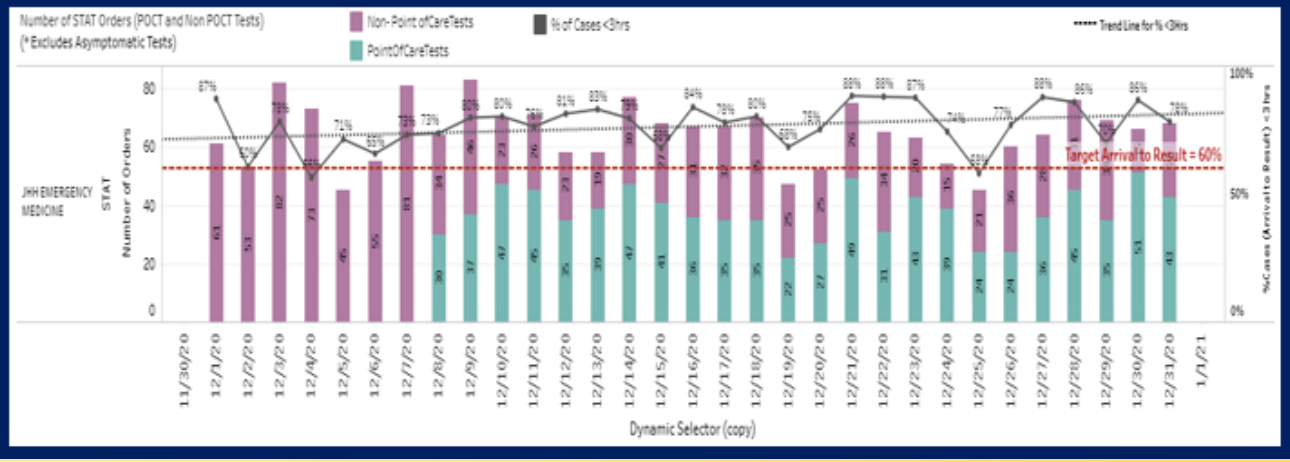


# Results within 3 hour of Patient Arrival - ED

## *Supportive Data for Sample Result Turn-Around Time: Comparing Lab to POCT Workflows*

**December 2020**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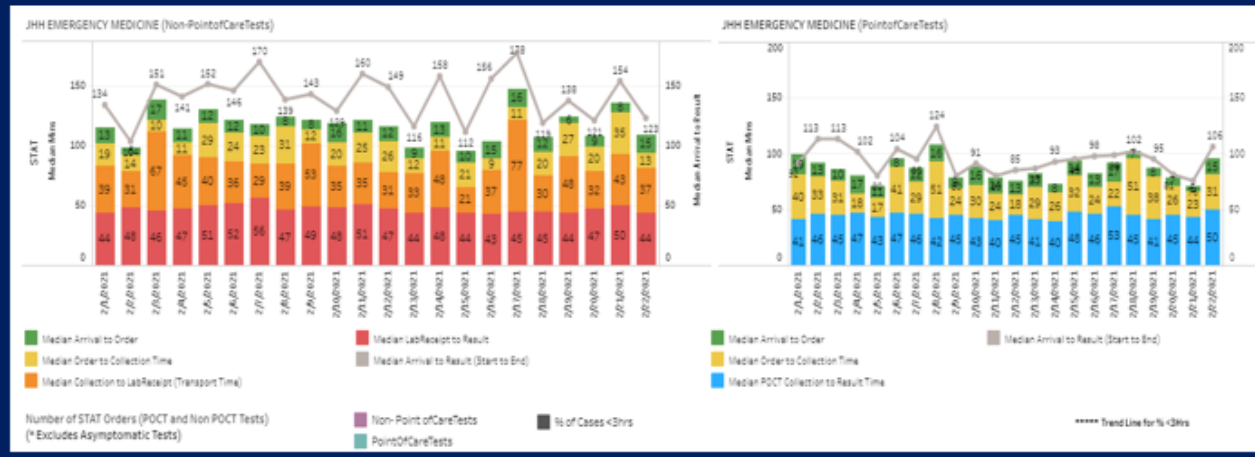


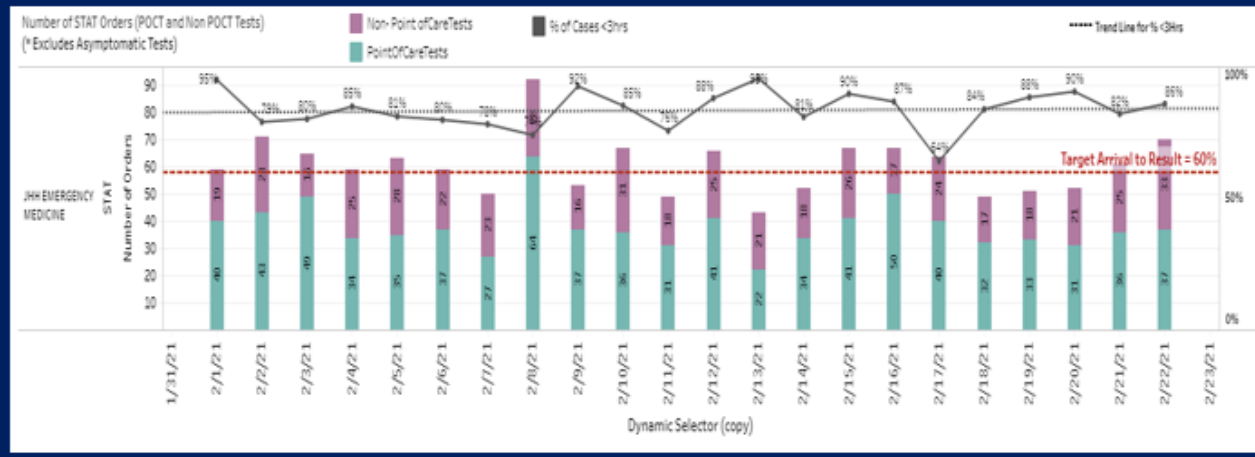

# Workflows

- Testing personnel and use of EMR/EHR
- How does the POCT get entered into the EMR/EHR?
- i.e., Tear Osmolality
- Single IT platforms = harmonize POCC duties and responsibilities

# 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 complex system?

# POCT Meetings

- **Monthly First Friday** – all JHM POCT
  - CLIA LD and local lab admin teams present
  - Master Project List
  - Software/Firmware Upgrades
  - Server Patches
  - New technologies/Field Studies
  - COVID POCT: monthly breakdown of use and QA issues

  *System wide communication

# Master Project List - Enterprise

**JHH CAP inspection March 16-17**
**EPIC/QML Upgrade March 17**
**EPIC FREEZE March 10th**

| Location or DEP/MPI ID | Interface Needed | Status | NOTES/JIRA/Updates | Address: | Need JACK Installed | Current Jack is Active | Next Step/Responsible Party | Submitted for PO | Submitted for CQI Reimbursements | Priority |
|---|---|---|---|---|---|---|---|---|---|---|
| JHM - Correction for after EPIC software upgrade issue | n/a | completed | JIRA EPICPROJ-34147 - POC- the result component POC QC Performed? no longer has hard stop | n/a | n/a | | 1/6/22: Patrice will reach out to her TS and Nicole to find out what options we have for a correction of the issue created by an EPIC upgrade<br>1/13/22: EPIC currently has the fix under development - from SLG<br>1/20/22: need a dowtime for deployment - looking at the one in March to deploy | | | |
| JHM Temp corrected Result display | n/a | in progress | After the addition of measured and temp corrected panels for standardization, results are not displaying in the correct order on the Result review tree | n/a | n/a | n/a | 2/24/22: Patrice trying to get in a meeting to resolve this<br>3/3/22: Patrice has a scheduled meeting for 3/9 to present to joint design to move temp corrected analytes to the top of the | | | |
| Suburban | Hemochron | in progress | Suburban is adding Hemochron instruments | Suburban hospital | ? | ? | 1/7/21; Julia's update- EPOC troubleshooting is priority at this time. We will try for July go live. More details to follow in coming weeks.<br>1/28/21: no further updates. | no | | 2 |

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# More POCT Meetings

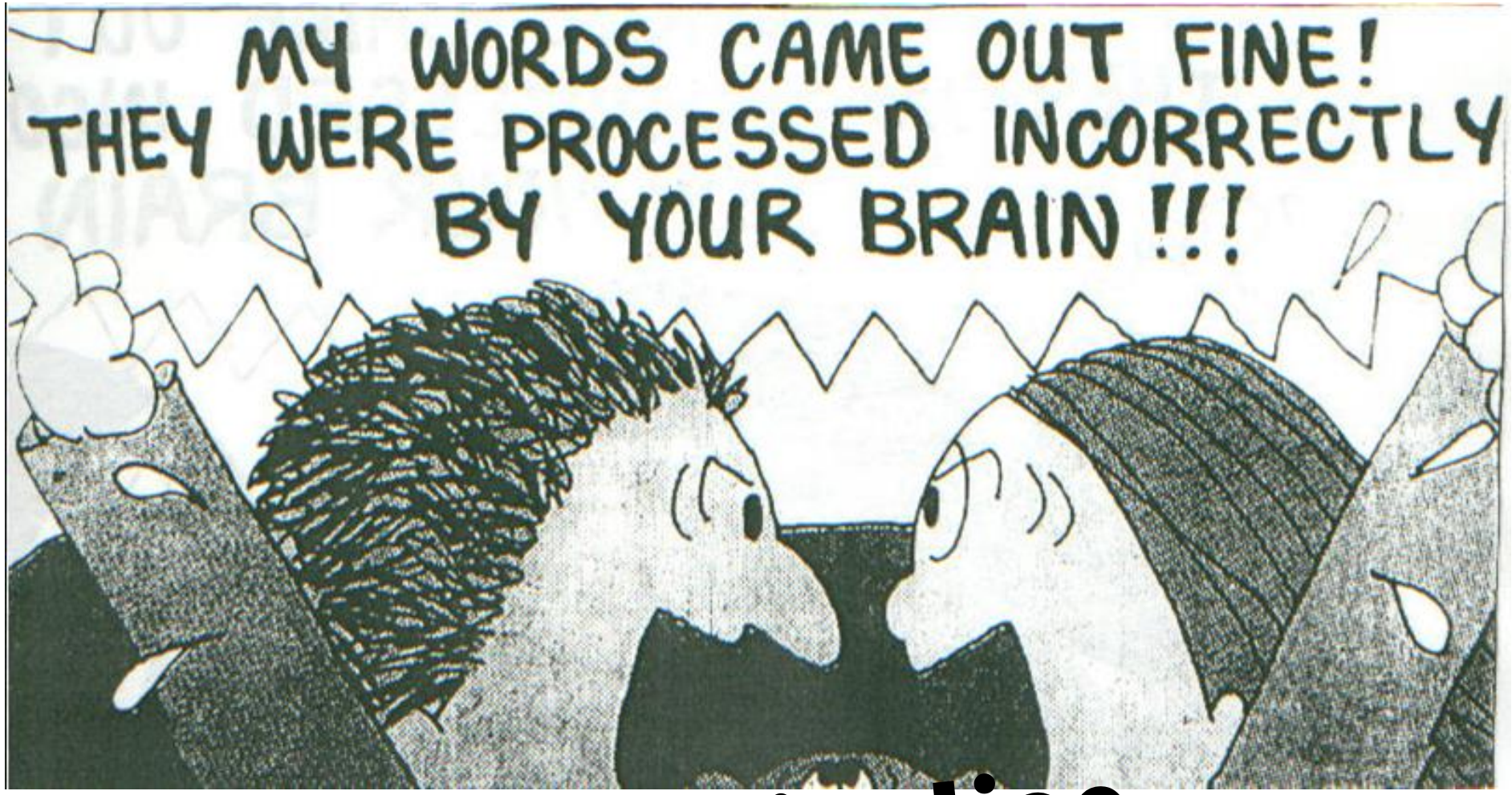
- **Monthly Third Friday** – POCCs only
  - Master Project List
  - Software/Firmware Upgrades
  - Inspection Preparedness
  - Opportunity for group support/ideas
  - COVID POCT: monthly supply concerns and resource sharing. Updates on new sites and expansion of testing

  *System wide communication

# Other Team Meetings

- Vendor calls for JHM POCT
  - Blood gases once a month
  - Connectivity vendor twice a month
- IT/EMR calls several times a week
  - All POCC's invited
  - All IT tickets reviewed and clinical teams invited adhoc
  - Master Project List

*System wide communication

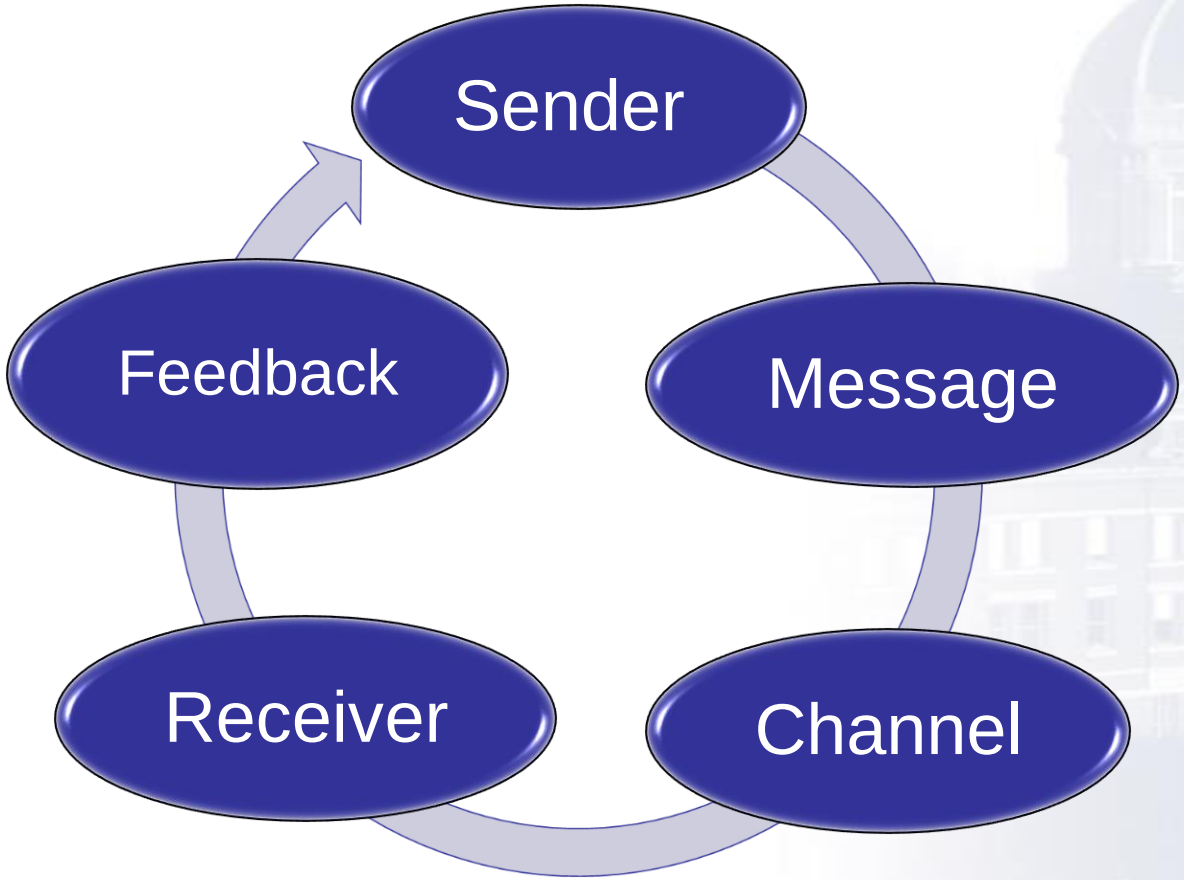



# Communication

Communication

Communication

# Communication Cycle



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| JHM - Correction for after EPIC software upgrade issue | n/a | completed | JIRA EPICPROJ-34147 - POC- the result component POC QC Performed? no longer has hard stop | n/a | n/a | | 1/6/22: Patrice will reach out to her TS and Nicole to find out what options we have for a correction of the issue created by an EPIC upgrade<br>1/13/22: EPIC currently has the fix under development - from SLG<br>1/20/22: need a dowtime for deployment - looking at the one in March to deploy | | | |
| JHM Temp corrected Result display | n/a | in progress | After the addition of measured and temp corrected panels for standardization, results are not displaying in the correct order on the Result review tree | n/a | n/a | n/a | 2/24/22: Patrice trying to get in a meeting to resolve this<br>3/3/22: Patrice has a scheduled meeting for 3/9 to present to joint design to move temp corrected analytes to the top of the | | | |
| Suburban | Hemochron | in progress | Suburban is adding Hemochron instruments | Suburban hospital | ? | ? | 1/7/21; Julia's update- EPOC troubleshooting is priority at this time. We will try for July go live. More details to follow in coming weeks.<br>1/28/21: no further updates. | no | | 2 |

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# Lesson Learned

- 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
- Helping clinical teams how to balance clinical demands with laboratory regulatory demands

# Patient Centered Medical Care

Supporting the clinical team helps them to better care for your patients and their support team

- Decrease unnecessary stress
- Decrease downtime
- Decrease user errors

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# Have You Considered?

- Monthly meeting with lab vendors such as Quest, Lab Corp and Johns Hopkins Medical Lab
- Monthly/Quarterly meetings with testing personnel, unit managers and trainers
- Meeting with Nurse Administration for high level topics
- Daily huddles on units/floors

# 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

# Future Goals

- Standardized electronic audit/rounding tool for all ambulatory and hospital sites
- Networking Events for all POCC's
- No New POCT Devices Without Interface Capabilities
- Managing Non-laboratory Devices Through Middleware (i.e., transcutaneous bili)

# What Have We Done Well – Ongoing/Long Term

- Enterprise IT platform
- Single enterprise POCT policy
- Increased overall communication with multidisciplinary teams and amongst enterprise POCC's

# What We Did Well – Pandemic

- Collaborative enterprise daily calls during pandemic
- Shared resources and laboratory supplies
- Metrics for improvement for new test requests (theory)

# Opportunities for Improvement

- Standardized POC test codes in EMR
- Standardized workflow for result entry
- Face-to-Face Quality Assurance
  - We measure metrics
  - We don’t follow up effectively

# Opportunities for Improvement, con't

- Hospital and University Ambulatory Sites
  - Quality oversight?
  - Polices and Procedures?
  - Billing?
- Mixed management modules
- JHCP? JHH?

# Questions


**Jeanne Mumford, MT(ASCP)**
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