Managing POCT: Trying to Control Testing in an Out-of-Control Environment

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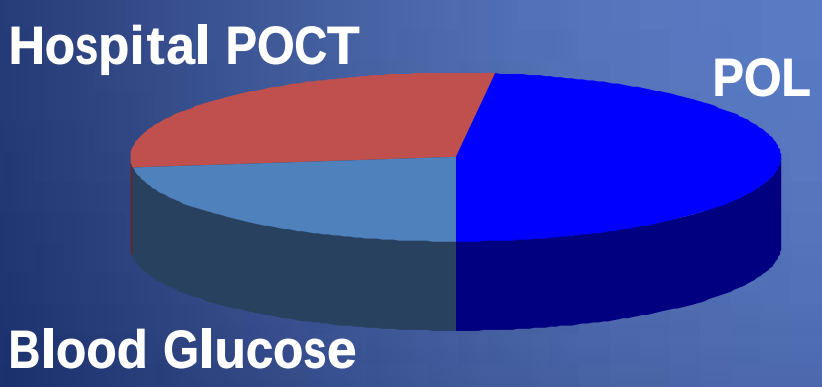
Learning Objectives

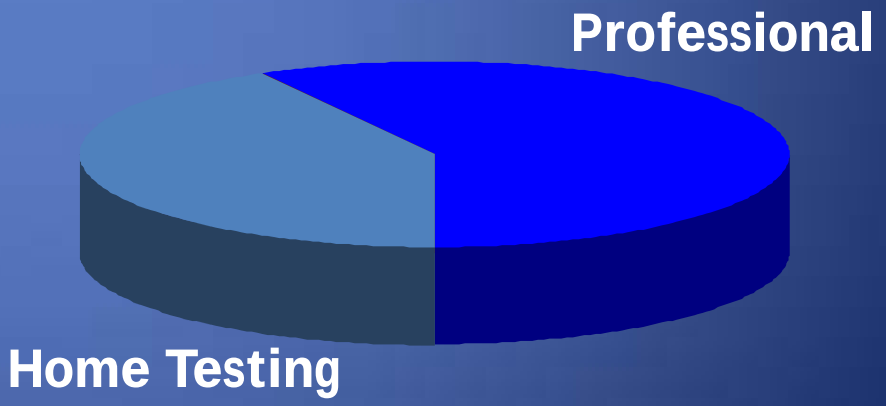
- Participants should be able to:
  - Discuss challenges associates with rapidly increasing number of POCT applications
  - Formulate strategies for efficiently managing a growing POCT program
  - Identify areas where POCT connectivity will be useful for improving efficiency and patient safety

POCT is Big Business

- Point-of-Care Testing (POCT) is rapidly growing field
  - $1.88 billion in 2005
  - $2.73 billion in 2010 (12% annual growth)



Stephans EJ. Developing Open Standards for Connectivity IVD Technology 1999;5:22,25



Cambridge Consultants POCT Diagnostic Market Report July 2006

POCT has Potential

- Immediate results = reduced time to treatment
- No lab transportation = reduced opportunity for errors
- Small volume of blood
- Increasing menu of available tests
- Easily incorporated into clinical workflow

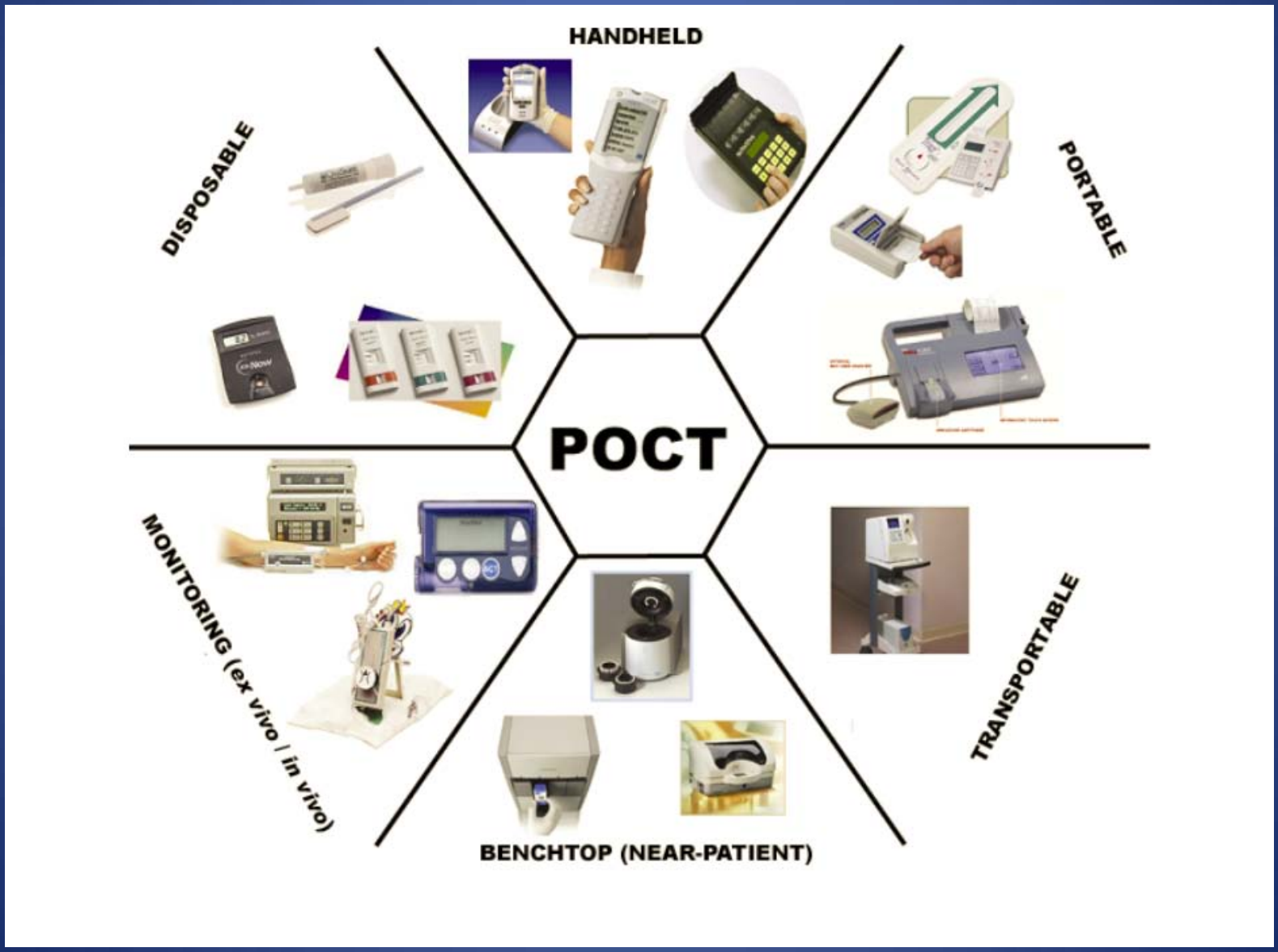
POCT is Essential (Sometimes)

- Some treatments are time sensitive and require rapid availability of results
  - e.g. cardiac markers, coumadin clinics
- Surgical intervention can be guided by lab results
  - e.g. IOPTH
- In theory, rapidly available results can lead to improved outcomes
  - Quick recovery/decreased length of stay
  - Increased throughput (ED, outpatient clinics)
  - Cost savings

The Purpose of POCT

- POCT should provide test results quickly, allowing early clinical diagnosis and intervention to improve patient outcomes
- Ideally, the outcome should be mutually beneficial for the patient, clinician, and institution
  - Quality indicators should be established and monitored/evaluated to ensure that expected outcomes are realized

Types of POCT



Explosion of Waived POCT

- Definition of Waived Test:
  - "simple laboratory examinations and procedures that are cleared by the federal government for home use; that employ methodologies that are so simple and accurate that erroneous results would be negligible; or that pose no reasonable risk of harm to the patient if the test is performed incorrectly."
- Focus is more often on the users than impact of results
- There are now >400 tests on the CLIA waived test list
- The list can be found at:
  - http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp

Explosion of Requested POCT Applications

- Typical menu includes glucose, INR and ACT, blood gases, and assorted manual tests (pregnancy, urine dipsticks, etc.)
- Then comes a request for creatinine to support Radiology or Oncology
- Then comes a request for increased menu in PICU and NICU to reduce blood usage
- Then comes a request for POCT in patient transport
- Then comes a request for …

“Non-Traditional” POCT Applications

US Army 14th Combat Support Hospital

Ortho-Diagnostics Blood Typing: ABO Blood Group

US Navy

Cardiac STATus: cTnI, CK-MB, Myoglobin

US Army 14th Combat Support Hospital

Rapidpoint Coag: PT, aPTT, Heparin Management Test

US Military, Local Surveyed Hospital

i-STAT: ACT, PT/INR, glucose, creatinine, cTnI, Na^+, K^+, Cl^-, Ca^{++}, pH, pCO_2, pO_2, SO_2, Hct, Hb, BUN, CK-MB, BNP

Hospitals, Evacuation Sites

Capillary Blood Glucose Meters

US Army, Navy, Marine Corps

Piccolo: Albumin, ALP, ALT, amylase, AST, BUN, creatinine, Ca, Cl , K , Na , Mg, LD, HDL, cholesterol, triglycerides, CK, glucose, TP, phosphorous, total bilirubin, direct bilirubin, TCO_2, GGT, uric acid

Donation to Local Red Cross

45,000 Blood Glucose Meters

US Air Force

Triage

Cardiac Panel: cTnI, CK-MB, myoglobin

Drugs of Abuse: Amphetamines, Methamphetamines

Kost GJ, Tran NK, et al. *Am J Clin Path* 2006;126:513-520.

Clinical Scenario #1

- Patient admitted to ICU with HIV-related complications
- During ICU stay, serial blood glucose measurements were made
  - Multiple, consecutive measurements were >200 mg/dL by central lab method, <10 by POCT
- Clinical team assumes error in the central lab measurement; patient subsequently expires
  - During clinical treatment, patient was given IVIG containing maltose
- Upon autopsy, error in glucose management is determined to be a contributing factor to the cause of death

Clinical Scenario #2

- 3 sites request expanded menu for BG analyzers at POC: NICU, Oncology, ED
  - Electrolytes, creatinine, glucose, lactate, etc.
- Each site makes a case for improved care, but lacks understanding of menu availability
  - ED: cardiac markers, NICU: bilirubin, Oncology: LFT's
- No site take into consideration specimen integrity checks for analytes
  - e.g. hemolysis check for K^+

Further Consideration in the NICU

- Who will do the testing?
  - RTs or Nursing
- What impact will this have on workflow of other tasks
- What about ordering & reporting of tests not ordered?
- Cost impact on institution
- Possibility for bedside testing
  - How many devices are needed?

Where to Start?

- Evaluation of technology
- Develop administrative plan
- Integrate connectivity of devices

Technology Evaluation

- Correlation of measurement with central lab
  - How do methodologies and measurements compare?
  - Will bias significantly affect clinical decisions?
  - Important for continuity of care

- Pre-analytical
  - Consider both endogenous & exogenous interferences
  - Can specimen collection (e.g. fingerstick technique) significantly affect the result?
  - How robust is the instrument?

Clinical Utility

- POCT is not a “black box” fix; nor is it something to do just because it’s available
- Does the POCT request fix the problem?
  - Will the test allow rule-in or rule-out diagnosis?
  - Why does the central or critical care/satellite lab not meet the need?
  - Can therapy or consultation be initiated based on POCT result?

Clinical Utility

- Faster results does not guarantee improved clinical outcome
- To assess clinical utility, need to evaluate:
  - Reason for ordering test
  - How the result will be utilized for patient care
  - Is POCT method appropriate for patient needs in that particular setting?
- Communication with clinical staff is vital for determination of clinical utility and implementation

Clinical Chemistry 46:4
543–550 (2000)

Laboratory Management

Clinical Outcomes of Point-of-Care Testing in the Interventional Radiology and Invasive Cardiology Setting

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Background: Point-of-care testing (POCT) can provide rapid test results, but its impact on patient care is not well documented. We investigated the ability of POCT to decrease inpatient and outpatient waiting times for cardiovascular procedures.

Methods: We prospectively studied, over a 7-month period, 216 patients requiring diagnostic laboratory testing for coagulation (prothrombin time/activated partial thromboplastin time) and/or renal function (urea nitrogen, creatinine, sodium, and potassium) before elective invasive cardiac and radiologic procedures. Overall pa-

0.02). For patients needing coagulation testing, wait times improved only when systematic changes were made in workflow (phase 4, 109 ± 41 min; n = 12; P = 0.01).

Conclusions: Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. Systematic changes in patient management may be required.

CVDL Outcomes Trial

- Prior to therapeutic intervention, patients require coagulation (PT/aPTT) and/or renal function testing (Na/K, BUN/Creat)
- Phase 1 – workflow and patient throughput determined using central lab testing.
- N = 135 patients over 95 days
- Despite arriving 120 minutes early if lab work needed, 44% of results not available prior to scheduled procedure time.
- Average patient wait time was 167 minutes

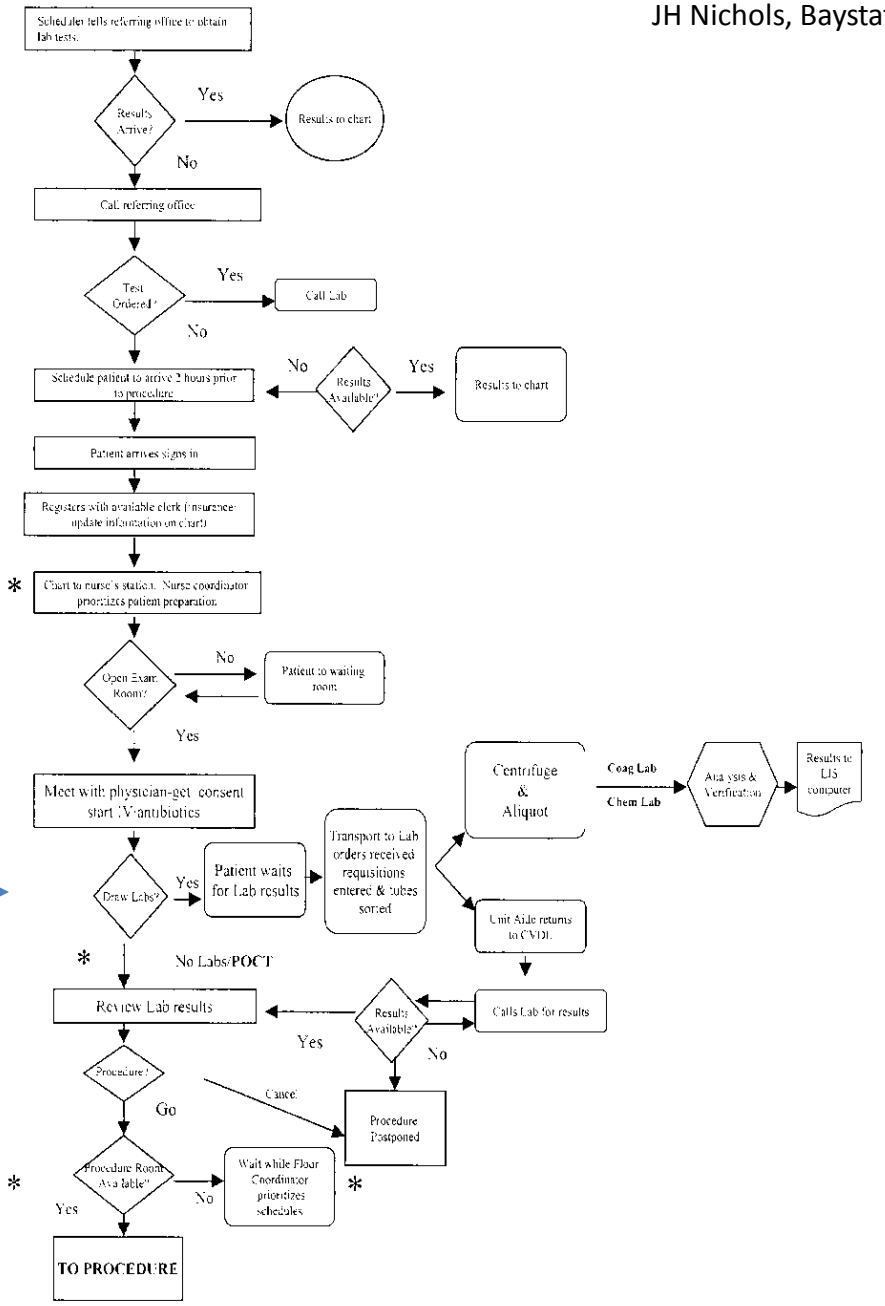

Fig. 2. CVDL patient workflow.

*, steps affected by implementation of POCT and workflow improvement initiatives. *IV*, intravenous drip; *Coag*, coagulation; *Chem*, chemistry; *LIS*, laboratory information system.

JHH CVDL Outcomes Trial

- POCT improved wait times over core laboratory, but not significantly.

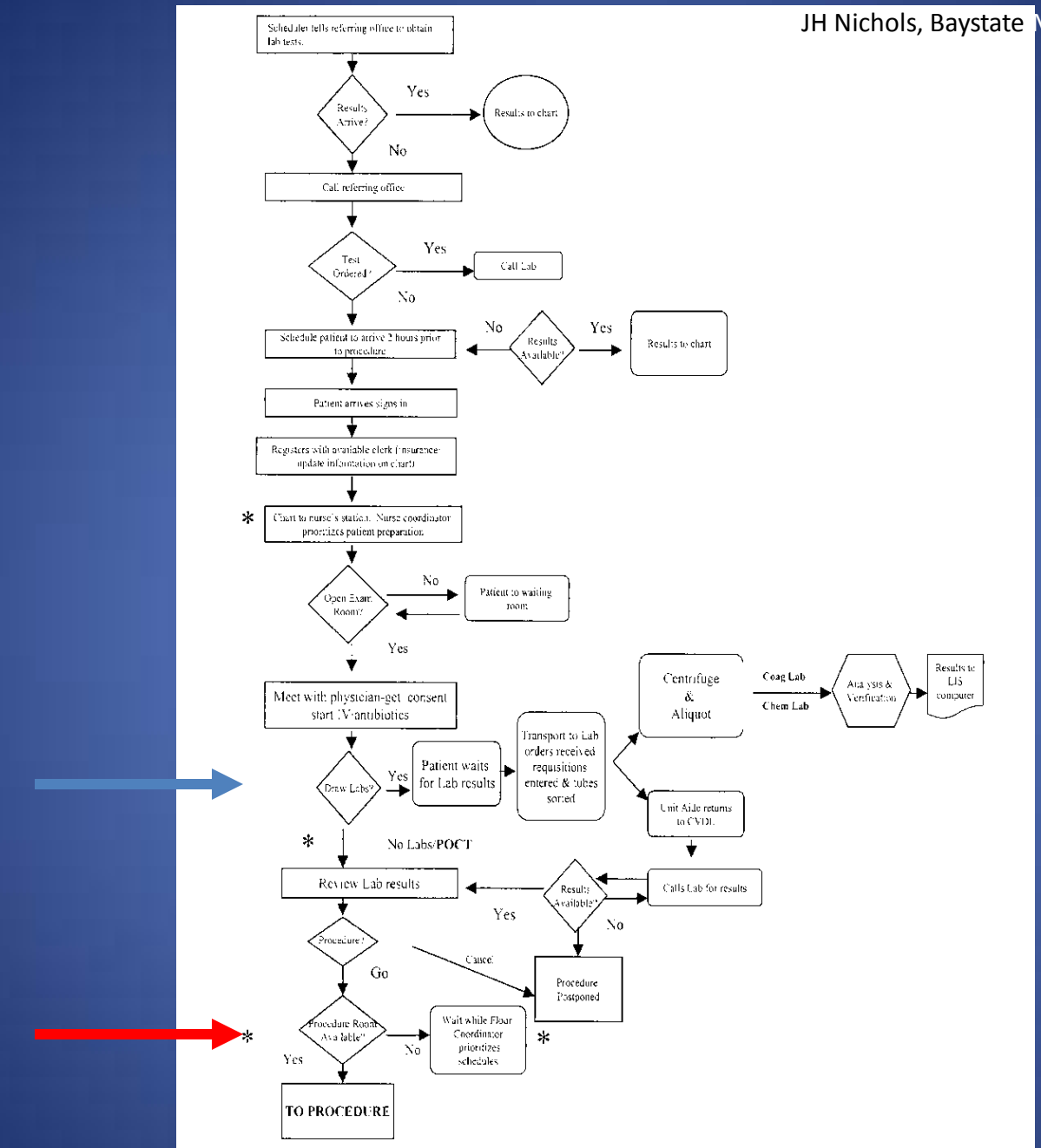

Fig. 2. CVDL patient workflow.

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JHH CVDL Outcomes Trial

- POCT improved wait times over core laboratory, but not significantly.
- Significant changes only occurred after unit workflow reorganized to optimize use of POCT results (implemented communication center between admit and procedure rooms); decreased wait times 63 mins for coag (N=9, $p = 0.014$) and 47 mins for renal (N=18, $p = 0.02$)

Administrative Plan & Support

- POCT Management is complex, so a robust administrative plan for support of the program is crucial for success
- There are dozens of sites, with multiple instruments and thousands of operators that don't have laboratory training
- Operators are focused on patient care and not instrument performance and QC

Program Management

- POCT is very decentralized compared to single location for central lab services
  - It is important not to try managing POCT in the same way as the lab
- Each site must be evaluated for staffing and regulatory requirements
- Management plan must include provisions for tracking operator competency and quality assurance

Johns Hopkins Hospital
Scope of Point of Care Program

Glucose Testing

Test Sites: 90

Operators: >3000

Meters: 230

Results: >30,000 monthly

Creatinine

Test Sites: 7

Operators: 40

Meters: 9

Results: >1000 monthly

Non-Device Tests

Test Sites: 28

Manual Tests: 5

POCT Coagulation

Test Sites: 12

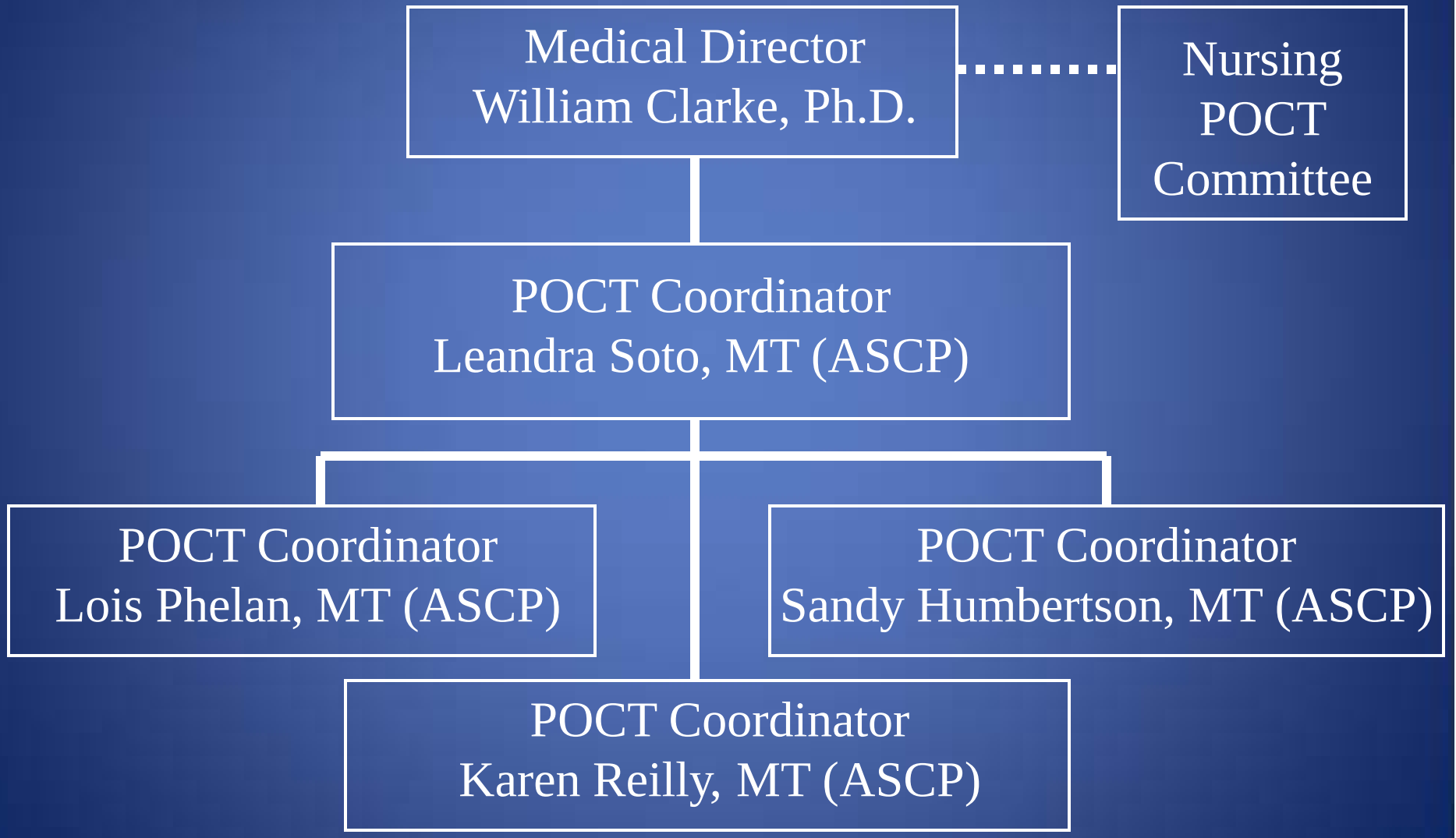
Tests: 3

Operators: 164

Meters: 26

Results: >4000 monthly

POCT Management at Johns Hopkins Hospital



JHH POCT Communication

- Reports
- Department of Nursing Newsletter

  ("Nursing Under the Dome")
- Websites
  - Department of Nursing
  - POCT program
- Periodic POCT updates and unit-specific communications via e-mail
- Targeted staff in-service training sessions
- Floor Presence

Comprehensive POCT Policy

- POCT program requirements and expectations included in hospital policy
- Policy explicitly states that any POCT comes through Dept. of Pathology
  - No direct vendor contact
  - Test can't be implemented without approval
- Policy includes provision for removal of testing if requirements are not met
- Policy states that physicians performing POCT (PPM not included) must undergo same testing & meet same competency criteria as anyone else doing POCT

Joint Ownership of Program

- Important for nursing/pharmacy/radiology and others to have active involvement in program management
  - Self-education and inspection (QA)
  - Take responsibility for ongoing training and education
- Schedule periodic joint leadership meetings
  - Allow communication of important points to users
  - Allow input from users for improved program efficiency

Education

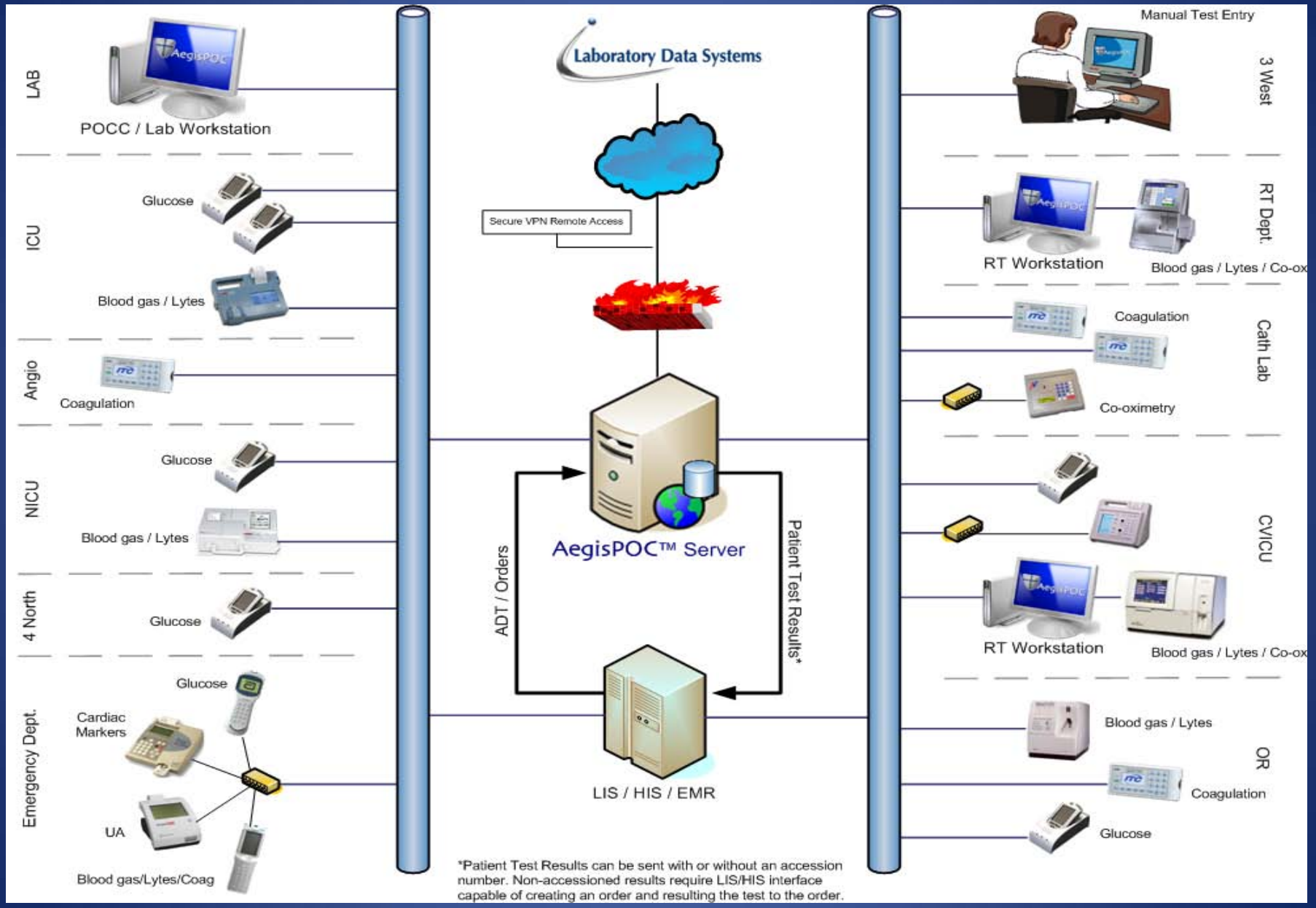
- Continuous education is important for quality of POCT program
  - Influx of new users
  - Sporadic users of technology
  - New developments in technology
- Train-the-trainer programs through nurse educators seem to be most effective
- Implementation of on-line educational programs improves access to material, & encourages increased participation
  - Also moves content control back to POCT office

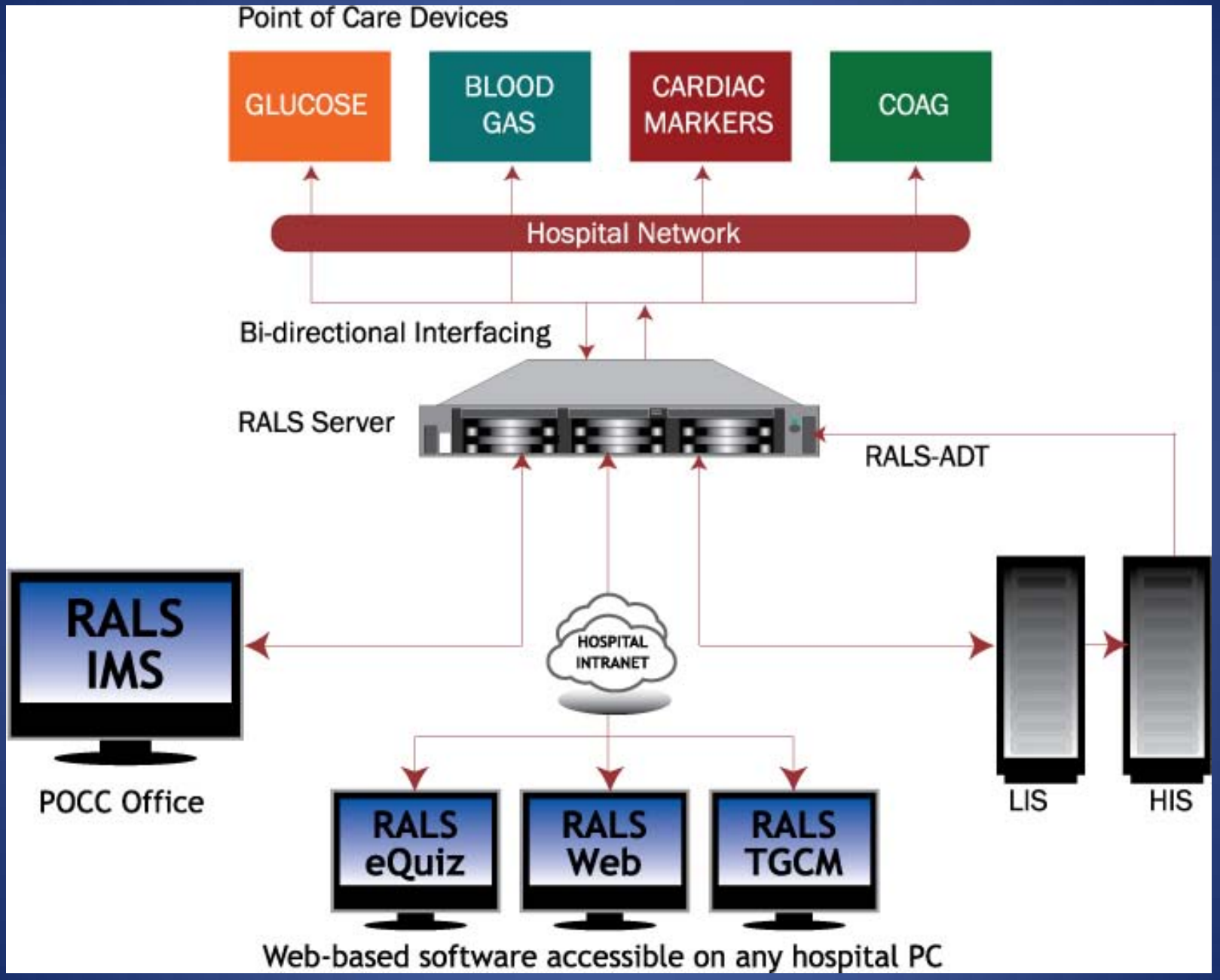
Importance of Connectivity

- As POCT applications increase & number of sites increase, connectivity become more important
  - Expectations increase, resources stay the same
- Connectivity can:
  - increase productivity and safety
  - ensure results are recorded in the EMR
  - facilitate billing for POCT
- Connectivity should not help reduce time spent on the floor with users … hopefully it will do the opposite

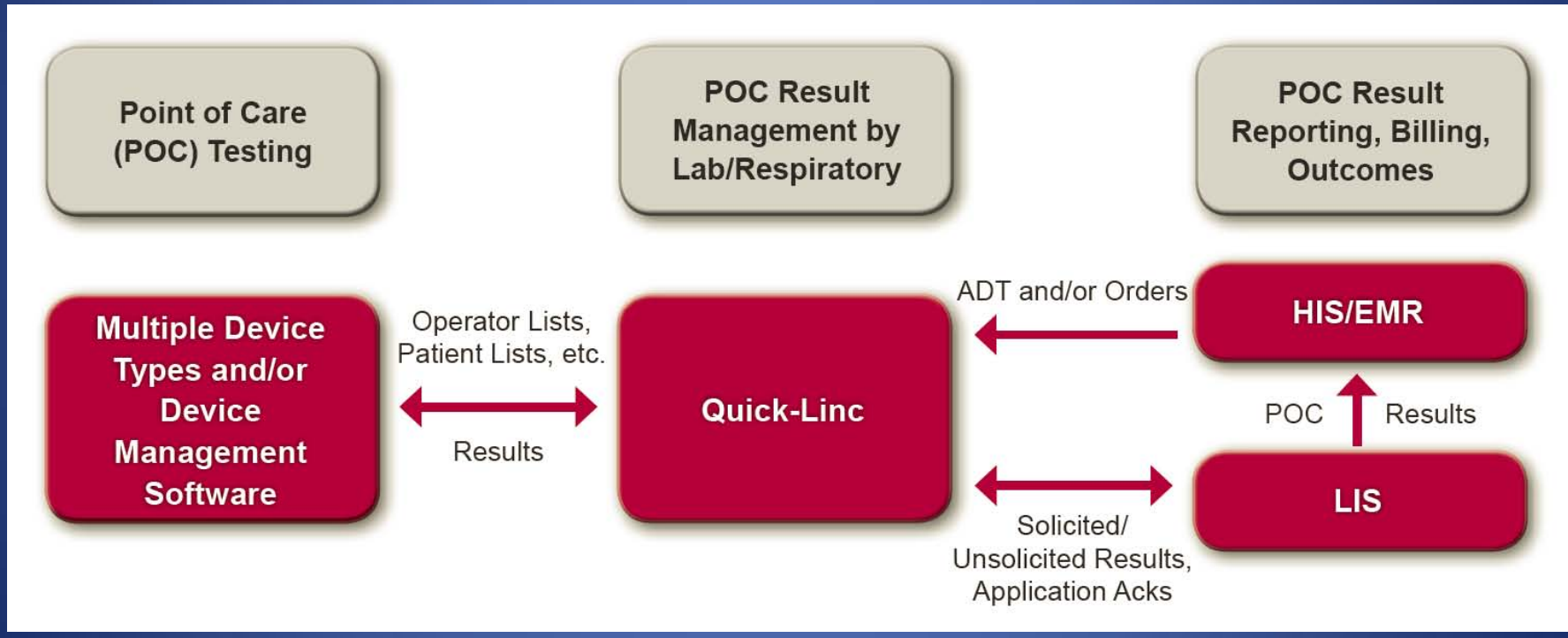
In Addition …

- Connectivity can automate QA data collection and clinical documentation
- A POCT informatics solution can automate data analysis and report generation/distribution
- Some IT solutions facilitate communication by sending messages to certain units or users through the POCT device
- Connectivity can increase quality by streamlining QC review and facilitating QC and operator lockout


Laboratory Data Systems
Secure VPN Remote Access
AegisPOC™ Server
ADT / Orders
Patient Test Results*
LIS / HIS / EMR
LAB
POCC / Lab Workstation
ICU
Glucose
Blood gas / Lytes
Angio
Coagulation
NICU
Glucose
Blood gas / Lytes
4 North
Glucose
Emergency Dept.
Glucose
Cardiac Markers
UA
Blood gas/Lytes/Coag
Manual Test Entry
3 West
RT Dept.
RT Workstation
Blood gas / Lytes / Co-ox
Cath Lab
Coagulation
Co-oximetry
CVICU
RT Workstation
Blood gas / Lytes / Co-ox
OR
Blood gas / Lytes
Coagulation
Glucose
*Patient Test Results can be sent with or without an accession number. Non-accessioned results require LIS/HIS interface capable of creating an order and resulting the test to the order.


Point of Care Devices
GLUCOSE
BLOOD GAS
CARDIAC MARKERS
COAG
Hospital Network
Bi-directional Interfacing
RALS Server
RALS-ADT
RALS IMS
POCC Office
HOSPITAL INTRANET
LIS
HIS
RALS eQuiz
RALS Web
RALS TGCM
Web-based software accessible on any hospital PC

TELCOR . . . empowering your laboratory



Connectivity: Pre-Implementation

- Important question: What do you want to do?
  - What is it that you want to accomplish with connectivity?
  - Operator management? Billing? Patient safety initiatives?
- As solutions are evaluated, make sure that vendor capability matches your plans/ambitions
- Speak to others that have already implemented connectivity (variety of vendors) and ask about their experiences and how they use the system
- Speak to your own IT department to determine whether your goals are compatible with what they have in place

Ask Questions!

- About the device …
  - Is your device POCT-1A compliant? If not, when will it be?
  - Does the device have an option for wireless connectivity? If so, what is the standard (e.g. 802.11n)?
  - If downloading requires a cable, can it connect to the network through a computer via USB or must it connect directly to the network jack?
  - Does the device collect all information needed for a complete patient record? (time/date, result, QC information, operator information, patient information)
  - Does the device support a bi-directional interface?
  - For which POCT information systems do you have an interface?

Ask Questions!

- About the data manager …
  - Is the device manager POCT-1A compliant?
  - How does your system handle manual POCT data?
  - How does the system handle exception reporting and LIS transfer errors?
  - What is the process for adding a new POCT device to the data manager?
  - What hardware is required to use the data manager? How is the data backed up?
  - Does the system automatically generate and deliver reports to designated users?
  - Does the data manager have remote access capability? Is there tiered access for basic users, advanced users, and/or ‘super’ users?

Ask Questions!

- About the interfaces …
  - Does your LIS support an interface to the data manager?
  - How does the vendor determine which devices for which they'll develop an interface?
  - How big is the difference between 'we can interface to a certain device' and actually having an interface?
  - Does the interface directly control the device, or does it interface through middleware?
  - What is the cost of an interface (license vs. purchase)? Who bears the cost of interface development or additional functionality?
  - How much will it cost to add devices to the system?

Wired versus Wireless

- First question to be asked is whether wireless is ‘necessary’ or just a cool feature
- How often is the wireless data transmitted & how would the ‘real-time’ data be used?
- Network compatibility is an important consideration
- Equally important is network security and device authentication

Summary

- Most of challenges in managing POCT are not scientific or technical, but are administrative, educational, or behavioral
- It's important to take a thoughtful, reasoned approach to formulating an administrative plan for any program – or addition of a new device/test
- Connectivity – when implemented correctly – can greatly improve efficiency and communication with POCT users
  - It also offers opportunity to improve quality by increasing focus on education rather than policing and reporting

Moving Forward

- Real-time connectivity can allow dynamic patient verification with the device, reducing errors and increasing patient safety
- POCT will be integrated into the larger picture of patient care systems
  - Connectivity across information systems will allow POCT results to be considered alongside other clinical data in the EMR
- POCT support staff can be automatically notified when results are flagged and a consult may be necessary
- Automated data management and documentation will allow the POCT coordinator to focus on education, training, and patient safety

QUESTIONS??

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