Optimizing Point-of-Care Testing: Key Strategies for Ensuring High-Quality Results

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Conflict of Interest Declarations: Scarlatescu Ecaterina

Relationships with for-profit and/or non-profit organization:

Speaker’s fees

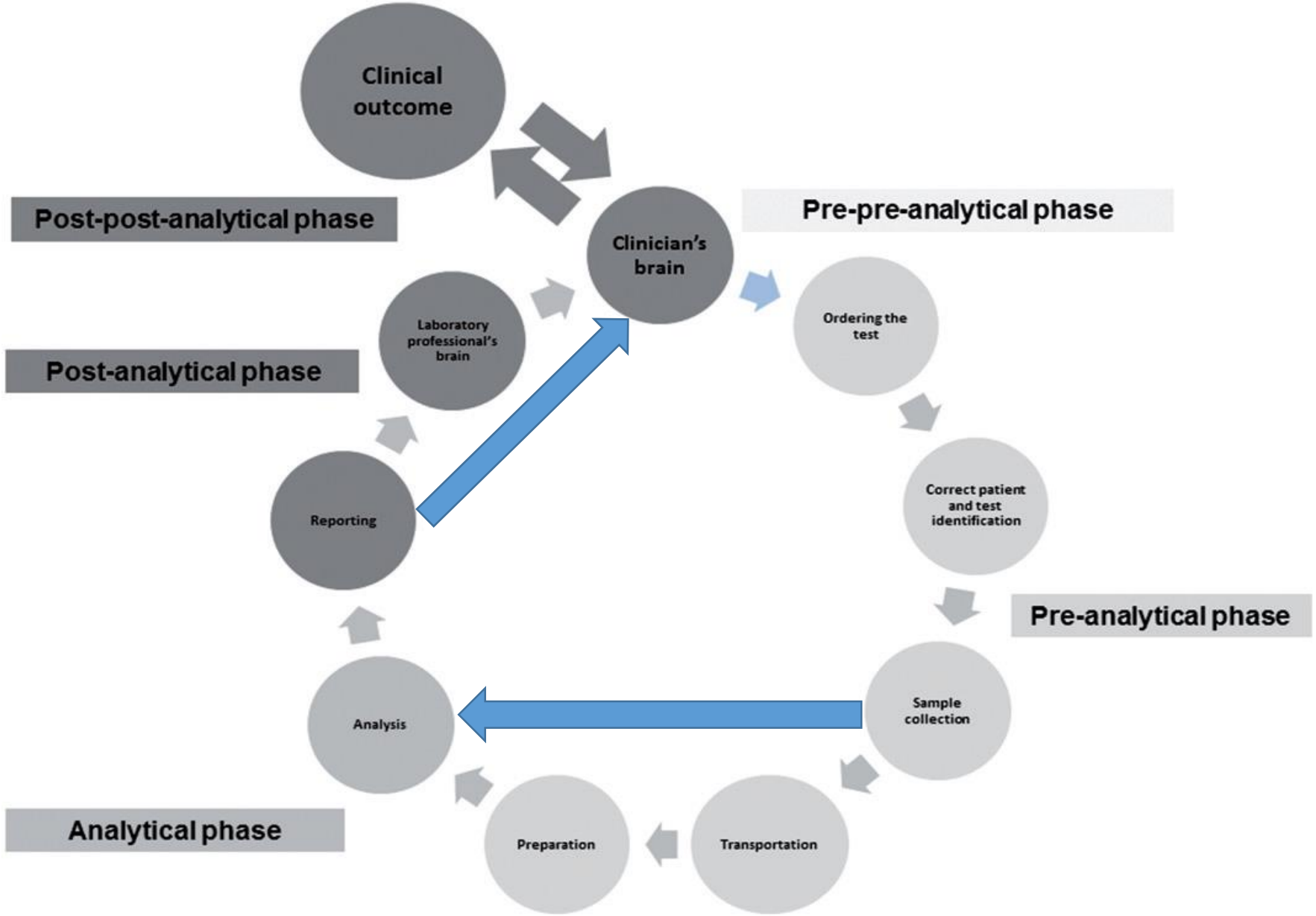
- Danube University Of Krems, Austria
- CSL Behring Germany
- EurAsia Heart Foundation Switzerland
- Werfen
- Prisum Healthcare Romania
- Vifor Pharma Romania

Point-of-Care Testing (POCT)

- Clinical laboratory testing conducted at or near the patient's bedside/site of care
- Performed by various HCP (sometimes by patients themselves)

Key Benefits of POCT:

- **Rapid TAT**: Provides quick results, enabling immediate clinical decisions
- **Improved Patient Outcomes**: Expedites clinical decisions and time-to-treatment.
- **Small Sample Volume**
- **Increased Accessibility**: remote or underserved areas, where central labs are distant
- **Cost-Effectiveness**



Florowski et al, Critical reviews in clinical laboratory sciences, 2017

POCT in my clinical practice

- BGA
- Pathfast analyzer
- ROTEM Delta, Sigma

Decentralized POCT management

What Can Go Wrong With POCT?

Real-life Case 1 in a busy mixed ICU

- L.D., 55 years old, male, known with COPD and IHD was admitted to the ICU for shortness of breath and chest pain
- Urgent blood gas analysis via POCT requested
- Manual specimen labeling procedures (no MRN requested)
- His results were switched erroneously with those of another patient - a young woman just brought from the OR

What Can Go Wrong With POCT?

Clinical Confusion

- The clinical team viewed the young woman's abnormal ABG parameters and focused on her- detailed clinical exam, supplemental tests ordered, oxygen therapy

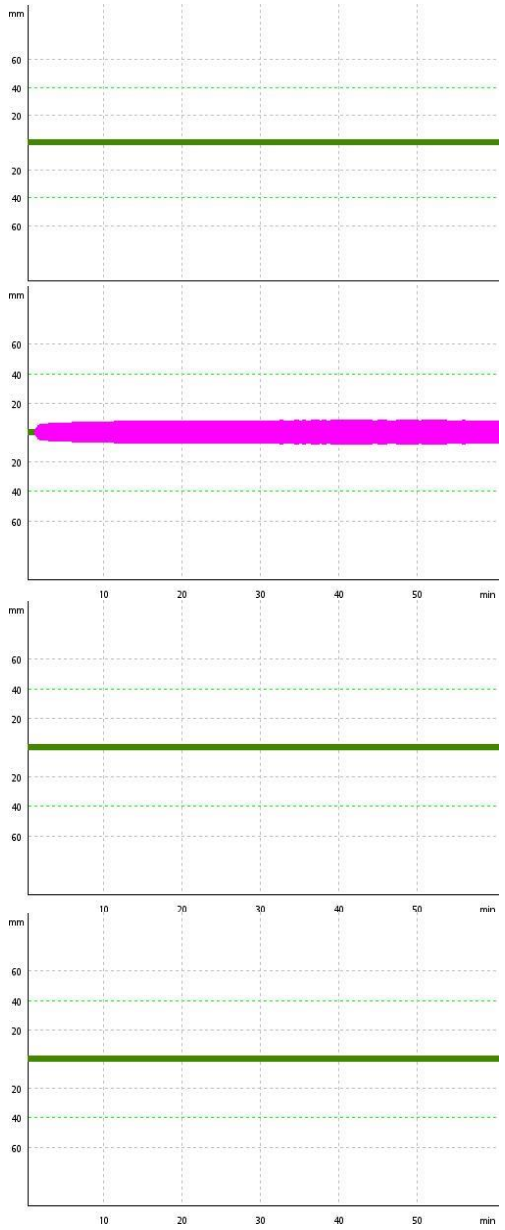
- Simultaneously, the COPD patient, critically in need of rapid intervention, did not receive prompt treatment leading to delayed diagnosis and management

- In the end, confusion was solved, ABG repeated, correct therapy applied to both patients
- Confusion led to waste of time, resources and delayed treatment for the sickest patient

What Can Go Wrong With POCT?

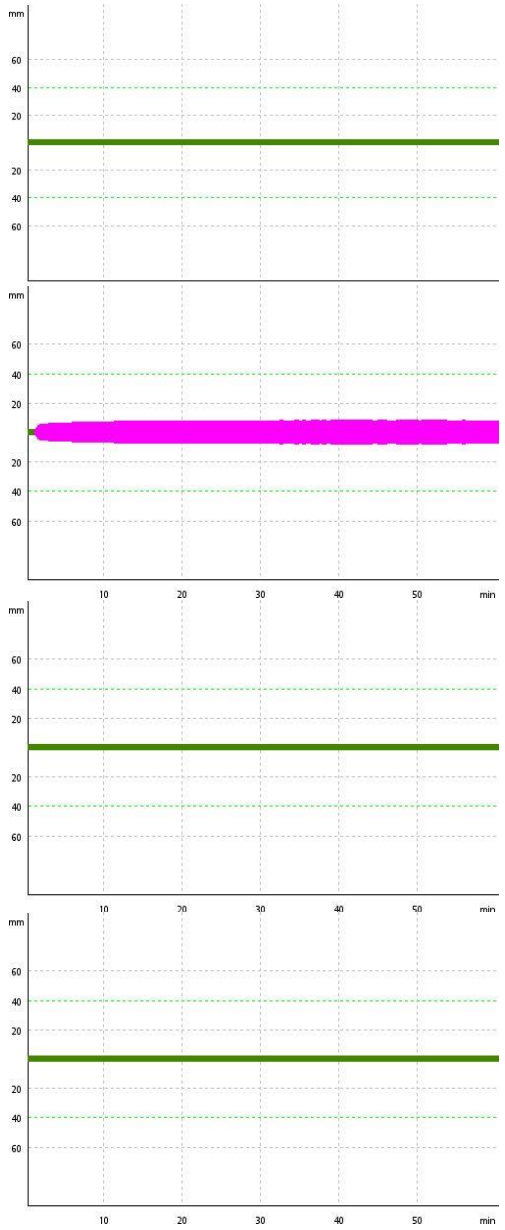
Real-life Case 2 in a busy mixed ICU

- C.F., 49 years old, female
- Known with cirrhosis due to HVC infection
- Admitted to ICU with SBP
- Mucosal bleeding, paracenthesis needed
- ROTEM analysis ordered



What Can Go Wrong With POCT?

Real-life Case 2 in a busy mixed ICU



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Why Optimize POCT?

- POCT results- immediately available to clinicians for action, with no prior review by a laboratory technologist, as would be the case with central laboratory reported results.
- POCT enables immediate action in acute cases, but result quality depends on robust strategies for accuracy, consistency, and compliance
- Error risks unique to decentralized settings- especially pre-analytic and operator issues.
- The HCP performing the POCT - minimal training in laboratory testing
- In busy settings HCP are constantly distracted by other tasks like drug administration, patient monitoring, data recording

Chokkalla et al, eJIFCC 2023
Julie Shaw, eJIFCC 2021

Most common errors with POCT

1. **Pre-analytical Errors** -the most frequent source of POCT inaccuracies (~70%)

(often go undetected by traditional QC methods)

- **Improper Patient and Specimen Identification**

- not using two patient identifiers in 45% of POCT in one study, compared to only 0.02% in central laboratory testing (Cantero et al, 2015)

- From an audit in 2016, Ottawa Hospital, 55 of the 306 results (ACT test)- incorrect patient identification

J. Shaw, eJIFCC 2021
J. Shaw, The Journal of Applied Laboratory Medicine 2021
Nichols et al, J Appl Lab Med. 2021
J. Shaw Practical Laboratory Medicine 2016

Most common errors with POCT

1. **Pre-analytical Errors** -the most frequent source of POCT inaccuracies (~70%)

(often go undetected by traditional quality control methods)

- **Sample Collection and Handling Issues** (iQM2 with IntraSpect)

- Micro-clots and clotting: common errors
- Microbubbles and air in sample: inaccurate results especially for BGA
- Hemolysis: visually detecting hemolysis in whole blood POCT samples is challenging
- Incorrect Specimen Type or Volume: often too low sample volume for BGA
- Interferences: POCT devices are highly susceptible to interfering substances

- **Improper Storage Conditions** (POCT reagents and devices), due to their portable nature, are often exposed to varying environmental conditions (light, humidity, temperature), which can denature enzymes or affect device

J. Shaw, eJIFCC 2021
J. Shaw, The Journal of Applied Laboratory Medicine 2021
Nichols et al, J Appl Lab Med. 2021
J. Shaw Practical Laboratory Medicine 2016

Most common errors with POCT

2. Analytical Errors –more frequent in POCT than in central lab

- **Device Malfunctions and Maintenance** (particularly in BGA)
- **Setting Wrong Units of Measurement**

3. Post-analytical errors

- **Documentation and Transcription Errors**- manual charting of POCT results is inconsistent and prone to errors
- **Electronic Results Mismatched**- even with electronic systems, there is a risk of matching test results to the incorrect patient

J. Shaw, eJIFCC 2021
J. Shaw, The Journal of Applied Laboratory Medicine 2021
Nichols et al, J Appl Lab Med. 2021
J. Shaw Practical Laboratory Medicine 2016

POCT is laboratory testing- therefore…

- anyone performing testing must understand the entire testing process from the pre-analytical phase to the post-analytical phase

- maintaining high quality is vital: poor POCT has direct consequences for patient safety and hospital credibility.

Quality Monitoring & Assurance in POCT: Turning Data Into Trust

- What actually drives POCT Quality? How to monitor it?
- Key Performance Indicators are our real-time “vital signs” for the POCT system.

….BUT…

- Quality Assurance & Regulatory Compliance- A major hurdle due to varied operators and decentralized nature
- Clinical (non-laboratory trained) staff often lack an understanding of the importance of quality control and quality assurance
- The focus of clinical staff is on taking care of the patient and quality procedures associated with POCT often add additional burden to an already hectic role

Key Performance Indicators (KPIs) for POCT Quality

The KPIs that matter most also for non-laboratory trained staff

- **Accuracy Checks:** Imagine not matching POCT result with central lab data!!! immediate alerts flag outliers before they cause harm.

- **Turnaround Time (TAT):** How fast are results delivered? A stroke patient gains precious minutes if TAT is tracked and optimised.

- **QC Compliance:** Did every device pass internal and external controls this morning? Failures mean instant “lockout”—no more risky testing

- **Operator Competency:** Only trained and up-to-date staff allowed. An expired credential? The analyzer says “no” until retraining is complete

- **Instrument Downtime:** Proactively flagged and fixed—no surprises in the middle of a code blue.

Quality Control (QC) in action- real procedures, real success

Implementation of POCT to a clinical unit impacts the workflow for staff that have to integrate processes related to POCT such as

- daily quality control testing
- instrument maintenance
- troubleshooting issues with POCT devices

Quality Control (QC) in action- real procedures, real success

Continuous vs. Intermittent QC

- Intermittent liquid QC- daily/ every 8 hours for BGA; weekly for ROTEM

- Continuous QC -iQM2 (GEM Premier 5000) real-time quality assurance, performing checks before, during, and after every sample + decreases the workload for the staff

- iQM2- includes new checks +IntraSpectTM technology, which detects errors during the sample measurement process (microclots, micro-bubbles, interferences, or any other transient errors)
- Immediate Automatic Correction: When errors are found, iQM2 initiates corrective actions instantly—either correcting, suppressing, or flagging results—and all steps are automatically documented, reducing manual intervention and regulatory burden.

- Rapid Resolution: Error detection and correction take minutes

Nichols et al, J Appl Lab Med. 2021
Venner et al, Clinical Biochemistry 2021
Westgard et al, Practical Laboratory Medicine 2022

Comprehensive Training & Competency Assessment

Implementation of POCT to a clinical unit may generate stress and discomfort for the staff in terms of

- training
- new tasks and responsabilities

Comprehensive Training & Competency Assessment

- HCP that run POCT should be competent with the safe and accurate operation of each POCT
- Diverse backgrounds of operators, usually without laboratory training + distracted by clinical tasks
- Comprehensive training to bridge knowledge gaps in laboratory practices is needed
- Single training event is not sufficient
- Ongoing competency, training, and support from the laboratory/ manufacturer are needed to maintain improved test performance

➢ **Cascade Training:** Competent staff members (superusers or trainers) can train others on wards

➢ **Superusers:** knowledgeable about QC, quality assurance, and safety regulations; they can provide immediate support and act as a liaison between medical staff and the laboratory/ manufacturer

Comprehensive Training & Competency Assessment

SHOULD INCLUDE

- Quality Control (QC) Procedures:
  - how and why QC is performed
  - how to troubleshoot QC failures
  - understand documentation requirements for QC.

- Maintenance: Direct observation of the performance of instrument maintenance and function checks is essential (Superusers to perform)

Competency Assessment- Not just a checkbox

Real-world competency assessment for the POCT use in a clinical unit has challenges:

- limited resources: staff and time (missed assessments, rushed onboarding)
- lack of staff adherence (complex, lengthy assessment and manual documentation)
- high personnel fluctuation

Competency Assessment

SHOULD INCLUDE

- Regular intervals: Competency must be reassessed after initial training and periodically thereafter, typically annually

- Triggered Retraining: updates if a competency issue is identified or if they perform testing infrequently

- Automated Re-certification: Some POCT software allows for automatic re-certification if an operator successfully performs a specified number of QC or patient tests within a defined period. Operators who do not meet these criteria are required to complete online training and an exam, and perform QC testing to regain certification

Effective Data Management and Connectivity

Appropriate data management is challenging:

Pre-testing

- With manual patient identification (time-consuming, prone to errors)

Post-testing

- In the absence of integration of POCT devices with centralized data management systems (paper charting- prone to errors)
- Even with device connectivity, the staff needs training to address connectivity issues

Effective Data Management and Connectivity

crucial for ensuring quality, reliability, and efficient patient care

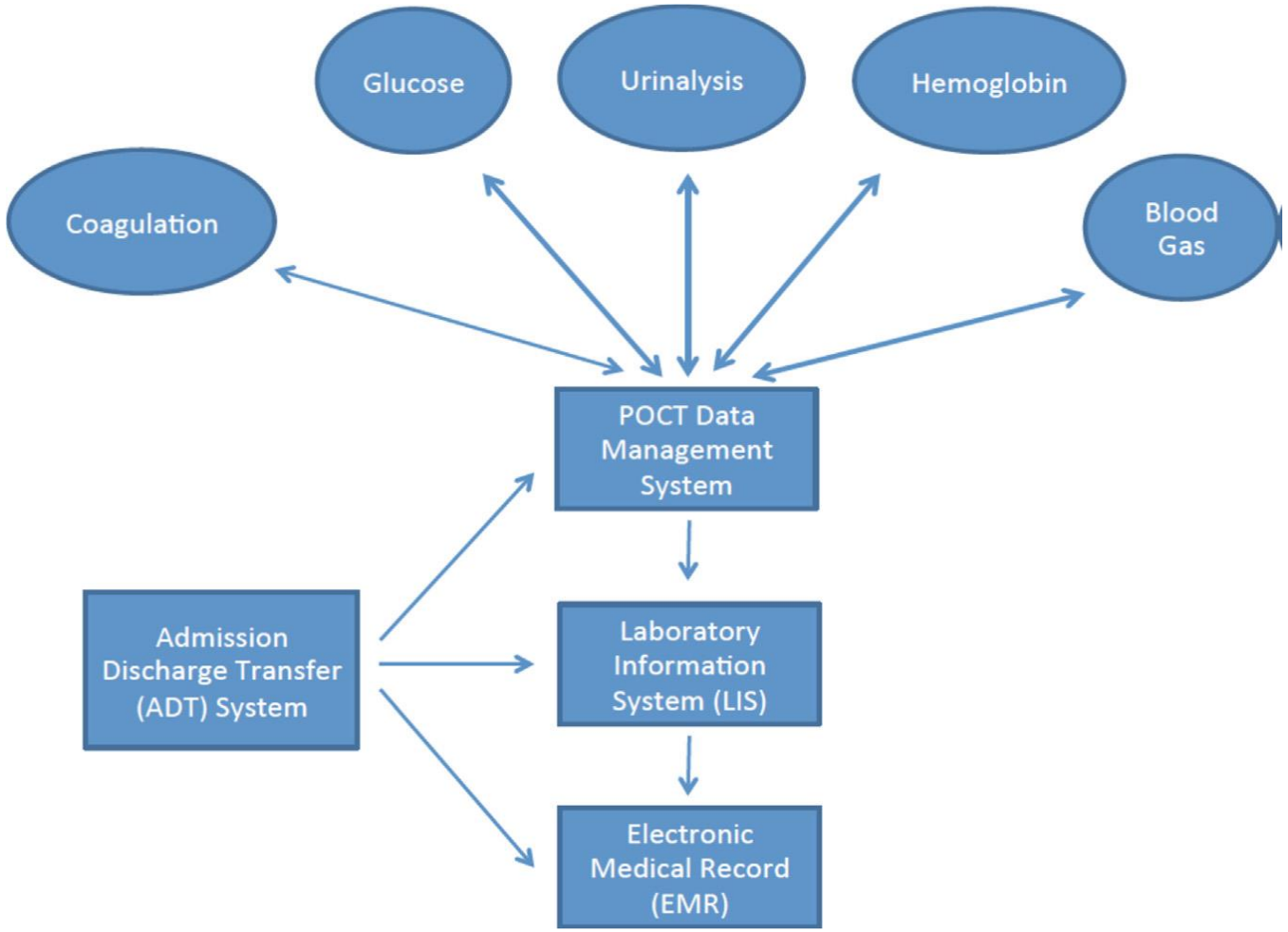
- POCT results are used to make clinical decisions
- The results should appear in the patient chart with corresponding units of measurement, reference intervals and critical values
- Lab results (including POCT) be traceable to the individual who performed the testing
- POCT results should be clearly differentiated from central lab

J.L.V.Shaw PracticalLaboratoryMedicine4 2016

Effective Data Management and Connectivity

IDEALLY

- Patient identification and integration with EMR
- Electronic charting of POCT results in the patient EMR



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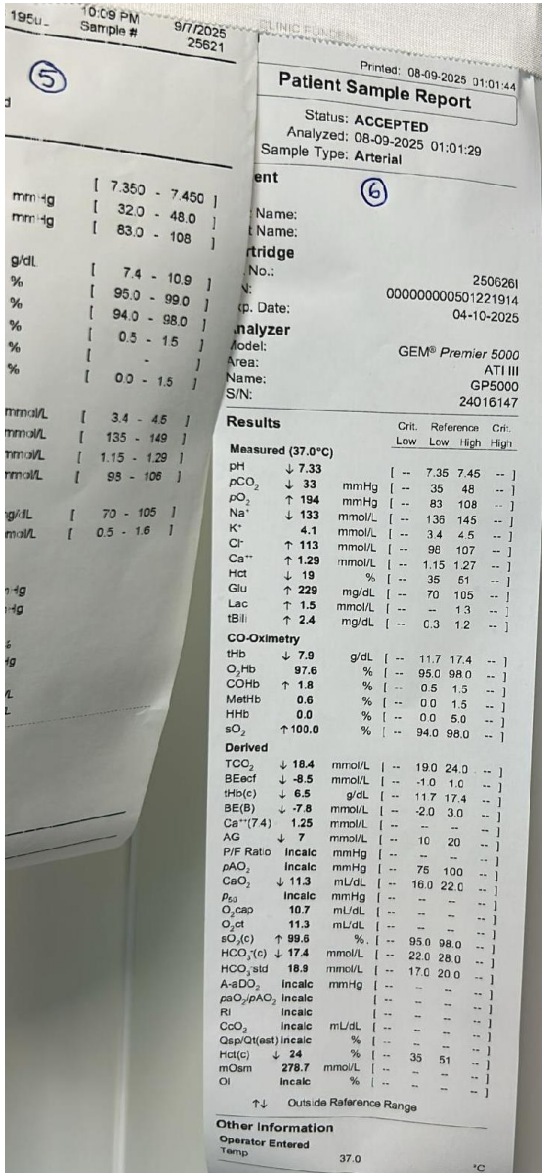
Effective Data Management and Connectivity

IDEALLY

- Patient identification and integration with EMR (barcode scanner)
- Electronic charting of POCT results in the patient EMR

REAL-WORLD

- Testing possible without mandatory patient/ sample identification
- Testing possible without operator authentification
- Paper charting still used in many hospitals- results transcribed incorrectly/ not recorded in patient's chart
- Connectivity loss, discharged battery, wireless signal interruptions-adding extra steps, can disrupt clinician routines



J.L.V.Shaw Practical Laboratory Medicine 4 2016

Effective Data Management and Connectivity

Key Data Management Features

Feature	How It Reduces Error
Operator authentication/lockout	Blocks untrained use
QC lockouts	Prevents testing outside QC intervals/ranges
Real-time data validation/alerts	Detects entry and identification errors instantly
Auto EMR/LIS integration	Eliminates manual reporting errors
Proficiency and performance surveillance	Targets retraining to high-risk operators
Inventory and expiry tracking	Stops use of wrong or expired consumables
Audit trails and electronic documentation	Allows traceability and quick error resolution

Interdisciplinary Collaboration & Oversight

Key ideas for successful communication between lab professionals and clinicians/ staff working with POCT in real life

- **"Start with Why" Approach:** Laboratory professionals should emphasize *why* proper procedures (e.g., quality control, maintenance) are critical for patient care, rather than simply enforcing compliance

- **Culture of Continuous Improvement**: Laboratory professionals can promote a culture of continual improvement rather than error-pointing

- Accurate Interpretation and Guidance: Lab professionals provide crucial context, guidance on test limitations, and explanations of result nuances, which help clinicians correctly interpret POCT data and avoid misdiagnosis

- Lab staff are essential for technical troubleshooting of POCT devices and investigating spurious results. Clear and regular communication of procedures and events can help reduce errors.

- Workflow Integration: Effective communication helps integrate POCT into clinical workflows, minimizing disruption and supporting the timely use of test results at the bedside

Interdisciplinary Collaboration & Oversight

Key ideas for establishing a multidisciplinary committee

Leadership and Membership

- Laboratory Professionals as Expert Resources (leaders)
- POCT Coordinators
- Clinical Staff (Operators)
- Can include infection control, IT staff

Conclusion and call to action

POCT in my clinical practice

- Training is provided by the supplier of each POCT device as part of the contract between the supplier and the hospital. What we need- competency assessment and reconfirmation
- We need improved data management features
- An interdisciplinary committee, ideally led by laboratory professionals is needed to provide expert advice on overall operations, oversee training and competency assessment, ensure quality assurance
- The close collaboration with laboratory professionals ensures that clinical needs are understood and met while upholding laboratory standards

CHALLENGES
AHEAD

Thank
You