POCT in haemostasis

the laboratories perspective

Karen M.K. De Vooght, PhD. Clinical Chemist

Department of Clinical Chemistry and Haematology



University Medical Center Utrecht

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- Merger of the Academic Hospital, Wilhelmina Children's Hospital and the Medical Faculty of Utrecht University
- 9600 employees
- 3254 students
- 695 million euro budget

•	Number of beds	1.042
•	Admissions	28.888
•	Average patient stay (in days)	8.3
•	Outpatient visits	332.376
•	Outpatients' treatments	16.307
•	Emergency room visits	20.668

Source: 2006





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Academic Hospital





Medical Faculty





Wilhelmina Children's Hospital





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What is Point of Care Testing?



- Bedside testing
- Near patient testing
- Physician's office testing
- Extra-laboratory testing
- Decentralized testing
- Offsite, ancillary and alternative site testing



What is Point of Care Testing?



EXAMPLES OF POC TESTS

- Blood gases: pH, pCO₂ pO₂
- Na, K, Ca, Cl-
- Lactate
- Glucose
- HbA1c
- Urea, creatinine
- Cholesterol, TGs
- BNP
- Troponin, CK-MB, myoglobin

- bilirubin
- PTH
- Paracetamol, salicylate
- Drugs of abuse
- Occult blood (faecal or gastric)
- Urinalysis: blood, albumin, hCG, ketones, glucose, leucocytes, pH, nitrite,
- CRP, Infections
- Coagulation, TEG
- Haemoglobin/haematocrit

Why Point of Care Testing?



Advantages of POCT:

- Reduced turn-around-time (TAT)
- Small sample volume
- Improved patient management
- Reduction in the administrative work



- Minimization of delays occurring during sample collection and sample requirement
- Reduction in the time delay resulting from the transport of the sample to the testing lab
- Reduction in the time delay resulting from having to log in (register) the sample
- Reduction in the time delay that results from the entry of a sample into a complex testing facility

Why Point of Care Testing?



Disadvantages of POCT:

- Massive training and education of nurses/doctors/patients needed
- Less control on the pre-analytical phase of testing
- Connectivity to LIS/HIS not always possible
- Analytical performance not always comparable to that of central laboratory analysers
- No primary check on results by central laboratory possible
- Often more expensive than the laboratory on a cost-per-test basis

When point of care testing?



POCT can only be useful when:

- the central laboratory cannot fulfill urgent clinical needs due to constraints in the organization's infrastructure
- dealing with situations outside a hospital setting where no central laboratory is available
- results are urgently needed to improve patient outcome
- POCT devices generate results that are comparable to those of the central laboratory

The clinical need is based on the question whether POCT speeds up decision making and results in better counseling, fewer visits to the hospital, better therapy, and in general affects patient outcome in a positive way.

Where point of care testing?



Most common sites:

- Patient's routine living environment (e.g. self-monitoring of glucose or PT-INR)
- Intensive care unit (e.g. blood gas and electrolyt measurements)

Other sites:

Ward, operating room, emergency room, admissions unit, mobile hospital, ambulance/helicopter, outpatient clinic (physician's office), pharmacy, and diagnostic and treatment center

POCT in UMC Utrecht

- Blood gases, Na⁺, K⁺, Ca²⁺, Hb, Ht, glucose, lactate Pediatric ICU, Neonatal ICU, OR, ER, CPB, cath lab, lungfunction dep
- Glucose
 All departments
- Activated clotting time (ACT)
 CPB
- PT-INR Heart/lung department
- Thromboelastography (TEG)
 OR







Assessing the need for a point-of-care testing service

- Which tests are required?
- What is the TAT required?
- What clinical question is being asked when requisiing this test?
- What clinical decision is likely to be made upon receipt of the result?
- What action is likely to be made upon receipt of the result?
- What outcome should be expected from the action taken?
- Why isn't the laboratory able to deliver the required service?
- Will POCT provide the required accuracy and precision of the result?
- Is there staff available to perform the test?
- Are there adequat facilities to perform the test and store the equipment and reagents?
- Will you abide by the organizations POCT policy?
- Are there operational benefits to this POCT strategy
- Are there economic benefits to this POCT strategy?
- Will a change in practice be required to deliver these benefits?
- Is it feasable to deliver the changes in practice that might be required?



Essential for good point of care testing:

- Approval Medical Staff
- Laboratories responsibility
- Well-trained and well-organized Point of Care team (Point of Care coordinator, Point of Care technicians, Clinical Chemist)
- Connectivity to LIS/HIS
- Good and reliable equipment
- Quality control program
- Tracibility of patient data (incl. operator and patient identification)



Point of Care team is responsible for:

- Full laboratory-based technical validation of analysers
- Training of nurses and doctors
- Certification of training or competence and posttraining surveillance
- Update sessions and continuing education
- Quality Control Program
- Consumables
- Standard Operating Procedures for POCT



Characteristics/Requirements of a POC analyser

- First results in a minute or less
- Portable instruments with consumable reagent cartridges
- A one- or two-step operating protocol
- The capability of performing direct specimen analysis on whole blood and urine
- Simple operating procedures that don't require a laboratory trained operator
- Flexible test menus
- Quantitative results with accuracy and precision comparable with those of the central laboratory
- Built-in/integrated calibration and quality control
- Ambient temperature storage for reagents
- *Results provided as hard copy, stored, and available for transmission*
- Low instrument cost
- Service by exchange
- Built-in regulatory record keeping

Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Edited by Burtis CA, Ashwood ER and Bruns DE. Fourth Edition.

Elsevier Saunders, St. Louis (USA)2006



Quality control program:

- Internal quality control system (electronical and liquid controls)
- Accredited external quality assessment program (problem's in case of whole blood analysis)

POCT in haemostasis: What?



- PT
- INR
- APTT
- thrombin time
- activated clotting time
- tests to monitor low molecular weight heparin
- plateled factor 4 heparin antibodies
- thrombelastography/thrombelastometry
- D-dimer testing



• Semi-automated and fully automated self-contained systems

Detection: Mechanical end-point detection or turbidimetry Handling: Pipetting of test sample and reagents into disposable cups Sample: Citrated plasma (centrifugation necessary!)





 APTT and PT testing in the in-patient setting may require evaluation and adjustment of institution-established therapeutic targets, clinical decisions points, and general workflow in the area affected by this testing.





PT-INR

- Varying thromboplastins and endpoint detection methods
- Designed to use capillary whole blood
- Designed primarily for patient use
- Data management capabilities to enhance professional use just starting to be available
- Be aware of expected differences between methods and increasing divergence at higher INR values (PT-INR > 4)
- Pick an instrument that most closely aligns with your laboratory INR







- Several devices available
- Originally intended as indicator of increased fibrinolysis and DIC
- Some are claimed to be suitable for negative prediction of DVT



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 Intended purpose should be examined in detail before using for any particular clinical purpose















Activated Clotting Time

- The use of ACT testing in cardiac surgery and cardiac catheterization laboratories shows the strongest impact on improving patient outcome
- Target times used in the clinical arena's stem from historical clinician comfort rather than clear evidence
- ACT is used in a larger number of other clinical applications with some indication, but insufficient conclusive evidence, to determine optimal patient treatment
- Its is critical that trials be designed and conducted to determine optimal use of and optimal target times for use of the ACT in all clinical arena's

Zucker ML. Tha National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines for Point of Care Coagulation testing. Point of Care 2007;4:223-226



• Thrombelastography/thromboelastometry



• Platelet aggregation





Future developments









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K.M.K. De Vooght, PhD. Clinical Chemist <u>k.devooght@umcutrecht.nl</u> Tel: +31-887558748