POCT: Effizienzgewinn oder Kostenfalle?
Klinische, organisatorische und ökonomische Dimensionen der patientennahen Labordiagnostik

23. VKD/VDGH – Führungskräfte-Seminar
„Der 7. Sinn im Krankenhaus“
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Topics

- Definition and Types of POCT Devices
- Defining Options and Limits for POCT
- Optimizing the Quality Assurance of POCT
- Cost Effectivity of POCT in Hospital Environments
POCT Definition
Characteristics of POCT

1. (Quantitative) laboratory analyses near the patient (bed-side testing)
2. Being performed outside a central (core) or decentralized lab
3. No sample pretreatment, whole blood being used as sample material
4. No pipetting steps
5. Use of ready-to-use reagents (cassettes or unit-use devices)
6. Purpose-made measuring devices for single (not serial) measurements
7. Operation by non-technicians (care-givers, physicians …)
8. Rapid availability of results
9. This allows immediate therapeutic responses by the attending physician
POCT - Fields of application

ICU/Operating room

Critical-care-testing:
Blood gases, electrolytes, lactate

ER

Emergency parameter:
Blood gases, electrolytes, glucose

Ambulance

Control parameter: Glucose, HbA1c

Emergence ambulance vehicle

Critical-care-testing:
Cardiac marker, glucose

Doctor’s office

Control parameter: Glucose, HbA1c, coagulation global tests

Patient at home

Self-monitoring:
Glucose, coagulation global tests
Types of POCT Devices for Clinical Applications

Overview
These dedicated systems apply ready-to-use reagents for single determinations. Sample matrix is unprocessed whole blood samples.

One characteristic for these devices is that the sensors are integrated in the test strips and are to be inserted in the reader instrument. Reagents and specimen react on the strip surface.

It is also characteristic for these systems that calibration is replaced by an electronic or physical standard which is measured whenever the device is turned on.
Glucometers for a hospital POCT network
Hospital and home-care POCT devices
Types of POCT Devices II - Benchtop Instruments

These are more complex analyzers being placed primarily in the functional areas of an ICU or in the ER. They use various analytical principles.

- **Blood gas analyzers:**
  - Biosensor techniques

- **Clinical chemistry analyzers:**
  - Small versions of devices known from the core lab

- **Hematological analyzers:**
  - Small versions of devices known from the core lab,
  - Alternative solution: “dry hematology”

- **Immunoassay analyzers:**
  - Small versions of devices known from the core lab or strip-based machines
Blood gas analyzers
Clinical chemistry analyzers

Hematology analyzers
Types of POCT Devices III – Hemostasis Analyzers

POCT-suitable methods with a high grade of complexity. In this case the control of a specialist (clinical chemist) is essential for operation

Combined analysis of plasmatic coagulation, thrombocyte function and fibrinolysis (Viscoelastic coagulation tests):

- Rotation thrombelastometry (ROTEM) (Pentapharm, Germany)
- Thrombelastography (TEG; Haemoscope, USA)
- Sonoclot (Sienco, USA)

Analysis of the platelet function (in vitro bleeding time and optical aggregometry):

- PFA-100 (Siemens, Germany)
- Whole blood aggregation (Multiplate, Dynabyte, Germany)
- Verify now (Accumetrics, USA)
ROTEM® stands for rotation thromboelastometry and is an enhancement of classical thromboelastography, a powerful technique for the assessment of blood coagulation disorders.
Types of POCT Devices IV - Continuous Monitoring

Available CGM System: Guardian RT/Medtronic MiniMed

- Self application by the patient possible
- On-line graphics of results
- Alarm signaling for extremes
- Measurements every 5 min
- Sensor electrode with tele-communication
- Two recalibrations per day
- Gestation time 72 h
Types of POCT Devices V – Nucleic Acid Testing (NAT)

These IVD products are based on an extensive portfolio of proprietary real-time PCR technologies that include:

- Closed cartridge systems (unit-use), automated sample preparation
- Real-time PCR instrumentation, direct heating thermal cycling
- Novel real-time PCR chemistries, freeze-dried PCR reagents (unit-use)

Isothermal amplification protocols are under development

- Recombinase-Polymerase Amplification (RPA) - isothermal DNA/RNA amplification (TwistDx, Alere)
- Helicase-dependent isothermal DNA amplification (Biohelix)
Defining Options and
Limits for POCT
in the Hospital Environment
The popularity of POCT keeps increasing and is based on the assumption that test results available in a very short timeframe assist caregivers with immediate diagnosis and/or clinical intervention to benefit patient outcomes.

The hospital POCT coordinator trying to implement POCT in the clinical services has first to ask two questions:

- Is POCT analytically reliable?
- Is POCT clinically valuable?

If the two answers are „yes“ then ask for the quality assurance of POCT.
## Central issues before and during the performance of point-of-care testing

<table>
<thead>
<tr>
<th>Medical result</th>
<th>Procedure</th>
<th>Quality</th>
<th>Financing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic advantage?</td>
<td>Where, how and who?</td>
<td>Technical test quality</td>
<td>Hospital: daily rates and DRGs</td>
</tr>
<tr>
<td>Organizational advantage?</td>
<td>IT</td>
<td>Legal requirements, e.g. RiliBÄK directive</td>
<td>Practice: Reimbursement systems</td>
</tr>
<tr>
<td></td>
<td>Hygiene</td>
<td>Pre- and post-analytics</td>
<td>Germany: EBM/GOÄ</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Accreditation</td>
<td></td>
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</tbody>
</table>

Assessment of Analytical Reliability
Quality Error Rates in Point-of-Care Testing

Maurice J. O’Kane, Paul McManus, Noel McGowan, and P.L. Mark Lynch

BACKGROUND: Although a theoretical consideration suggests that point-of-care testing (POCT) might be uniquely vulnerable to error, little information is available on the quality error rate associated with POCT. Such information would help inform risk/benefit analyses when one considers the introduction of POCT.

METHODS: This study included 1 nonacute and 2 acute hospital sites. The 2 acute sites each had a 24-h central laboratory service. POCT was used for a range of tests, including blood gas/electrolytes, urine pregnancy testing, hemoglobin A1c (Hb A1c), blood glucose, blood ketones, screening for drugs of abuse, and urine dipstick testing. An established Quality Query reporting system was in place to log and investigate all quality errors associated with POCT. We reviewed reports logged over a 14-month period.

RESULTS: Over the reporting period, 225 Quality Query reports were logged against a total of 407 704 POCT tests. Almost two-thirds of reports were logged by clinical users, and the remainder by laboratory staff. The quality error rate ranged from 0% for blood ketone testing to 0.65% for Hb A1c testing. Two-thirds of quality errors occurred in the analytical phase of the testing process. These errors were all assessed as having no or minimal adverse impact on patient outcomes; however, the potential adverse impact was graded higher.

CONCLUSIONS: The quality error rate for POCT is variable and may be considerably higher than that reported previously for central laboratory testing.
Defects (%) of all performed tests are defined by a Quality Query Report system.

### Table 1. Breakdown of POCT quality errors by test type.

<table>
<thead>
<tr>
<th>Test type</th>
<th>Number of tests</th>
<th>Number of defects</th>
<th>Defect, % of total tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood gas/electrolytes</td>
<td>22,687</td>
<td>119</td>
<td>0.52</td>
</tr>
<tr>
<td>Blood gas/electrolytes/troponin</td>
<td>5,809</td>
<td>10</td>
<td>0.17</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>8,879</td>
<td>14</td>
<td>0.158</td>
</tr>
<tr>
<td>Glucose</td>
<td>303,389</td>
<td>71</td>
<td>0.02</td>
</tr>
<tr>
<td>Drugs of abuse</td>
<td>247</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Hb A₁c</td>
<td>1,236</td>
<td>8</td>
<td>0.65</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>64,370</td>
<td>2</td>
<td>0.003</td>
</tr>
<tr>
<td>Blood ketones</td>
<td>1,087</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

\[a\] Roche Omni S, Roche Diagnostics.
\[b\] i-STAT, Abbott Point of Care Inc.
\[c\] Clearview HCG, Inverness Medical Innovations Inc.
\[d\] Performa, Inform II and Advantage meters, Roche Diagnostics.
\[e\] Nal von Minden-Drug screen.
\[f\] DCA 2000, Siemens Healthcare Diagnostics.
\[g\] Siemens-Multistix, Siemens Healthcare Diagnostics.
\[h\] Abbott Medisense, Abbott Laboratories.

### Table 3. Breakdown of POCT quality errors by phase in the analytical process.

<table>
<thead>
<tr>
<th>Phase</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preanalytical</td>
<td>72</td>
<td>32</td>
</tr>
<tr>
<td>Analytical</td>
<td>147</td>
<td>65.3</td>
</tr>
<tr>
<td>Postanalytical</td>
<td>6</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Tested analyzers were Afinion, DCA Vantage, In2It, InnovaStar, Nycocard, Clover, A1CNow, Quo-Test

**CONCLUSIONS:** Only the Afinion and the DCA Vantage met the acceptance criteria of having a total CV 3% in the clinically relevant range. The EP-9 results and the calculations of the NGSP* certification showed significant differences in analytical performance between different reagent lot numbers for all Hb A$_{1c}$ POC instruments.

* NGSP = National Glycohemoglobin Standardization Program
Assessment of Clinical Significance
A prospective randomized controlled trial of point-of-care testing on the coronary care unit

PO Collinson, C John, S Lynch, A Rao, R Canepa-Anson, E Carson and D Cramp

Background: We report the results of a prospective randomized controlled trial comparing point-of-care testing (POCT) with central laboratory testing (CLT) in a six-bed coronary care unit in a district general hospital.

Methods: 263 consecutive admissions with chest pain and suspected acute coronary syndrome were randomized to measurement of cardiac troponin T by POCT or CLT only. Patient management was according to a pre-specified protocol utilizing clinical features, electrocardiographic changes and cardiac biomarkers (creatine kinase and cardiac troponin T) to define management. Outcome measures were diagnostic accuracy compared with CLT as 'gold standard', result turnaround time, mortality and length of stay in all patients and those with a protocol-driven early discharge policy.

Results: Diagnostic accuracy and mortality was equivalent in the POCT and CLT arm. Overall there was no difference in length of stay. In the pre-specified early discharge group (n = 64) there was a significant reduction in median length of non-coronary care unit stay (145.3 h versus 79.5 h) and overall hospital stay (209.3 h versus 149.9 h) in those randomized to POCT.

Conclusion: A combination of rapid biochemical diagnosis and structured decisionmaking reduces length of hospital stay.
Point-of-Care Testing for Hb A$_{1c}$ in the Management of Diabetes:  
A Systematic Review and Metaanalysis

Lubna Al-Ansary, Andrew Farmer, Jennifer Hirst, Nia Roberts, Paul Glasziou, Rafael Perera, and Christopher P. Price

BACKGROUND: The measurement of hemoglobin A$_{1c}$ (Hb A$_{1c}$) is employed in monitoring of patients with diabetes. Use of point-of-care testing (POCT) for Hb A$_{1c}$ results at the time of the patient consultation potentially provides an opportunity for greater interaction between patient and caregiver, and more effective care.

OBJECTIVE: To perform a systematic review of current trials to determine whether POCT for Hb A$_{1c}$ compared with conventional laboratory testing, improves outcomes for patients with diabetes.

METHODS: Searches were undertaken on 4 electronic databases and bibliographies from, and hand searches of, relevant journal papers. Only randomized controlled trials were included. The primary outcome measures were change in Hb A$_{1c}$ and treatment intensification. Metaanalyses were performed on the data obtained.

RESULTS: Seven trials were found. There was a nonsignificant reduction of 0.09% (95% CI −0.21 to 0.02) in the Hb A$_{1c}$ in the POCT compared to the standard group. Although data were collected on the change in proportion of patients reaching a target Hb A$_{1c}$ of <7.0%, treatment intensification and heterogeneity in the populations studied and how measures were reported precluded pooling of data and metaanalysis. Positive patient satisfaction was also reported in the studies, as well as limited assessments of costs.

CONCLUSIONS: There is an absence of evidence in clinical trial data to date for the effectiveness of POCT for Hb A$_{1c}$ in the management of diabetes. In future studies attention to trial design is needed to ensure appropriate selection and stratification of patients, collection of outcome measures, and action taken upon Hb A$_{1c}$ results when produced.
**Bleeding and Transfusion Requirements**
*(when using TEG or ROTEM)*

<table>
<thead>
<tr>
<th>Blood component</th>
<th>TEG</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBCs (mL)</td>
<td>354 ± 487</td>
<td>475 ± 593</td>
<td>0.12</td>
</tr>
<tr>
<td>FFP (mL)</td>
<td>36 ± 142</td>
<td>217 ± 463</td>
<td>&lt;0.04</td>
</tr>
<tr>
<td>PLT concentrates (mL)</td>
<td>34 ± 94</td>
<td>83 ± 160</td>
<td>0.16</td>
</tr>
<tr>
<td>RBCs (% patients)</td>
<td>22/53</td>
<td>31/52</td>
<td>0.06</td>
</tr>
<tr>
<td>FFP (% patients)</td>
<td>4/53</td>
<td>16/52</td>
<td>0.002</td>
</tr>
<tr>
<td>PLT concentrates (% patients)</td>
<td>7/53</td>
<td>15/52</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

* Modified from Shore-Lesserson et al.²

Goodnough LT, Hill CC. Use of point-of-care testing for plasma therapy. Transfusion. 2012;52:56S-64S.
Optimizing the Quality Assurance of POCT
Assuring Quality in Point-of-Care Testing

Evolution of Technologies, Informatics, and Program Management

Kent Lewandrowski, MD; Kimberly Gregory, MT(ASCP), NCA, CLS; Donna Macmillan, MBA, MT(ASCP)

• Context.—Managing the quality of point-of-care testing (POCT) is a continuing challenge. Advances in testing technologies and the development of specialized informatics for POCT have greatly improved the ability of hospitals to manage their POCT program.

Objectives.—To present the evolving role of technology improvement, informatics, and program management as the key developments to ensure the quality of POCT.

Data Sources.—This presentation is based on a review of the literature and on our experiences with POCT at the Massachusetts General Hospital (Boston).

Conclusions.—Federal and state regulations, along with accreditation standards developed by the College of American Pathologists and The Joint Commission, have established guidelines for the performance of POCT and have provided a strong incentive to improve the quality of testing. Many instruments for POCT have incorporated advanced design features to prevent analytic and operator errors. This, along with the development of connectivity standards and specialized data management software, has enabled remote review of test data and electronic flow of information to hospital information systems. However, documentation of manually performed, visually read tests remains problematic and some POCT devices do not have adequate safeguards to prevent significant errors. In the past 2 decades the structure of a successful POCT management program has been defined, emphasizing the role of POCT managers working in conjunction with a pathology-based medical director. The critical skill set of POCT managers has also been identified. The POCT manager is now recognized as a true specialist in laboratory medicine.

Comprehensive POCT Administration

- Administration of user-ID
- Administration of control samples
- Consolidation of new POCT systems
- Overview of POCT device usages
- Documentation of QC reports
- Transmission of monthly QC reports
- Transmission of patient reports
- Courtesy for handling errors/problems
- Continuous education for POCT users
- Blockade of erroneous POCT systems
The POCT coordination in a hospital can realize incremental savings for POCT by controlling the whole process chain within the decentralized device network.

Savings in the order of approx. 50,000 € per year can be achieved in a 1000-bed-hospital compared to an not administrated POCT infrastructure.

However, the POCT coordination office needs at least one full-time med-tech position, which costs approx. 50,000 € per year.
Cost Effectivity of POCT in the Hospital Environment
Cost-effectiveness analyses

Economic considerations and cost-effectiveness analyses concerning the use of hPOCT greatly depend on the individual settings.

In general, cost-effectiveness is the result of costs (expenditure on personal and material, overhead, etc.), receipts, and the possibilities of savings.

Regarding these factors, the assessment of costs and benefits of POCT has to be evaluated separately, for each of the different areas of use. Moreover, cost-effectiveness of POCT not only depends on direct costs for measuring a parameter but also on the consequences of quickly knowing the measurement results.
One example from a study, performed by Howanitz and Jones, portrays this situation:

Analytical costs per glucose test were found to be lower for central laboratory glucose testing than for POCT, which, in turn, was highly variable and dependent on volume.

It must be considered that hPOCT has a higher cost-per-test due to the manual nature of single measurements, while it offers the potential of substantial savings through enabling rapid delivery of results and reduction of facility costs.
<table>
<thead>
<tr>
<th></th>
<th>Labor</th>
<th>Zeiten, Durchschnitt [s]</th>
<th>Kosten, Durchschnitt [€]</th>
<th>POCT</th>
<th>Zeiten, Durchschnitt [sec]</th>
<th>Kosten, Durchschnitt [€]</th>
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</thead>
<tbody>
<tr>
<td>Anforderung der Analyse</td>
<td>30</td>
<td>0,182</td>
<td>Anforderung von Analyse</td>
<td>20</td>
<td>0,121</td>
<td></td>
</tr>
<tr>
<td>Erstellung einer Arbeitsplatzliste *</td>
<td>120</td>
<td>0,033</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Wegezeit zur Blutentnahme (Labor-Station)</td>
<td>60</td>
<td>0,500</td>
<td>Wegezeit zum Patienten Station-Patientenzimmer</td>
<td>30</td>
<td>0,182</td>
<td></td>
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<tr>
<td>Blutentnahme</td>
<td>60</td>
<td>0,500</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wegezeit von Blutentnahme (Station-Labor)</td>
<td>60</td>
<td>0,500</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vorbereiten der Analysengeräte *</td>
<td>360</td>
<td>0,100</td>
<td>Qual.kontrolle-Gerät (techn. Stand) **</td>
<td>120</td>
<td>0,073</td>
<td></td>
</tr>
<tr>
<td>Analytik *</td>
<td>300</td>
<td>Pers.kost. 0,083, Sachkost. 0,126</td>
<td>Blutentnahme und Messung</td>
<td>180</td>
<td>Pers.kost. 1,094, Sachkost. 0,262</td>
<td></td>
</tr>
<tr>
<td>Qual.kontrolle (täglich) *</td>
<td>30</td>
<td>Pers.kost. 0,008, Sachkost. 0,001</td>
<td>Qual.kontrolle (1x wöchentlich) **</td>
<td>180</td>
<td>Pers.kost. 0,016, Sachkost. 0,008</td>
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<tr>
<td>Qual.kontrolle (monatlich) *</td>
<td>60</td>
<td>0,001</td>
<td>Qual.kontrolle monatlich **</td>
<td>60</td>
<td>0,002</td>
<td></td>
</tr>
<tr>
<td>Techn. Validation *</td>
<td>120</td>
<td>0,033</td>
<td>Techn. Validation **</td>
<td>30</td>
<td>0,018</td>
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<td>Med. Validation *</td>
<td>20</td>
<td>0,006</td>
<td>Med. Validation **</td>
<td>20</td>
<td>0,017</td>
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<tr>
<td>Befunddruck (auf Station) *</td>
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<td>0,008</td>
<td>Befunddokumentation</td>
<td>60</td>
<td>0,365</td>
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<tr>
<td>Vorlage beim Arzt</td>
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<td>Vorlage beim Arzt</td>
<td>30</td>
<td>0,182</td>
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</tr>
<tr>
<td>Summe Personalkosten</td>
<td>1,954</td>
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<td>Summe Personalkosten</td>
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<td>1,970</td>
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<tr>
<td>Summe Sachkosten ***</td>
<td>0,127</td>
<td></td>
<td>Summe Sachkosten ***</td>
<td></td>
<td>0,270</td>
<td></td>
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<tr>
<td><strong>Summe Insgesamt</strong></td>
<td><strong>2,081</strong></td>
<td></td>
<td><strong>Summe Insgesamt</strong></td>
<td></td>
<td><strong>2,240</strong></td>
<td></td>
</tr>
</tbody>
</table>

* durchschnittliche Serienlänge: 30 Einzelproben je Lauf; ** durchschnittliche Serienlänge: 10 Einzelproben je Tag; *** ohne Reparatur-/Wartungskosten
It should, however, be considered that ...

Usually, the addition of easy to perform POCT processes to a nursing unit has no impact on the number of staff or hours worked if the number of analyses per day does not exceed the number of beds by more than 3 times. Therefore, it could be argued that it does not represent a labor cost, but rather a change in productivity.

Such arguments, however, must be seen in light of largely unchanged fixed costs in the central laboratory and of the substantial and not increasable workload of caregivers in many critical hospital sites. An expansion of an existing hPOCT service needs therefore a critical appraisal.
The usefulness of POC troponin T testing for the management of patients with chest pain in primary health care (PHC) centres is controversial. This study shows that: it may be cost saving but at the expense of missed cases of acute myocardial infarction or unstable angina.
Effizienzgewinn oder Kostenfalle?

Szenarios ohne Blutzuckerbestimmungen
Effizienzgewinn oder Kostenfalle?
Effizienzgewinn oder Kostenfalle?
Effizienzgewinn oder Kostenfalle?
Schlussfolgerungen
Es ist möglich, auch bei einer Vollkostenrechnung in einem budgetierten Krankenhaus mit durchdachten diagnostischen Konzepten im klinischen Bereich Einsparungen zu erzielen und dabei wirtschaftlich erfolgreich zu sein.

Um Wartezeiten zu verkürzen und den diagnostischen Ablauf zu beschleunigen, müssen Organisationsprozesse für eine schnelle Analyse von Patientenproben im Zentrallabor optimiert und gleichzeitig eine sinnvolle POCT-Architektur bei den Akutbehandlungsplätzen geschaffen werden.
• Bei Einführung von POCT sind neben labormedizinischen Aspekten auch die klinischen und organisatorischen Dimensionen zu beachten, die sich in jedem Krankenhaus individuell darstellen.

• Ein Übermaß an POCT trifft auf begründeten Widerstand des zusätzlich belasteten Pflegepersonals und kann zur Kostenfalle werden.
Vielen Dank für Ihre Aufmerksamkeit!
Future Trends for POCT

- Continuous monitoring of several parameters
- NAT
- Telemonitoring
- Direct-to-Consumer Testing
Acknowledgement for Financial Support:

- Fraunhofer ISI Begleitforschung
- NANODEM
- BMBF „Mobile Diagnostiksysteme (BioMST-MoD)"
Conclusions

In summary, 34 out of 43 BG systems were completely assessed, and 27 (79.4%) of these 34 systems fulfill the minimal accuracy requirements of the standard DIN EN ISO 15197:2003. Only 18 (52.9%) of 34 systems fulfilled the minimal accuracy requirements if tighter criteria of the current draft revision of ISO 15197 are considered. Because inaccurate systems bear the risk of false therapeutic decisions, regular and standardized evaluation of BG meters and test strips should be requested in order to ensure adherence to quality and accuracy standards.
Bias according to Bland and Altman. Error bars represent 95% limits of agreement (≈ 1.96 × standard deviation). For the calculation of the bias of each system, only data of 180 unpre-pared blood samples (BG conc ≥50 and <400 mg/dl) were included.

Accu-Chek® Mobile + Performa were both tested with different test strip chemistries. The test strip chemistry was either maltose depen-dent (left) or maltose independent (right).
Electrolytes in sick neonates – which sodium is the right answer?

Richard I King, Richard J Mackay, Christopher M Florkowski, Adrienne M Lynn

Difference between laboratory analyser (indirect ISE) and POCT blood-gas analyser (direct ISE) Na\(^+\) with decreasing albumin concentration. Box represents the IQR, horizontal line – median and whiskers the 10th and 90th centiles.

In hypoproteinaemic states, indirect ISE results in pseudohyponatraemia

**Objectives:** To assess the impact of point-of-care testing (POCT) for troponin I (cTnl) measurement on the time to anti-ischemic therapy (TAIT) for patients with suspected non-ST-segment elevation acute coronary syndrome (NSTE-ACS) presenting to the emergency department (ED).

**Methods:** This was an open-label, randomized, single-center trial conducted in a university-affiliated hospital. cTnl measurement of patients with suspicion of NSTE-ACS coming to the ED was randomly allocated to POCT or central hospital laboratory testing (CHLT). The authors compared patients’ baseline characteristics, time to anti-ischemic therapy, and medical outcomes between the randomized groups, in all study participants and in high-risk NSTE-ACS (cTnl level ≥ 0.10 μg/mL), and in those with low suspicion ACS (no chest pain and no ST deviation).

**Results:** Of the 860 patients enrolled, 113 were high-risk NSTE-ACS patients, including 53 (46.9%) allocated to POCT and 60 (53.1%) to CHLT. POCT was associated with decreased time to anti-ischemic therapy of about three-quarters of an hour, which was due to a shorter time to physician notification of cTnl level, in both all and subgroup participants. In contrast, neither ED length of stay nor medical outcomes differed between study groups.

**Conclusions:** Point-of-care testing for cTnl measurement might be clinically relevant for ED patients with a suspicion of NSTE-ACS, particularly for high-risk patients with a low suspicion of ACS.
Comparisons of Time Lags in min (Median + Interquartile Range [IQR]) between Patients Allocated to the POCT or to the Central Hospital Laboratory Testing (CHLT) for Cardiac Troponin

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>POCT (n = 419)</th>
<th>CHLT n = 414</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>From presentation to blood sample collection</td>
<td>75 (70–80)</td>
<td>65 (60–70)</td>
<td>0.005</td>
</tr>
<tr>
<td>From blood collection to physician notification of first cTnI</td>
<td>38 (35–42)</td>
<td>109 (104–115)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>From Presentation to AIT</td>
<td>151 (139–162)</td>
<td>198 (187–210)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length of stay at ED (min), median (IQR)</td>
<td>309 (204–411)</td>
<td>307 (229–401)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

Abbreviations:
Low-suspicion ACS referred to patients presenting no chest pain and non-ST-deviation NSTE-ACS with elevated cTnI; ED = emergency department; IQR = interquartile range; NSTE-ACS = non–ST-segment elevation acute coronary syndrome; AIT = anti-ischemic treatment.
Early and late outcome prediction of death in the emergency room setting by point-of-care and laboratory assays of cardiac troponin I

Per Venge, MD, PhD, a Claes Öhberg, MD, a Mats Flodin, BSc, b and Bertil Lindahl, MD, PhD a-c Uppsala, Sweden

Background  Point-of-care (POC) assays of cardiac troponins are common in the emergency department setting. The question raised was as follows: What is the clinical impact of the results of POC assays of cardiac troponins as compared with sensitive laboratory assays?

Conclusions  The current POC cTnl assays are less sensitive for outcome prediction of patients with myocardial injury. The clinical judgment of the patient with suspected myocardial ischemia should not solely rely on results from POC assays. If a clinical suspicion of myocardial injury remains despite negative cTnl results with the POC assays, such results should be complemented by results from sensitive laboratory assays. (Am Heart J 2010;160:835-41.)
The % of patients who died within 35 months who had levels above the 99th percentile cutoffs of the 4 cTnl assays, respectively. Significant differences between the laboratory and the 2 POC assays are seen.

Venge et al. Am Heart J 2010;160:835-41
Connection of POCT Systems to the HIS and LIS

- **Ambulance X**: Glucometer via PC
- **Ward Y**: Glucometer via LAN-Box
- **ICU Z**: Blood gas system via LAN-Box

- **HIS/LIS network**
- **Central lab**: Patient cumulative report
- **2 POCT servers**
- **QC-documentation**: Patient results
- **Patient data files**
- **HIS/LIS network**: HIS
- **HIS**
- **Hospital computer center**: Patient data files
- **LIS**: Patient results
- **Medical Engineering**: Connection of POCT Systems to the HIS and LIS
Receipts and Savings
The potential of economic and organizational improvements should always be considered, for example, by optimizing the time course of work in the central laboratory or in the outpatient clinic. This comprehensive approach was applied by Adams et al. when they calculated overall costs for different clinical pathways for testing and treatment of chlamydia and gonorrhea. They predicted the highest savings for a rapid pathway that makes use of nucleic acid amplification test POCT testing. On the other hand, payment in medical practices largely depends on services delivered, so that the individual POCT analysis is charged for accordingly.
Economic considerations are also relevant at a higher level. If screening with laboratory tests could reduce the use of expensive imaging procedures, this might lead not only to overall savings in the health system but also to a reduction in the revenue in other diagnostic disciplines as well. In a hospital setting, the fixed costs in the laboratory are often largely unchanged. For self-monitoring in the home setting, it should be taken into account that costs for medical consultations can be reduced.

Da die POCT-Kosten im Krankenhaus durch den Pflegesatz beziehungsweise die DRG-Erlöse abgegolten sind, sind sie einerseits im Zusammenhang mit einer medizinisch-fachlichen Bewertung und der Frage, welche Alternativkonzepte zur gleichwertigen Krankenversorgung realisierbar sind, zu bewerten. Andererseits muss die Möglichkeit von ökonomisch/organisatorischen Verbesserungen, zum Beispiel durch die Optimierung der zeitlichen Abläufe im Zentrallabor oder im Ambulanzbereich in Betracht gezogen werden.
MULTIPLATE - Impedance aggregometry

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Comprehensive platelet diagnostics
### List of laboratory parameters currently available using POCT

<table>
<thead>
<tr>
<th>Clinical application</th>
<th>Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid-base balance, blood gases</td>
<td>pH, pCO₂, pO₂</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>Na⁺, K⁺, Cl⁻, Ca²⁺_ion, Mg²⁺_ion</td>
</tr>
<tr>
<td>Metabolites</td>
<td>Cholesterol, HDL-cholesterol, triglycerides, creatinine, urea, uric acid,</td>
</tr>
<tr>
<td></td>
<td>bilirubin, lactate, ammonia</td>
</tr>
<tr>
<td>Enzymes</td>
<td>Amylase, alkaline phosphatase, CK, AST, ALT, γ-GT</td>
</tr>
<tr>
<td>Coagulation</td>
<td>Activated clotting-time (ACT), activated partial thrombo-plastin time (aPTT),</td>
</tr>
<tr>
<td></td>
<td>prothrombin time (PT, INR), D-dimer, platelet function tests, ex-vivo bleeding time</td>
</tr>
<tr>
<td>Hematology</td>
<td>Hemoglobin, hematocrit, erythrocytes, leukocytes, thrombo-cytes</td>
</tr>
<tr>
<td>Hemoglobin fractions</td>
<td>CO-Oximetry</td>
</tr>
<tr>
<td>Cardiac markers</td>
<td>TnT, Tnl, myoglobin, CK-MB, BNP/NT-pro-BNP</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>Glucose, HbA₁₀, microalbumin, minimal invasive continuous glucose monitoring</td>
</tr>
<tr>
<td>Acute-phase proteins</td>
<td>CRP</td>
</tr>
<tr>
<td>Allergy in-vitro diagnostics</td>
<td>Allergy specific IgE</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>Antibodies against mutated citrullinated vimentin (anti-MCV)</td>
</tr>
<tr>
<td>Therapeutic drug monitoring, drugs-of-abuse screening</td>
<td>Therapeutic drugs, alcohol, amphetamines, barbiturates, benzodiazepines,</td>
</tr>
<tr>
<td></td>
<td>cannabinoids, cocaine, methadone, opiates</td>
</tr>
<tr>
<td>Infectious agents</td>
<td>HIV, infectious mononucleosis, <em>Chlamydia trachomatis</em>, <em>Trichomonas vaginalis</em>, <em>Plasmodium falciparum and vivax</em>, Influenza A and B, <em>Steptococcus A and B</em></td>
</tr>
<tr>
<td>Fertility</td>
<td>hCG, LH and FSH, sperm count</td>
</tr>
<tr>
<td>Urine diagnostics</td>
<td>Urine strips (pH, protein, glucose, ketones, bilirubin, uro-bilinogen, nitrite, leukocytes, erythrocytes), microalbumin, NMP22 bladder carcinoma check</td>
</tr>
<tr>
<td>Stool diagnostics</td>
<td>Blood</td>
</tr>
</tbody>
</table>