POCT: Effizienzgewinn oder Kostenfalle?

Klinische, organisatorische und ökonomische Dimensionen der patientennahen Labordiagnostik

23. VKD/VDGH – Führungskräfteseminar

„Der 7. Sinn im Krankenhaus“

25. Februar 2016, Berlin

Peter B. Luppa

Institut f. Klinische Chemie u. Pathobiochemie, TU München

Topics

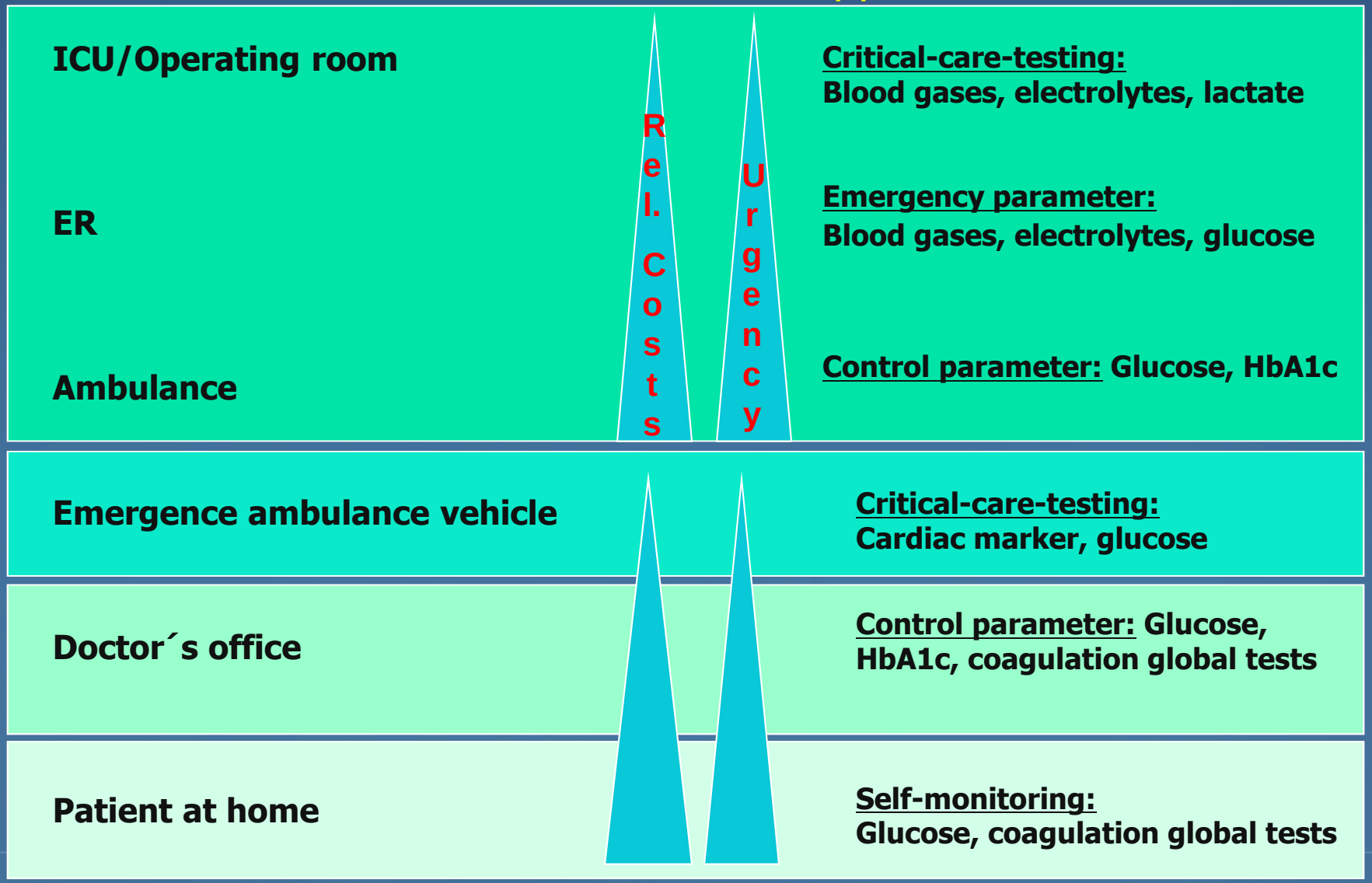
- Definition and Types of POCT Devices
- Defining Options and Limits for POCT
- Optimizing the Quality Assurance of POCT
- Cost Effectivity of POCT in Hospital Environments

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 bood 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



Types of POCT Devices for Clinical Applications

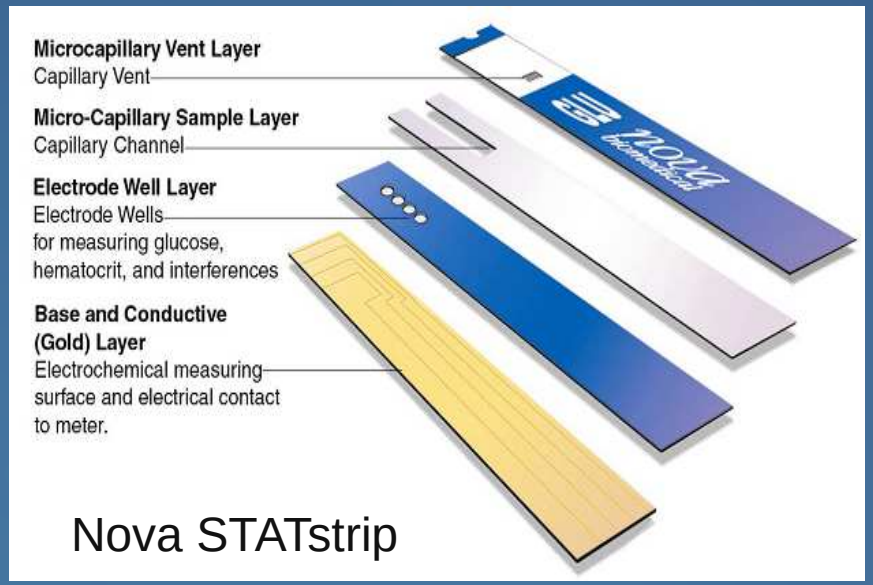
Overview

Types of POCT Devices I - Unit-use Devices

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

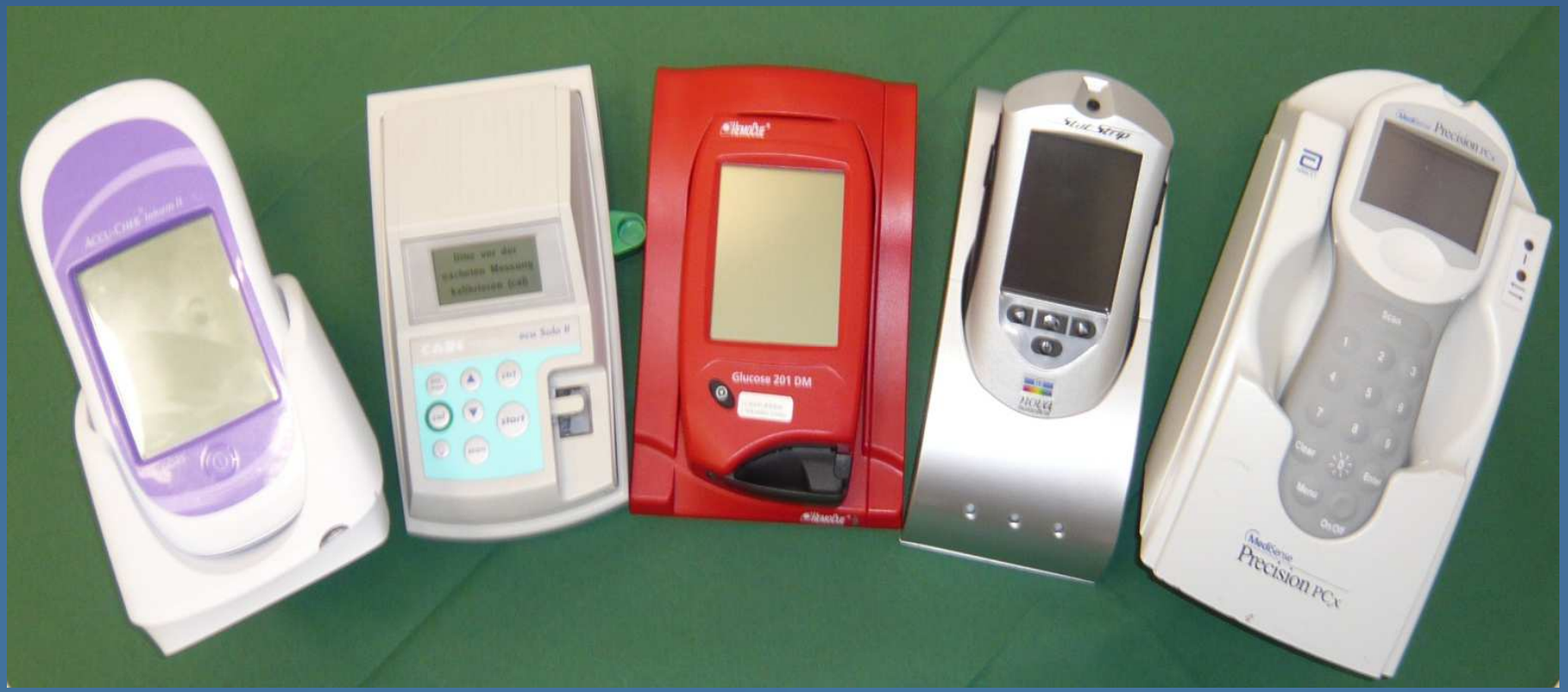
One characteristic for these devices is that the sensors are integrated in the test strips and are to be inserted in the reader instrument. Reagents and specimen react on the strip surface.

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.



Nova STATstrip

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

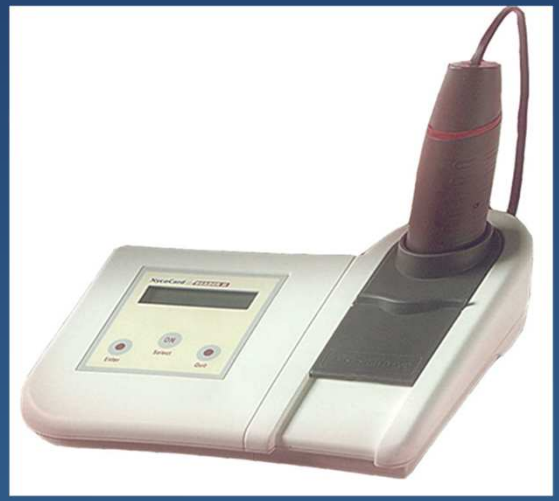
- Blood gas analyzers:
  Biosensor techniques

- 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

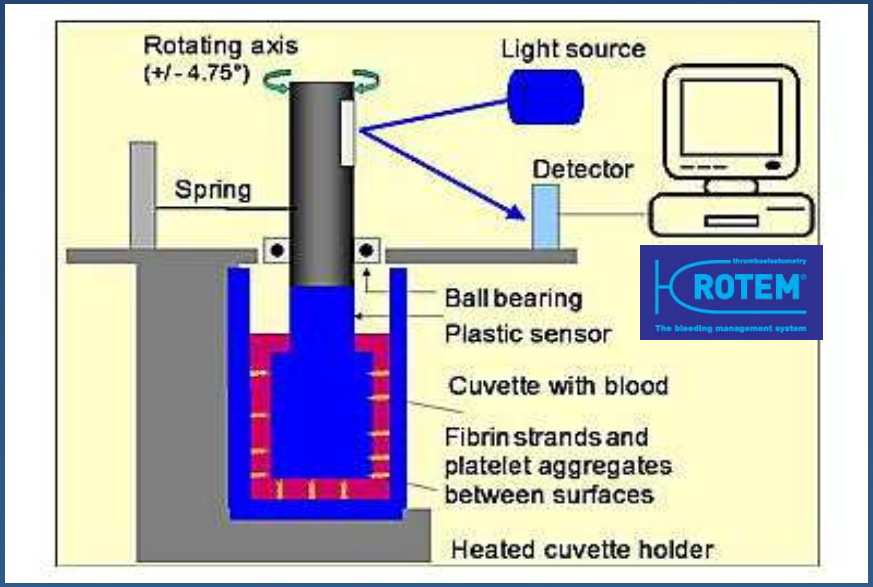
POCT-suitable methods with a high grade of complexity. In this case the control of a specialist (clinical chemist) is essential for operation

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

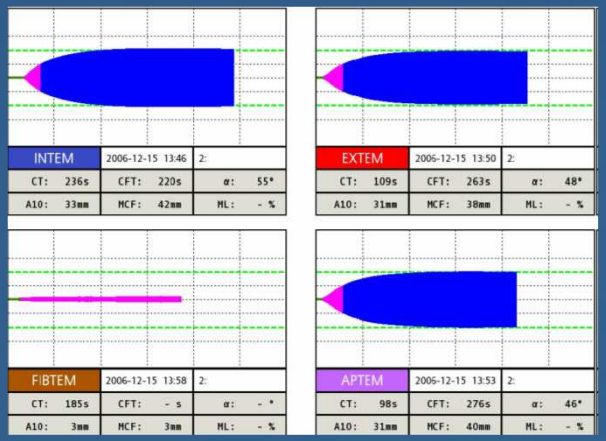
- Rotation thrombelastometry (ROTEM) (Pentapharm, Germany)
- Thrombelastography (TEG; Haemoscope, USA)
- Sonoclot (Sienco, USA)

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.

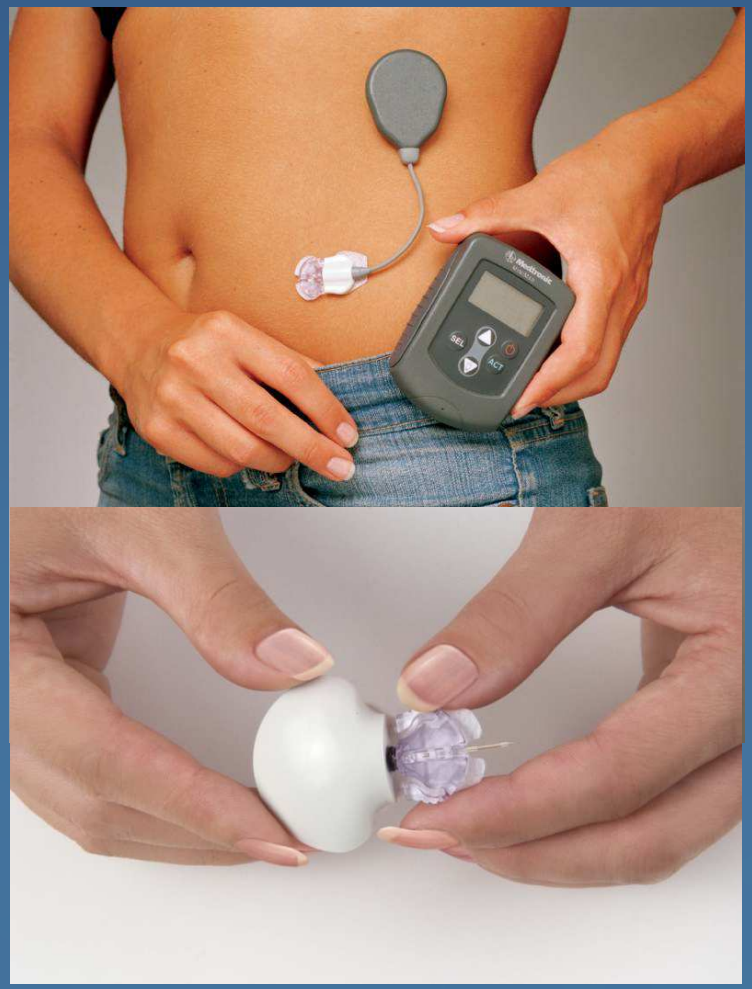


Analysis in emergency lab

Online transmission

Interpretation/action by ER/ICU doctors

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)

GeneXpert
Cepheid
Sunnyvale,
CA, USA

enigmadiagnostics
securing rapid results

Enigma ML (mini lab)
Enigma (Salisbury, UK)

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

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

Junker R, Schlebusch H, Luppa PB. Point-of-care testing in hospitals and primary care. Dtsch Arztebl Int. 2010 Aug;107(33):561-7

Assessment of Analytical Reliability

Clinical Chemistry 57:9
1267–1271 (2011)

Point-of-Care Testing

Quality Error Rates in Point-of-Care Testing

Maurice J. O'Kane,[1*] Paul McManus,[1] Noel McGowan,[1] and P.L. Mark Lynch[1]

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 A_{1c} (Hb A_{1c}), 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 A_{1c} 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.

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

Test type	Number of tests	Number of defects	Defect, % of total tests
Blood gas/electrolytes[a]	22 687	119	0.52
Blood gas/electrolytes/ troponin I[b]	5809	10	0.17
Pregnancy[c]	8879	14	0.158
Glucose[d]	303 389	71	0.02
Drugs of abuse[e]	247	1	0.4
Hb A_{1c}[f]	1236	8	0.65
Urinalysis[g]	64 370	2	0.003
Blood ketones[h]	1087	0	0

[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.

Defects (%) of all performed tests are defined by a Quality Query Report system

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

	N	%
Preanalytical	72	32
Analytical	147	65.3
Postanalytical	6	2.7

O'Kane MJ, McManus P, McGowan N, Lynch PL. Quality error rates in point-of-care testing. Clin Chem. 2011;57:1267-71.

Clinical Chemistry 56:1
44–52 (2010)

Point-of-Care Testing

Six of Eight Hemoglobin A_{1c} Point-of-Care Instruments Do Not Meet the General Accepted Analytical Performance Criteria

Erna Lenters-Westra[1,2*] and Robbert J. Slingerland[1,2]

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.

Ann Clin Biochem. 2004 Sep;41(Pt 5):397-404.

Point-of-Care Testing for Hb A_{1c} in the Management of Diabetes: A Systematic Review and Metaanalysis

Lubna Al-Ansary,[1,2*] Andrew Farmer,[2] Jennifer Hirst,[2] Nia Roberts,[3] Paul Glasziou,[4] Rafael Perera,[2] and Christopher P. Price[5]

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.

Clinical Chemistry 57:4; 568–576 (2011)

Bleeding and Transfusion Requirements* (when using TEG or ROTEM)

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

* 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.

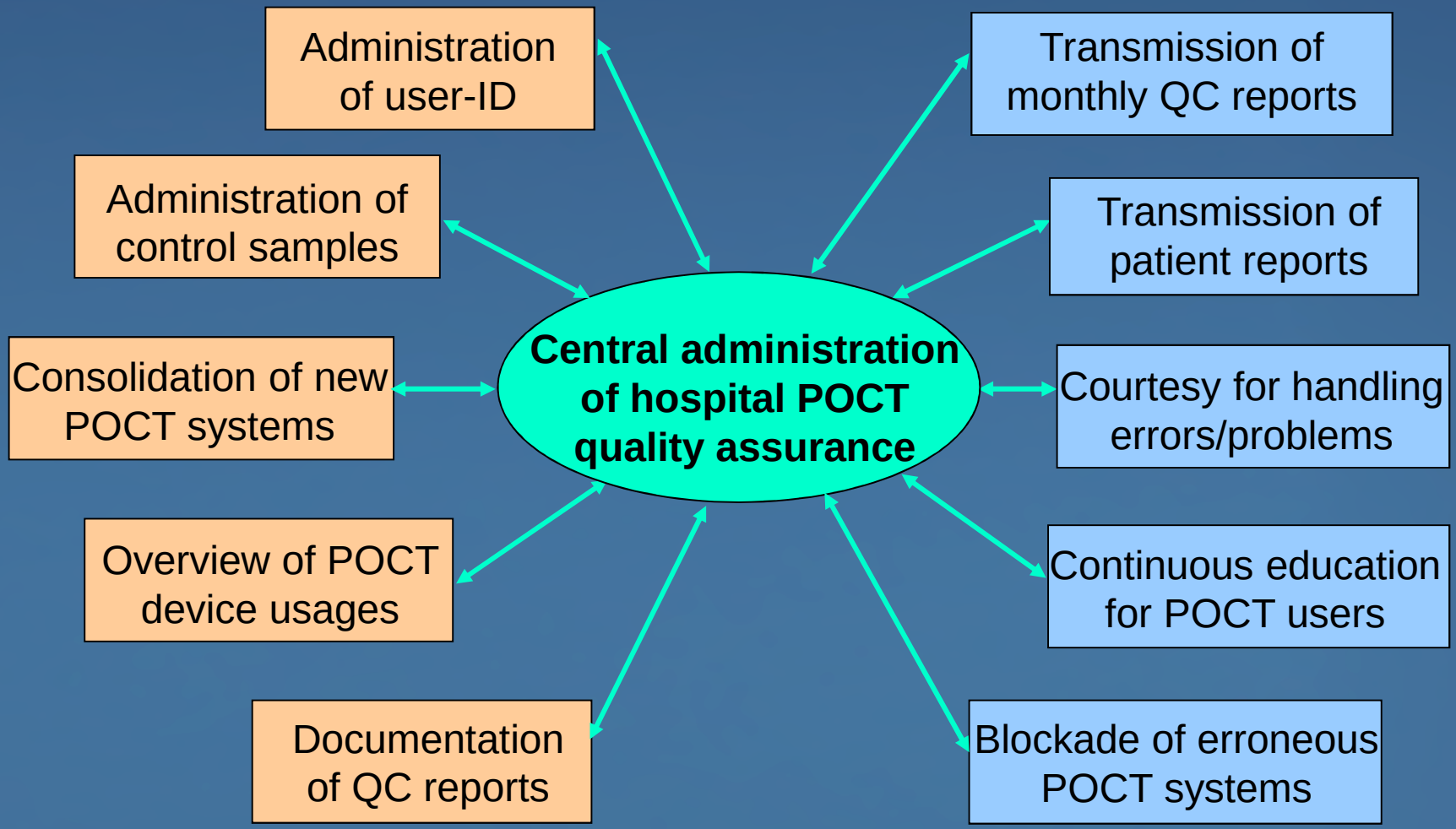
Data Sources.—This presentation is based on a review of the literature and on our experiences with POCT at the Massachusetts General Hospital (Boston).

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.

(*Arch Pathol Lab Med.* 2011;135:1405–1414; doi: 10.5858/arpa.2011-0157-RA)

Lewandrowski K, Gregory K, Macmillan D. Assuring quality in point-of-care testing: Evolution of technologies, informatics, and program management. Arch Pathol Lab Med. 2011;135:1405-14.

Comprehensive POCT Administration



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.

Kosten der Glukosebestimmung im Vergleich von POCT und Labor

Labor	**Zeiten, Durch-schnitt** [s]	**Kosten, Durch-schnitt** [€]	**POCT**	**Zeiten, Durch-schnitt** [sec]	**Kosten, Durch-schnitt** [€]
Anforderung der Analyse	30	0,182	Anforderung von Analyse	20	0,121
Erstellung einer Arbeitsplatzliste *	120	0,033			
Wegezeit zur Blutentnahme (Labor-Station)	60	0,500	Wegezeit zum Patienten Station-Patientenzimmer	30	0,182
Blutentnahme	60	0,500			
Wegezeit von Blutentnahme (Station-Labor)	60	0,500			
Vorbereiten der Analysengeräte *	360	0,100	Qual.kontrolle-Gerät (techn. Stand) **	120	0,073
Analytik *	300	Pers.kost. 0,083 Sachkost. 0,126	Blutentnahme und Messung	180	Pers.kost. 1,094 Sachkost. 0,262
Qual.kontrolle (täglich) *	30	Pers.kost. 0,008 Sachkost. 0,001	Qual.kontrolle (1x wöchentlich) **	180	Pers.kost. 0,016 Sachkost. 0,008
Qual.kontrolle (monatlich) *	60	0,001	Qual.kontrolle monatlich **	60	0,002
Techn. Validation *	120	0,033	Techn. Validation **	30	0,018
Med. Validation *	20	0,006	Med. Validation **	20	0,017
Befunddruck (auf Station) *	30	0,008	Befunddokumentation	60	0,365
Vorlage beim Arzt	---		Vorlage beim Arzt	30	0,182
Summe Personalkosten		*1,954*	*Summe Personalkosten*		*1,970*
Summe Sachkosten ***		*0,127*	*Summe Sachkosten* ***		*0,270*
Summe insgesamt		***2,081***	***Summe insgesamt***		***2,240***

* 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 un-changed 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.

Table IV. Mean cost per patient (SEK) at 2009 prices.

	PHC centres with POCT-TnT ($n = 128$)	PHC centres without POCT-TnT ($n = 68$)	Mean difference (95% confidence interval[1])
Primary care and transport:	2106	2115	−10 (−455 to 358)
PHC centre	1862	1892	
Troponin T test	172	–	
Ambulance transport	65	215	
Other means of transportation	6	9	
Hospitalization:	5744	7264	−1520 (−8650 to 4028)
Emergency department	235	442	
Coronary care unit	78	1471	
Cardiology/medical ward	4774	4528	
ICU/thoracic ICU	656	824	
Investigations:	1375	1769	−394 (−1799 to 830)
Coronary catheterization	706	997	
Echocardiogram	327	356	
Exercise test	185	223	
Computed tomography scan	47	89	
Fractional flow reserve	109	103	
Interventions:	2023	4861	−2838 (−11 174 to 3420)
PCI bare metal stent	175	329	
PCI drug-eluting stent	644	–	
Coronary artery bypass graft	1204	4532	
Total cost	11 247	16 010	−4763 (−20 046 to 7257)

The usefulness of POC troponin T testing for the management of patients with chest pain in primary health care (PHC) centres is controversial.

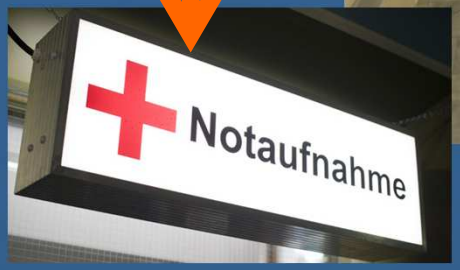
This study shows that: it may be cost saving but at the expense of missed cases of acute myocardial infarction or unstable angina.

Staffan Nilsson, Agneta Andersson, Magnus Janzon, Jan-Erik Karlsson & Lars-Åke Levin (2014) Cost consequences of point-of-care troponin T testing in a Swedish primary health care setting, Scandinavian Journal of Primary Health Care, 32:4, 241-247

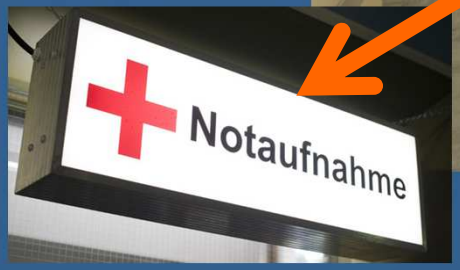
Effizienzgewinn oder Kostenfalle?

Szenarios ohne Blutzuckerbestimmungen

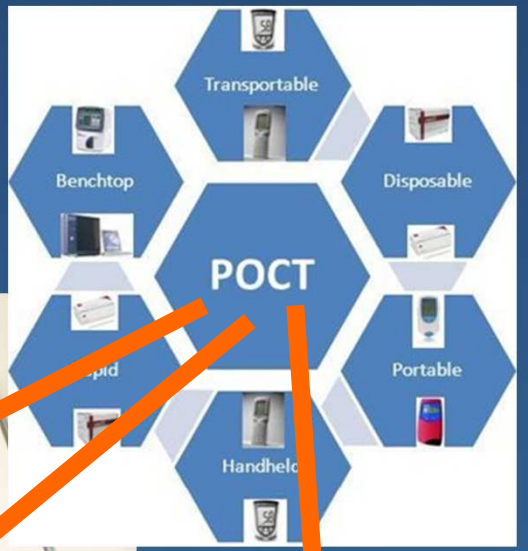
Effizienzgewinn oder Kostenfalle?

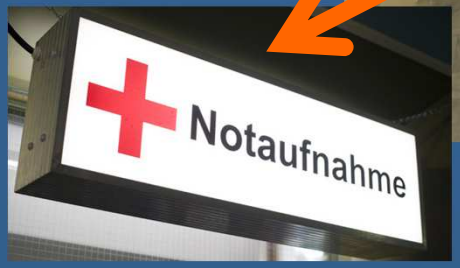


Effizienzgewinn oder Kostenfalle?



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 labor-medizinischen 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 Pflege-personals 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)"

Journal of Diabetes Science and Technology
Volume 6, Issue 5, September 2012

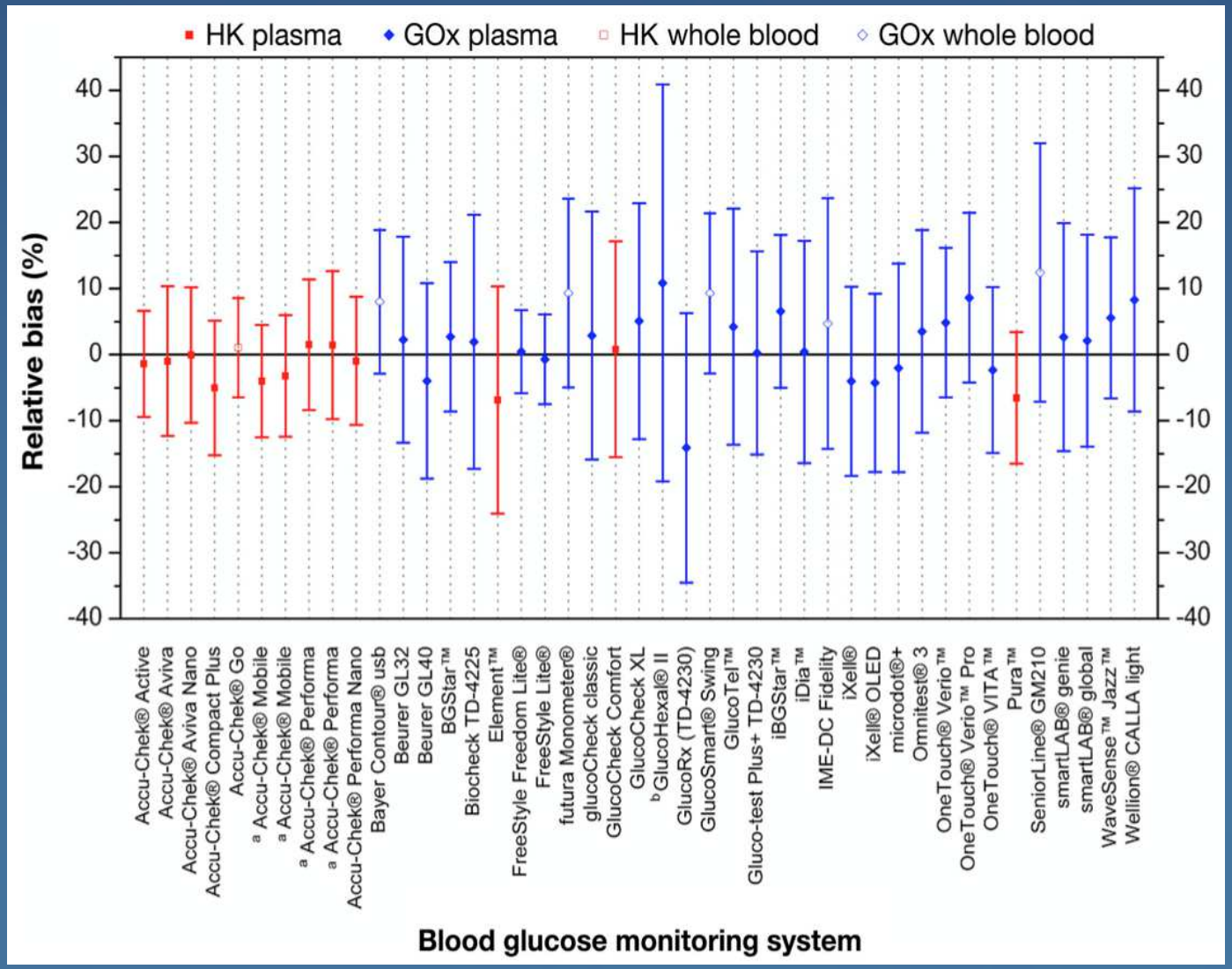
ORIGINAL ARTICLE

System Accuracy Evaluation of 43 Blood Glucose Monitoring Systems for Self-Monitoring of Blood Glucose according to DIN EN ISO 15197

Guido Freckmann, M.D., Christina Schmid, Ph.D., Annette Baumstark, Ph.D., Stefan Pleus, M.S., Manuela Link, M.E., and Cornelia Haug, M.D.

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.

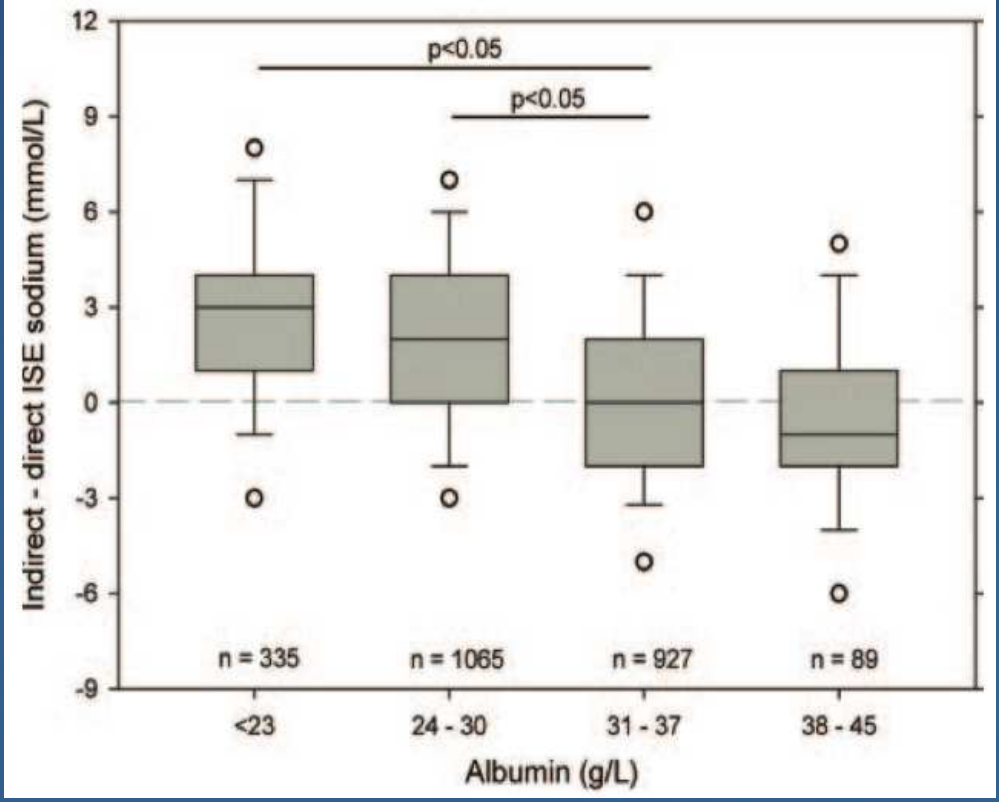
Accu-Chek® Mobile + Performa were both tested with different test strip chemistries. The test strip chemistry was either maltose depen-dent (left) or maltose independent (right).

4

Short research report

Electrolytes in sick neonates – which sodium is the right answer?

Richard I King,[1] Richard J Mackay,[1] Christopher M Florkowski,[1] Adrienne M Lynn[2]



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 pseudohypernatriaemia

King RI, et al. Arch Dis Child Fetal Neonatal Ed 2013;98:F74–F77

2

Impact of Point-of-care Testing in the Emergency Department Evaluation and Treatment of Patients with Suspected Acute Coronary Syndromes

Bertrand Renaud, MD, Patrick Maison, MD, Alfred Ngako, MD, Patrick Cunin, MD, Aline Santin, MD, Jérôme Hervé, MD, Mirna Salloum, MD, Marie-Jeanne Calmettes, MD, Cyril Boraud, MD, Virginie Lemiale, MD, Jean Claude Grégo, MD, Marie Debacker, MD, François Hémery, MD, Eric Roupie, MD

Objectives: To assess the impact of point-of-care testing (POCT) for troponin I (cTnI) 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. cTnI 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 (cTnI level ≥ 0.10 μg/mL), and in those with low suspicion ACS (no chest pain and no ST deviation).

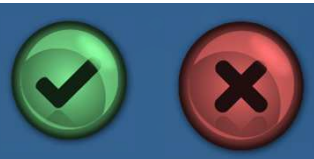
Results: Of the 860 patients enrolled, 113 were high-risk NSTE-ACS patients, including 53 (46.9%) allocated to POCT and 60 (53.1%) to CHLT. POCT was associated with decreased time to anti-ischemic therapy of about three-quarters of an hour, which was due to a shorter time to physician notification of cTnI 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 cTnI 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.

Benaud B et al. Acad Emerg Med 2008;15:216-224

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

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



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.

3

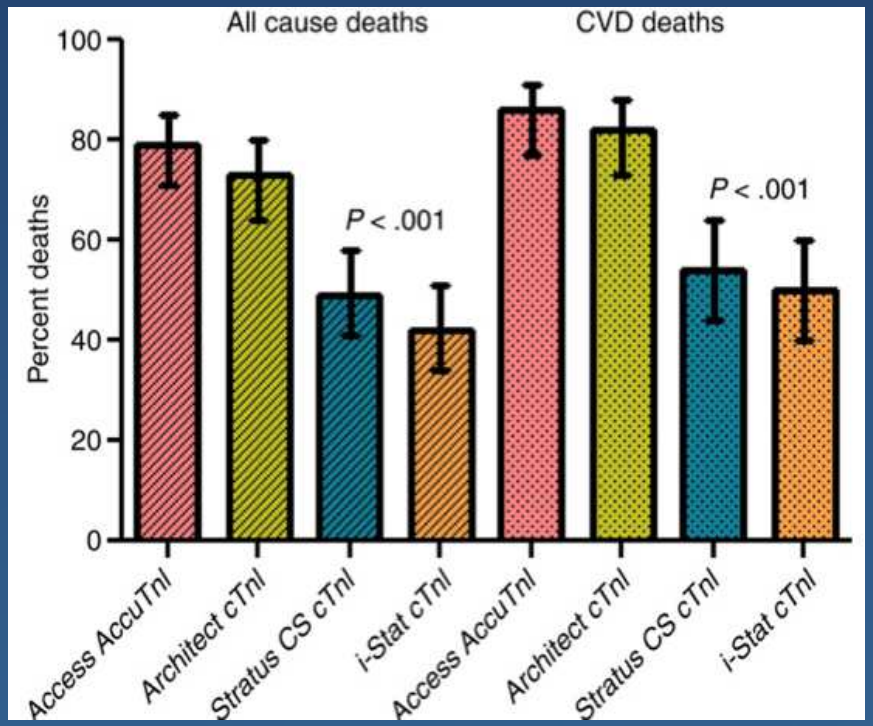
Early and late outcome prediction of death in the emergency room setting by point-of-care and laboratory assays of cardiac troponin I

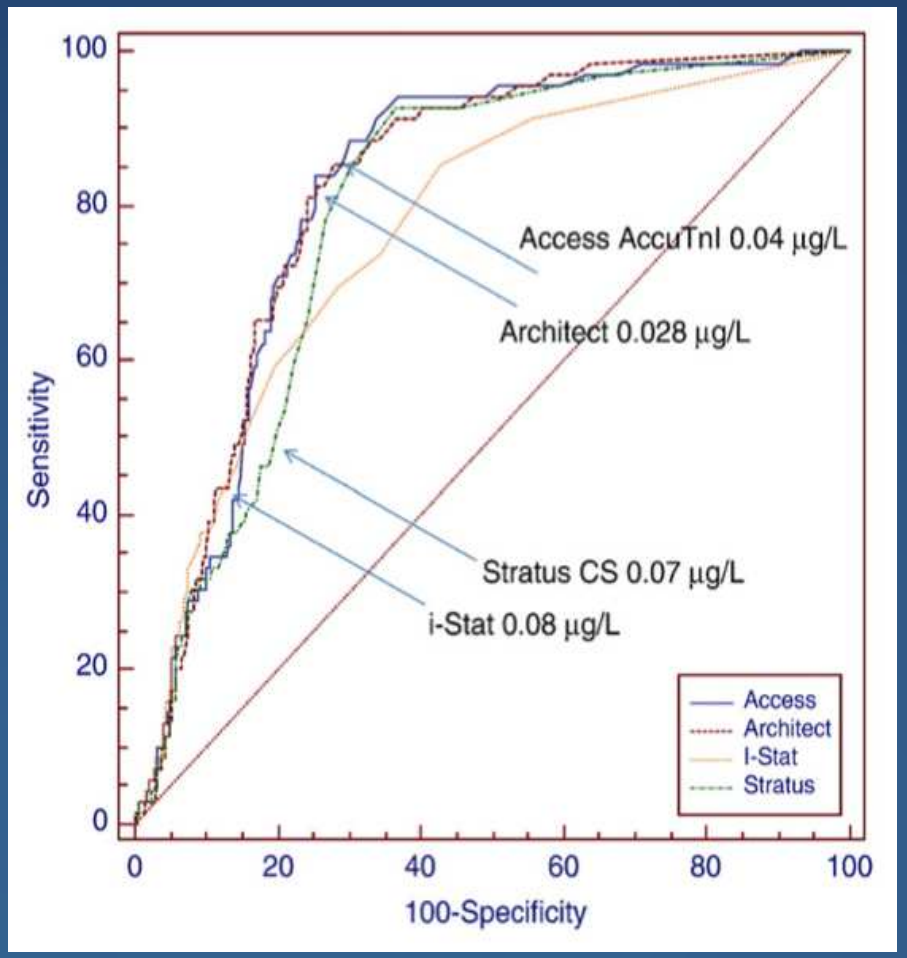
Per Venge, MD, PhD,[a] Claes Öhberg, MD,[a] Mats Flodin, BSc,[b] and Bertil Lindahl, MD, PhD[a,c] *Uppsala, Sweden*

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 cTnI 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 cTnI results with the POC assays, such results should be complemented by results from sensitive laboratory assays. (Am Heart J 2010;160:835-41.)

Venge et al. Am Heart J 2010;160:835-41

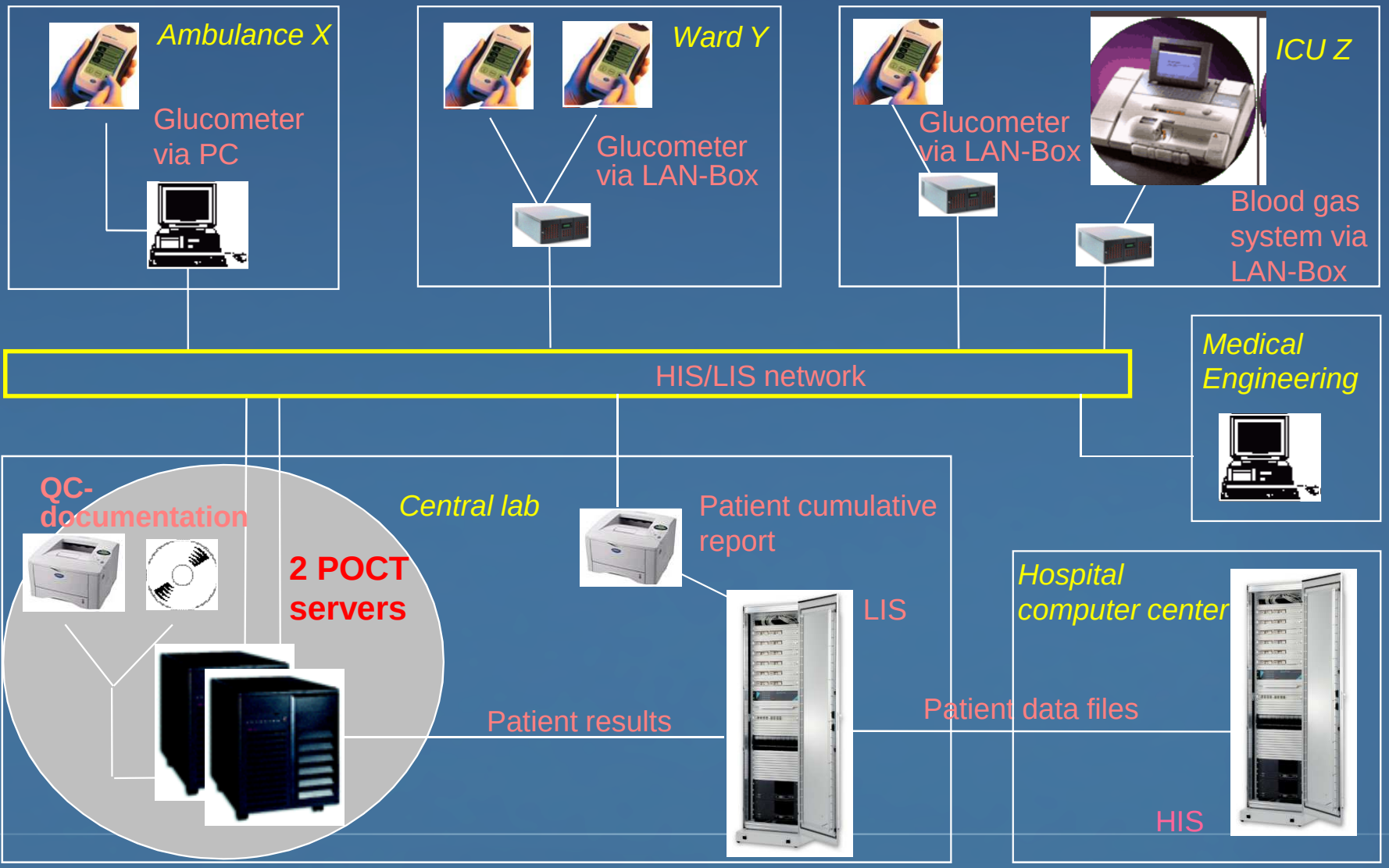




The % of patients who died within 35 months who had levels above the 99th percentile cutoffs of the 4 cTnI assays, respectively. Significant differences between the laboratory and the 2 POC assays are seen.

Venge et al. Am Heart J 2010;160:835-41

Connection of POCT Systems to the HIS and LIS



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 al96 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.75

Echte Kosten-Nutzen-Analysen der POCT-Analytik im Krankenhaus sind bisher nicht publiziert worden, insbesondere nicht für den deutschsprachigen Raum mit den hier vorliegenden speziellen Regelungen zur Kostenerstattung medizinischer Leistungen.
Im Allgemeinen gilt aber, dass POCT-Verfahren mit deutlich höheren Kosten verbunden sind als herkömmliche Labortests. Neben höheren Kosten für Geräte und Reagenzien fällt zusätzliche Arbeitszeit an, die gegebenenfalls im Stellenplan der Klinik beziehungsweise der Praxis berücksichtigt werden muss. Die Fixkosten des Labors im Krankenhaus bleiben oft aber weitgehend unverändert.

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.

Junker R, Schlebusch H, Luppa PB. Point-of-care testing in hospitals and primary care. Dtsch Arztebl Int. 2010 Aug;107(33):561-7

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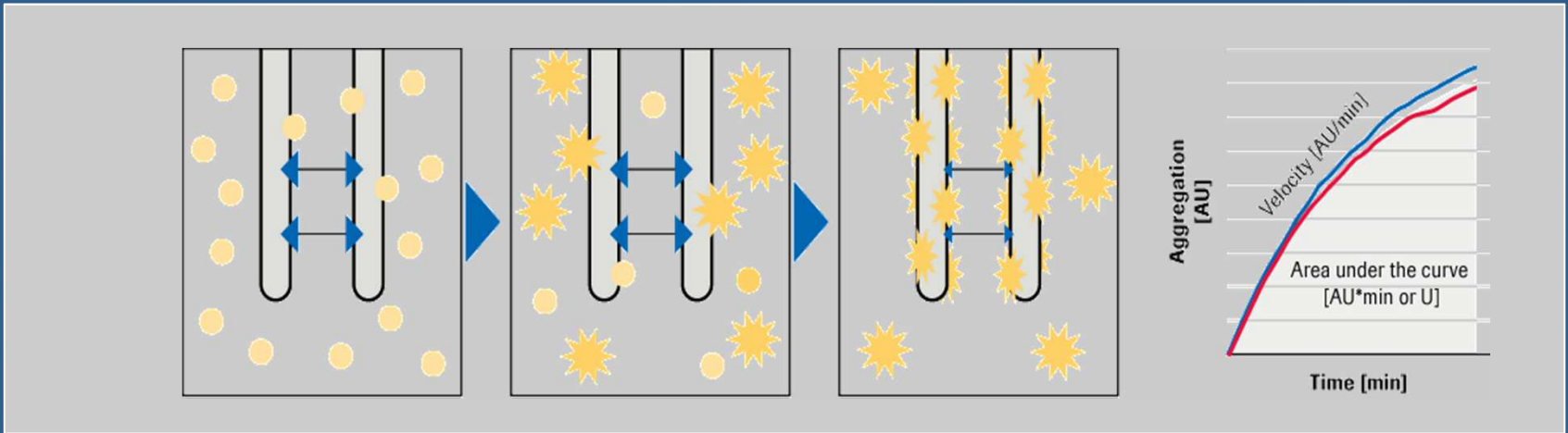

List of laboratory parameters currently available using POCT

Clinical application	Parameter
Acid-base balance, blood gases	pH, pCO_2, pO_2
Electrolytes	Na^+, K^+, Cl^-, $Ca^{++}{}_{ion.}$, $Mg^{++}{}_{ion}$
Metabolites	Cholesterol, HDL-cholesterol, triglycerides, creatinine, urea, uric acid, bilirubin, lactate, ammonia
Enzymes	Amylase, alkaline phosphatase, CK, AST, ALT, γ-GT
Coagulation	Activated clotting-time (ACT), activated partial thrombo-plastin time (aPTT), prothrombin time (PT, INR), D-dimer, platelet function tests, ex-vivo bleeding time
Hematology	Hemoglobin, hematocrit, erythrocytes, leukocytes, thrombo-cytes
Hemoglobin fractions	CO-Oximetry
Cardiac markers	TnT, TnI, myoglobin, CK-MB, BNP/NT-pro-BNP
Diabetes mellitus	Glucose, HbA_{1c}, microalbumin, minimal invasive continuous glucose monitoring
Acute-phase proteins	CRP
Allergy in-vitro diagnostics	Allergy specific IgE
Rheumatology	Antibodies against mutated citrullinated vimentin (anti-MCV)
Therapeutic drug monitoring, drugs-of-abuse screening	Therapeutic drugs, alcohol, amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates
Infectious agents	HIV, infectious mononucleosis, *Chlamydia trachomatis, Trichomonas vaginalis, Plasmodium falciparum and vivax,* Influenza A and B, *Steptococcus A and B*
Fertility	hCG, LH and FSH, sperm count
Urine diagnostics	Urine strips (pH, protein, glucose, ketones, bilirubin, uro-bilinogen, nitrite, leukocytes, erythrocytes), microalbumin, NMP22 bladder carcinoma check
Stool diagnostics	Blood