

New
building
Isala



POCT Quality in Hospital incl IC

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20 mei 2013

Slingerland, Euromedlab, 2013



Similar values health-care chain!

- HbA1c at GP: 64 mmol/mol
- HbA1c in lab: 53 mmol/mol
- 4 x GP → Lab → GP

5.5 mmol/mol difference is critical.



Point-of-care Testen

POCT (ISO?)

- Bed-side test
- Near patient
- Mobile, handheld or smaller
- *Professionals: 1 device, more patients, monitoring*

Home-use Testing (ISO 15197)

- *Patients: 1 device, 1 patient, monitoring*

Point-of-service Testing (POST) (ISO?)

- Preventive Medical Testing
- *Clients, Professionals, Commercial Parties:
1 device, 1 or more clients, monitoring and diagnosis*

Harmonisation/standardisation within health-care chain

- ISO 15197: 20% (→15%), 0.83 mmol/L
- ISO 15189: organisation
- Hospital: 10-15%
- ICU (CLSI POCT12 A3): 12.5%
- Difference home-use testing vs. POC-testing

Criteria introduction POC in Hospital

1. Guided by/responsibility of the Central Laboratory.
2. Acceptable analytical performance! (Validation Central Lab).
3. Connectivity to Central Laboratory for data management
4. Education by or under supervision of the POC coordinator
5. Only accredited users!
6. IQ and PT coordinated by the POC coordinator.
7. Ordering of reagent/cartridges by Lab (new lot number!!).
8. Frequent check results with lab methods.

Mobile Health-Care

- **40%** of consumers would pay for *mobile remote monitoring*
- **40%** of physicians say they could eliminate up to **30%** office visits by using mobile health strategies

Less credentials on digital highway!



improve the privacy, security, and
convenience of online transactions!

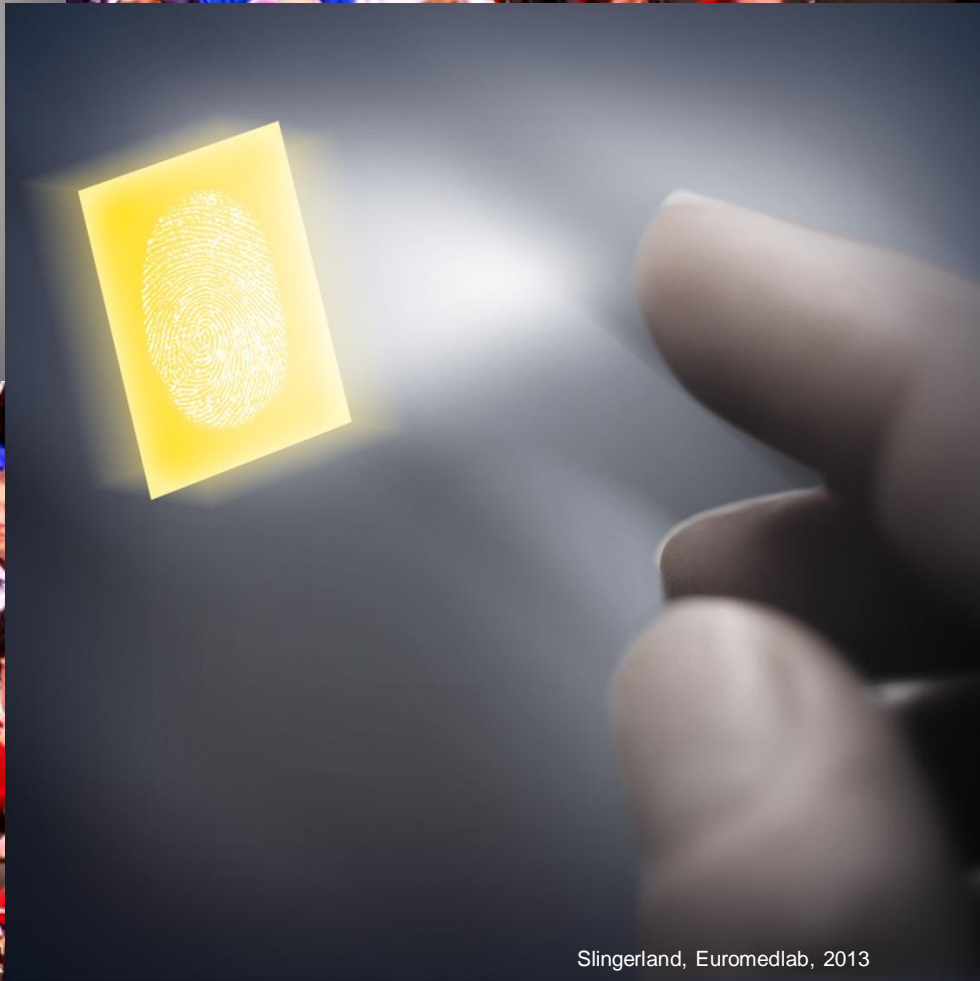
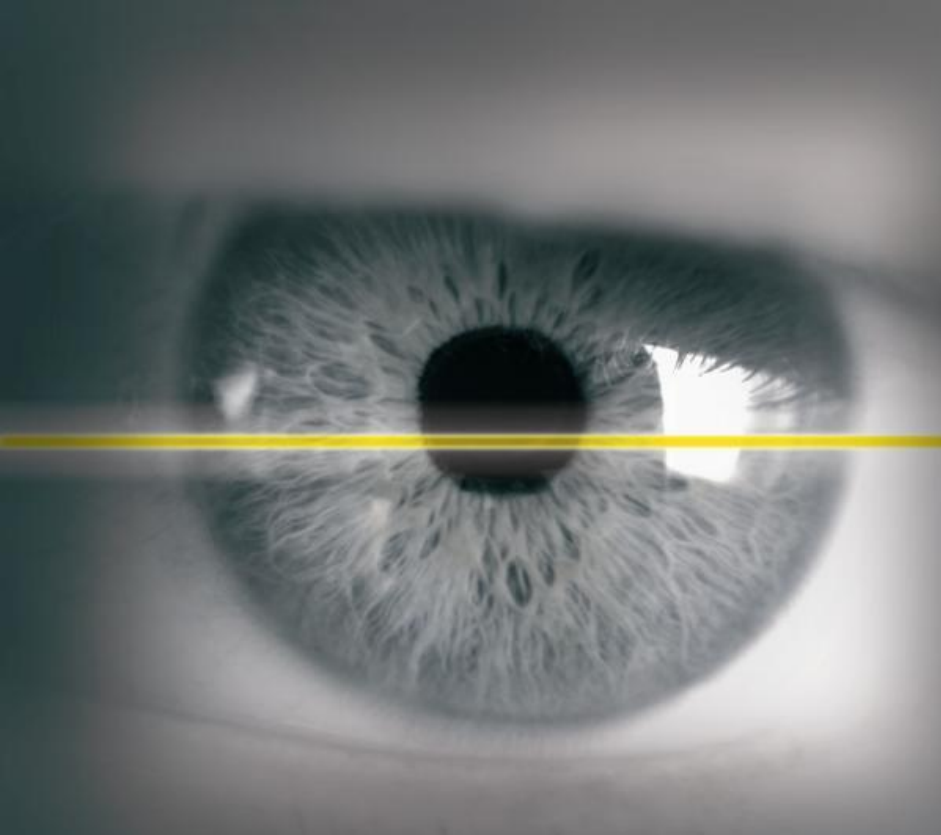
- In 2012 NIST funded pilot projects (News Released, feb 1, 2012).
 - *interoperable trusted online credentials that go beyond simple users IDs and passwords*
- National Strategy for Trusted Identities in Cyberspace (NSTIC).



Authentication vs. Identification

'you say who you are' (identification) +
'you prove who you are' (authentication)





Sesam's Cloud Solution Utmost Safety (US/NIST4)

Example: who's entering?



eHealth, hospitals
(portals), EPR,
point-of care
testing, social
media, etc.

*Hey, this is Joann her device, so this must be uh ...Joann
Welcome Joann, go ahead!*



eHealth, hospitals
(portals), EPR,
point-of care
testing, social
media, etc.

*Hey, this is Joann her device... and this is Joann her life finger as well!
Welcome Joann, go ahead!*

Biometrics Integrated in Devices

FP sensor + Sesam!

For desktop & laptop/netbook/ultrabook

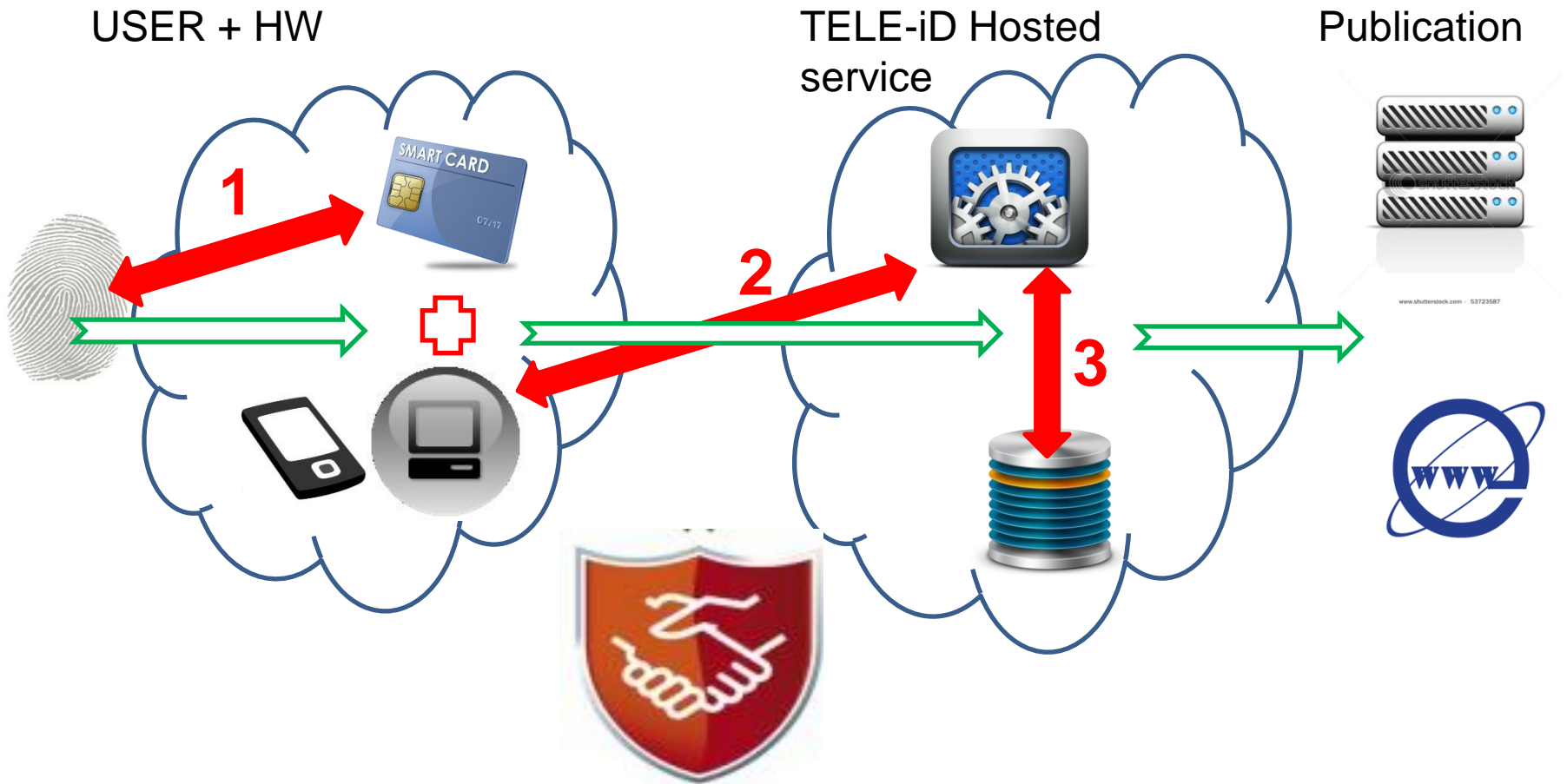


Reader + card

For mobile devices (smartphone and tablet)



Sesam's Anonymous authentication technology



 Sesam's 3 step process: 1/ biometric authentication, 2/ device authentication, 3/ attribute authorization



Biometrical health card

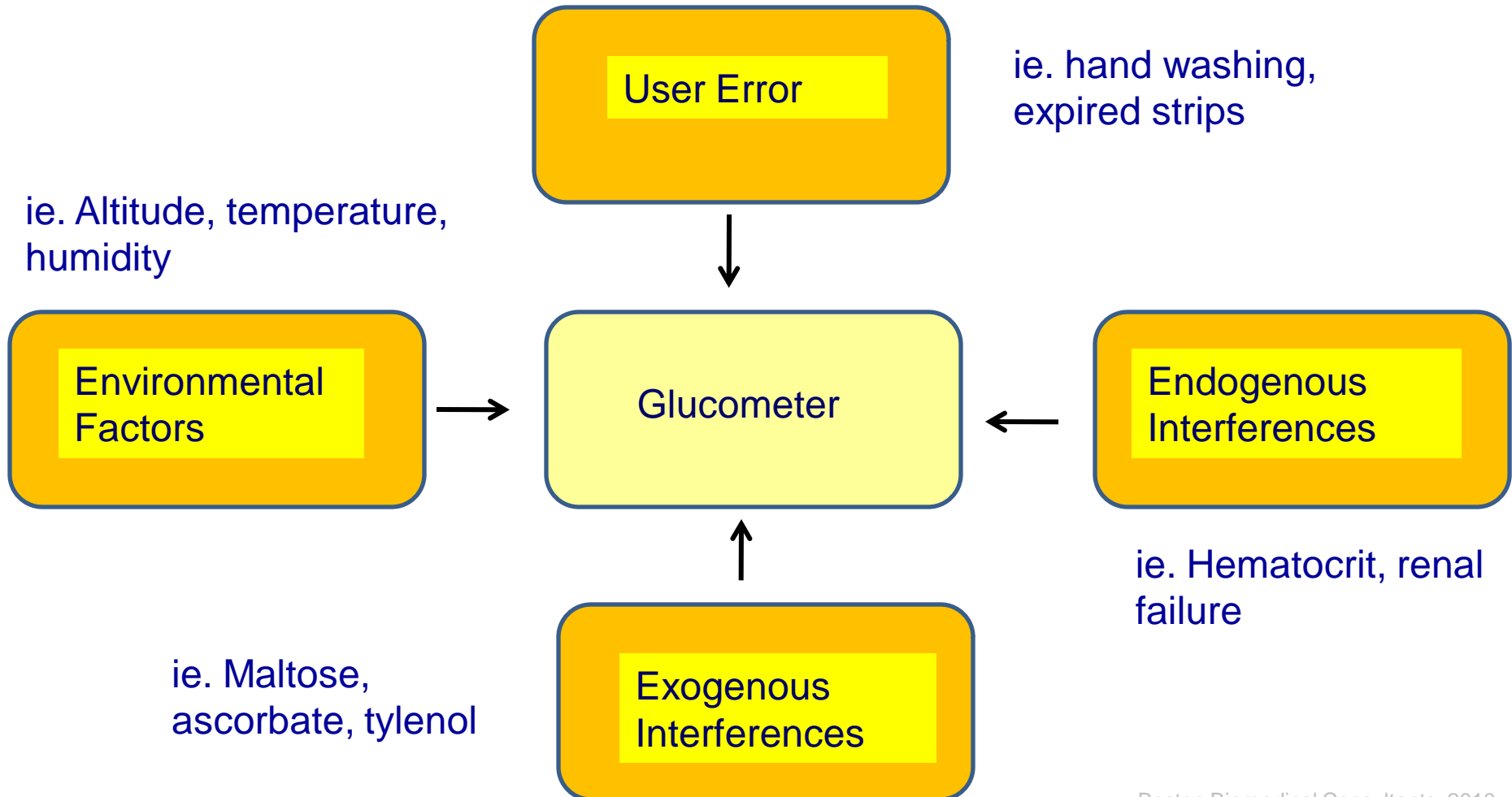
'you say who you are' (identification)



'you prove who you are and proof what you have'
(authentication)

198 users, 10 health providers,
2 years in use,
no inlog problems,
patients and IT-administrators like it!

Factors Affecting Glucometer Performance





Professional Point of Care Testing

- Docking station/wireless
- Low sensitivity interferences, ideally none
- More than 1 patient measured
- E-learning preferred/mandatory
- Total allowable error: <10%
- **EQUAS mandatory; commutable material**
- Authentication needed



How confirm glucose meter is functioning properly?

Analyze Quality Control Materials

- Stable material (aliquots, vials)
- Should **preferably** have the same matrix as the test specimens



- Manufacturer QC materials tend to be
 - buffered stabilized aqueous solution of D glucose
 - (NOT whole blood)**

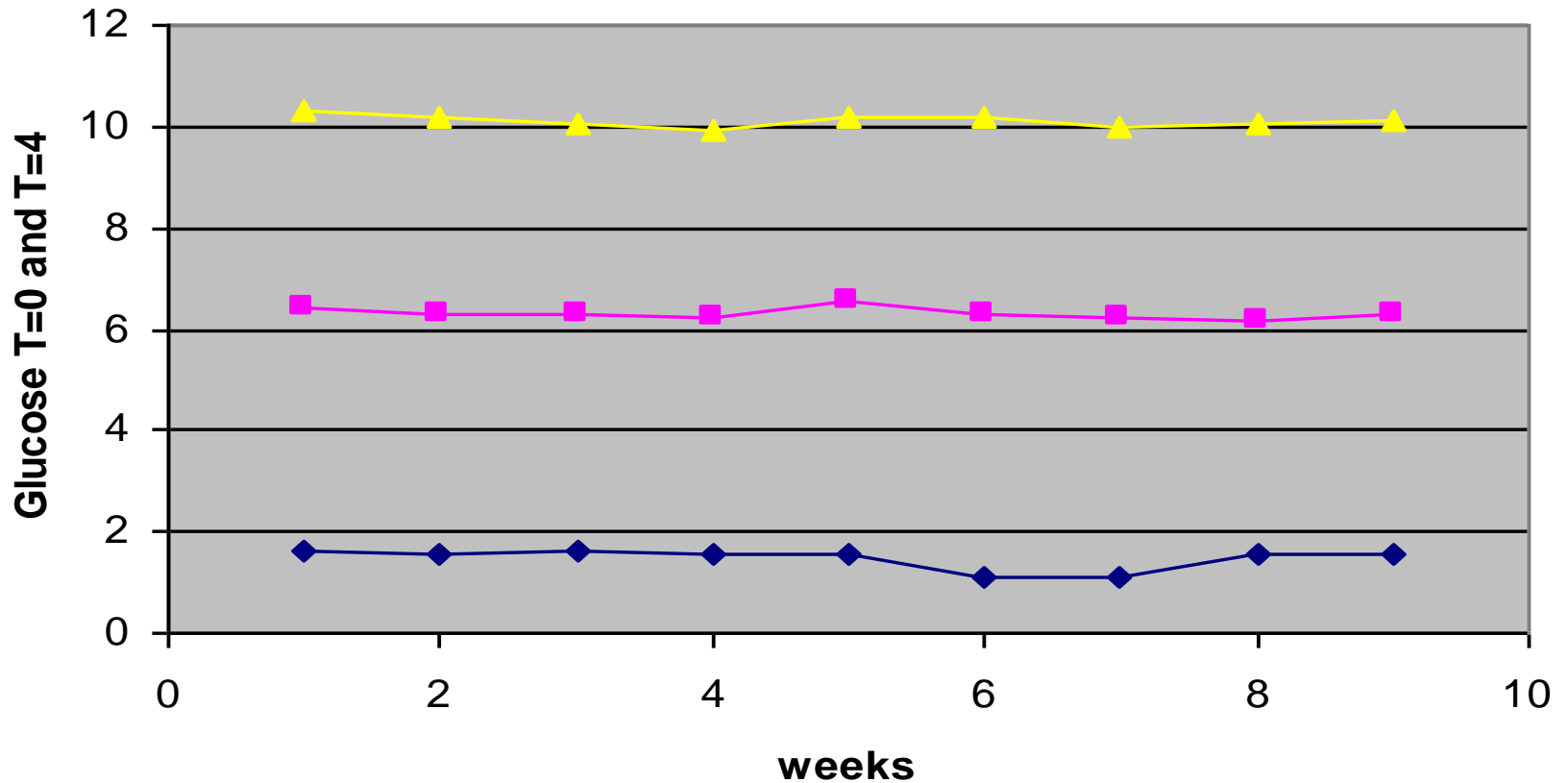
Stable whole blood control material



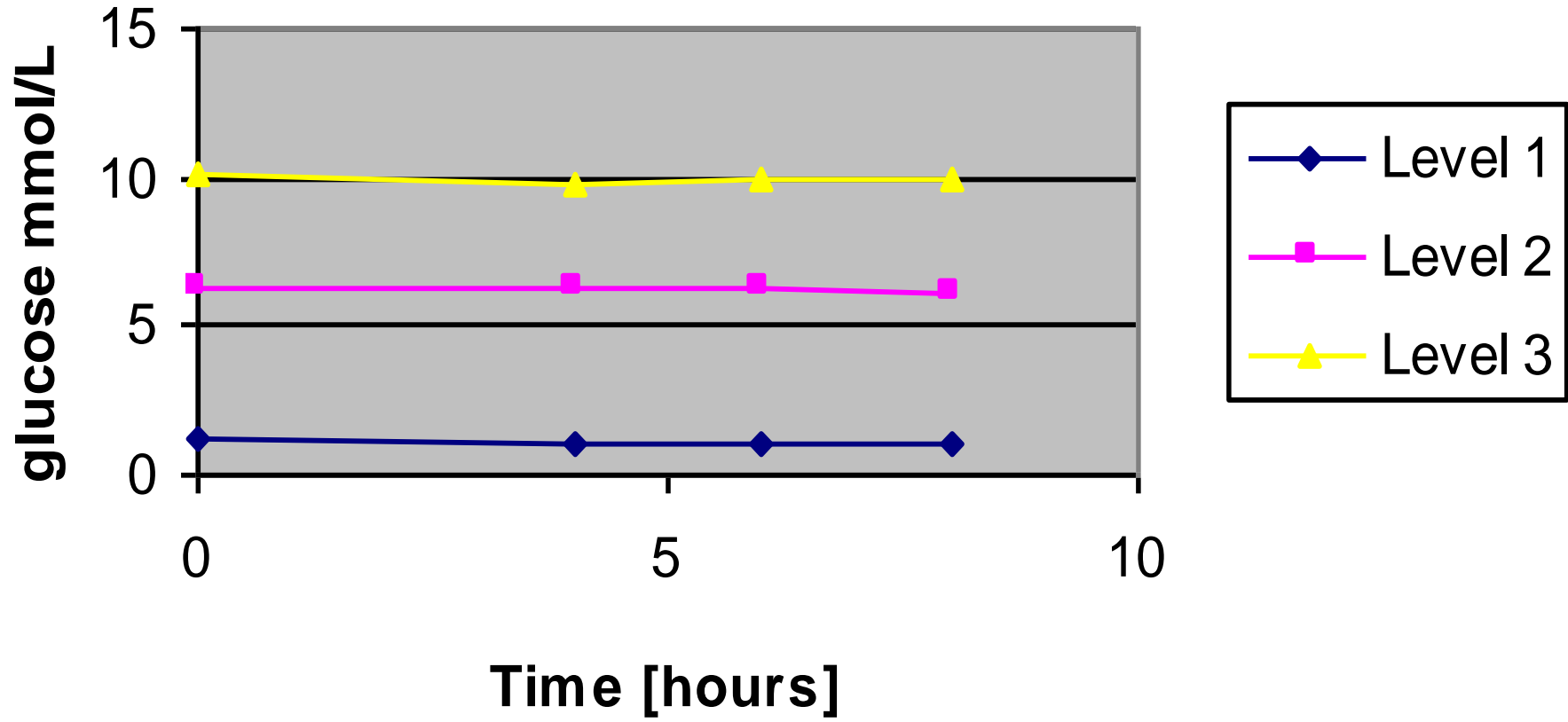
**A whole blood glucose Quality Control (CueSee)
that is stable for >2 months.**

QueSee EQUAS-glucose

Stability over 9 weeks



Stability QueSee glucose after reconstitution



CueSee

Stable whole blood commutable EQUAS material!?

Not all instruments: Roche Accucheck Inform!

Patient glucometers!

External Proficiency Testing (like SKML/CAP) and QC do NOT detect **patient related factors** that could influence glucose meter performance!!

Need to investigate **patient specific factors** that can influence glucose meter performance!

Continuous vs. intermittent glucose measurements

- **Comparability of data?** **Statistical imbalance**
- **What is decisive info?** **Percentage hypo, mean, median value, % time within therapeutic range, % time outside range?**
- **Number of data influence results!** **Central tendency and dispersion are influenced by the frequency of measurement!**
- **Valid for which period?** **Interferences?**
- **Trend-information!** **Rate accuracy?**

Continuous **Interstitial** Invasive Glucosemeters

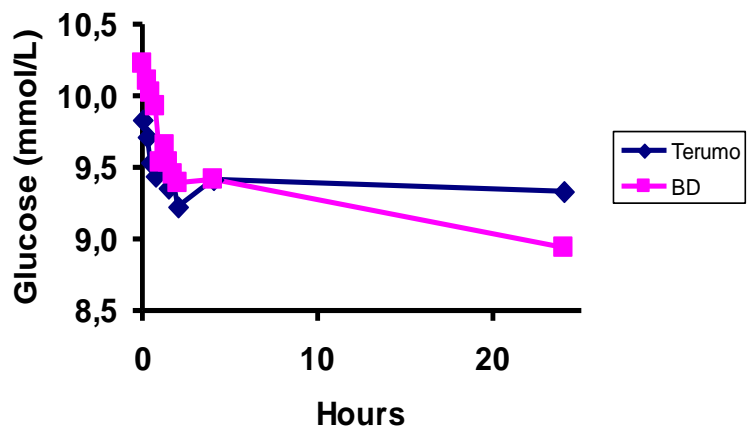
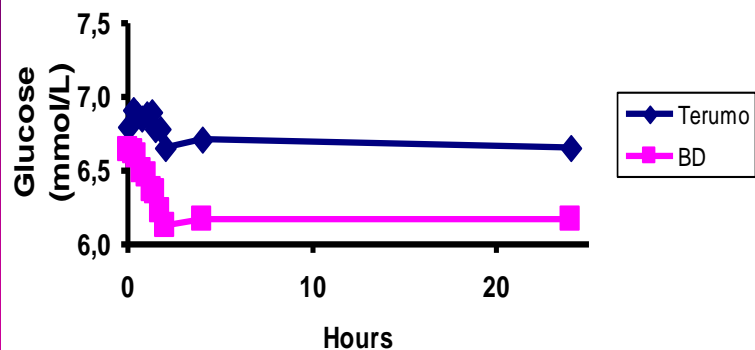
- **Difference in sampling places.**
- **Differences between interstitial fluid and plasma! (delay time 20-40 min)**

Invasive Continuous **Blood** Glucosemeters

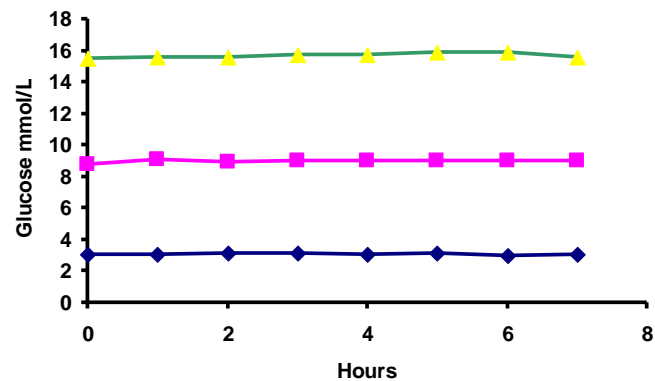
- **Calibrate with venous/arterial/capillary blood measurements?**
 - [*Logtenberg et al. Diabetes Technol Ther. 2009 Jan;11\(1\):31-7*](#)
- **Lab measurement: transport time → glycolysis!**

Transportation

Plasma glucose in different tubes



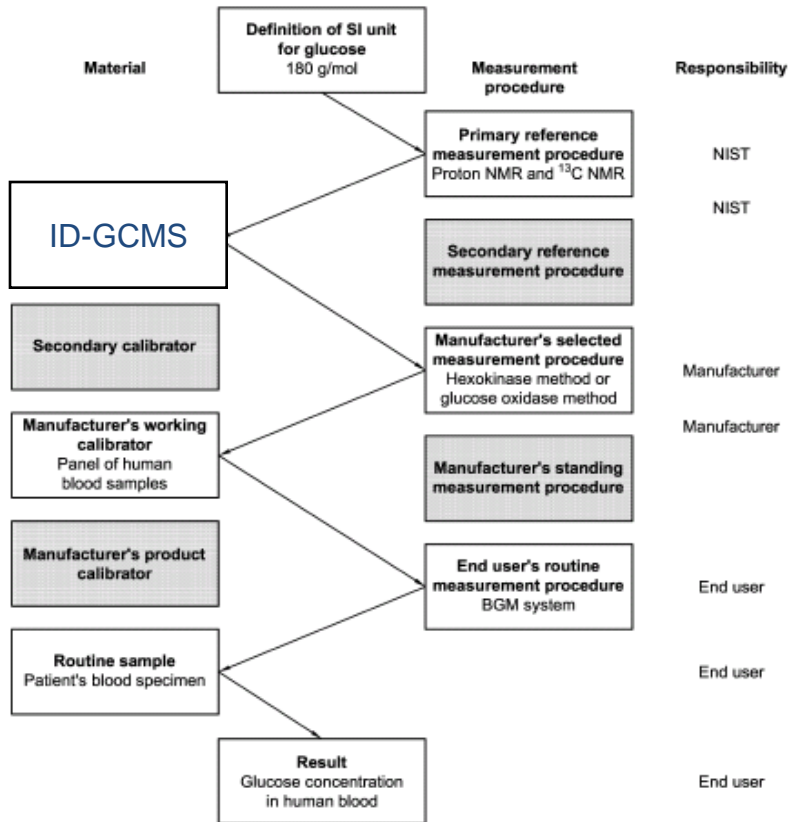
Perchloric acid supernatant at RT



Tubes problem!

Traceability!

Traceability chain



Perchloric acid whole blood
hexokinase
method + hematocrit measurement

NOTE 1 The illustration of a full traceability chain is taken from ISO 17511:—, 4.2.2 h). Steps that are not used in this particular calibration scheme are shaded in grey.

NOTE 2 This example is not intended to represent the only possible traceability chain for a blood-glucose monitoring system.

^a NIST SRM917b refers to the Certificate of Analysis issued by the National Institute of Standards and Technology (NIST) for the standard reference material (SRM) 917b, D-glucose (dextrose), used for calibration in this example.

Non-Invasive Continuous Glucosemeters

- **Can't compare with lab-method! Need patient all the time!**
- **What is the reference meter? -->Best POCT-glucosemeter!**

Non-invasive glucosemeters!



Non-invasive glucosemeters!





- Split sample
- Barcode scanning, or better biometric recognition
- No home-use instruments: $\geq 1\%$ of patients problem with interfering substances



To Err Is Human? POC Error!

- Strips too long exposed to air
- Strips left on counter → risk reuse
- QC materials vs. built-in electronic controls
- No control process for hemolysis (K+)
- Need for centrifugation/separation to detect hemolysis
- Too much/too little sample volume

Human Proof POC!

- ID error: use of colleague pass (*solution available!*)
- ID error of patient (*solution available!*)
- No transfer of data, lost connection, no warning
- Expired reagents
- Reagents stored under wrong conditions
- No cleaning → transmitting infectious diseases
- No fast answer for stat samples



Go/No-Go Decision Diagnostics?

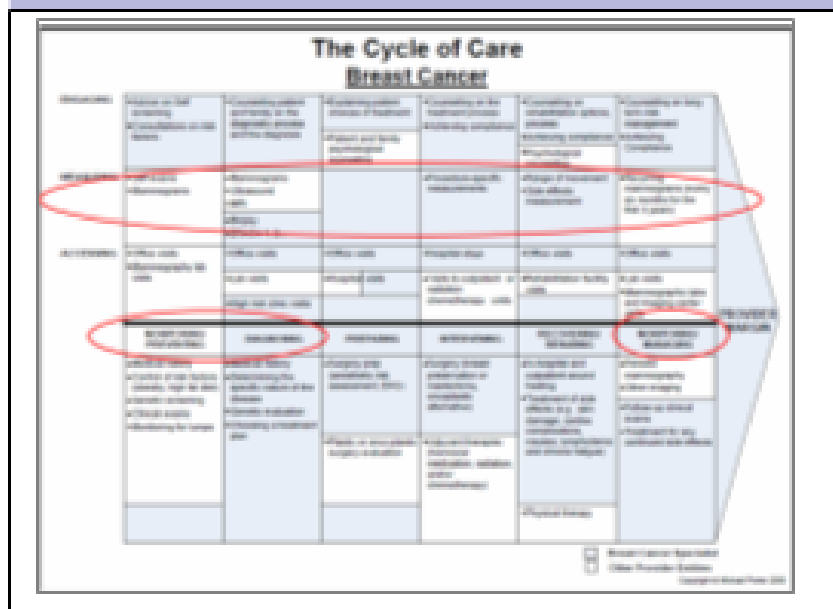
- On what grounds?
- Economic impact whole society?
- Economic decision model

(Boston University, Nijerode University, Isala Clinics)

What is the role of diagnostics in healthcare?

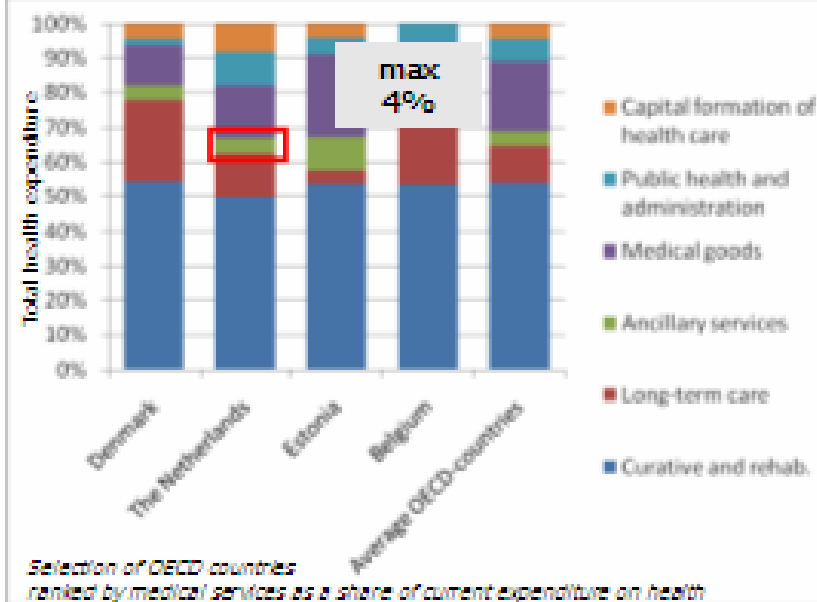
Diagnostics influence as much as 60-70% of healthcare decision making while the expenditure on diagnostics is even less than 4% of the total health expenditure.

Diagnostics influence 60-70% of decision-making in healthcare



Sources: Porter 2009, Redefining Healthcare. Lewin Group 2005, The value of diagnostics Innovation, adoption and diffusion into healthcare. SAN-rapport 2010, Medische diagnostische centra zijn cruciaal voor huidige, zinnige en zuivere zorg in de eerste lijn.

Expenditure on diagnostics is less than 4% of the total health expenditure



Selection of OECD countries ranked by medical services as a share of current expenditure on health

Source: OECD, System of health accounts, 2008

Why is it difficult to assess the value of diagnostics?

Difficulties arise due to the complex definition and the unknown value of diagnostics.

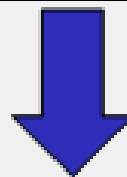
Two issues on diagnostics

Issue I; Complex definition of diagnostics

Diagnostics are complex to define, traditionally diagnostic devices are defined by their technology

Issue II; Unknown value of diagnostics

As diagnostics do not have a direct impact on health outcome, the value of diagnostics is difficult to determine



**Conclusion: there is no available methodology
to assess the value of diagnostics**



How to Decide to Implement New Diagnostics?

An Example: Added Value Troponin-T in the Health Care Chain!

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Submitted to CCLM

Conclusions

- Difference POCT, Home-use Testing, POST
- Authentication → biometrical recognition
- EQUAS: commutable material
- Glucose: comparability of data, traceability
- POCT errors
- Economic model for diagnostics

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Questions?

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