

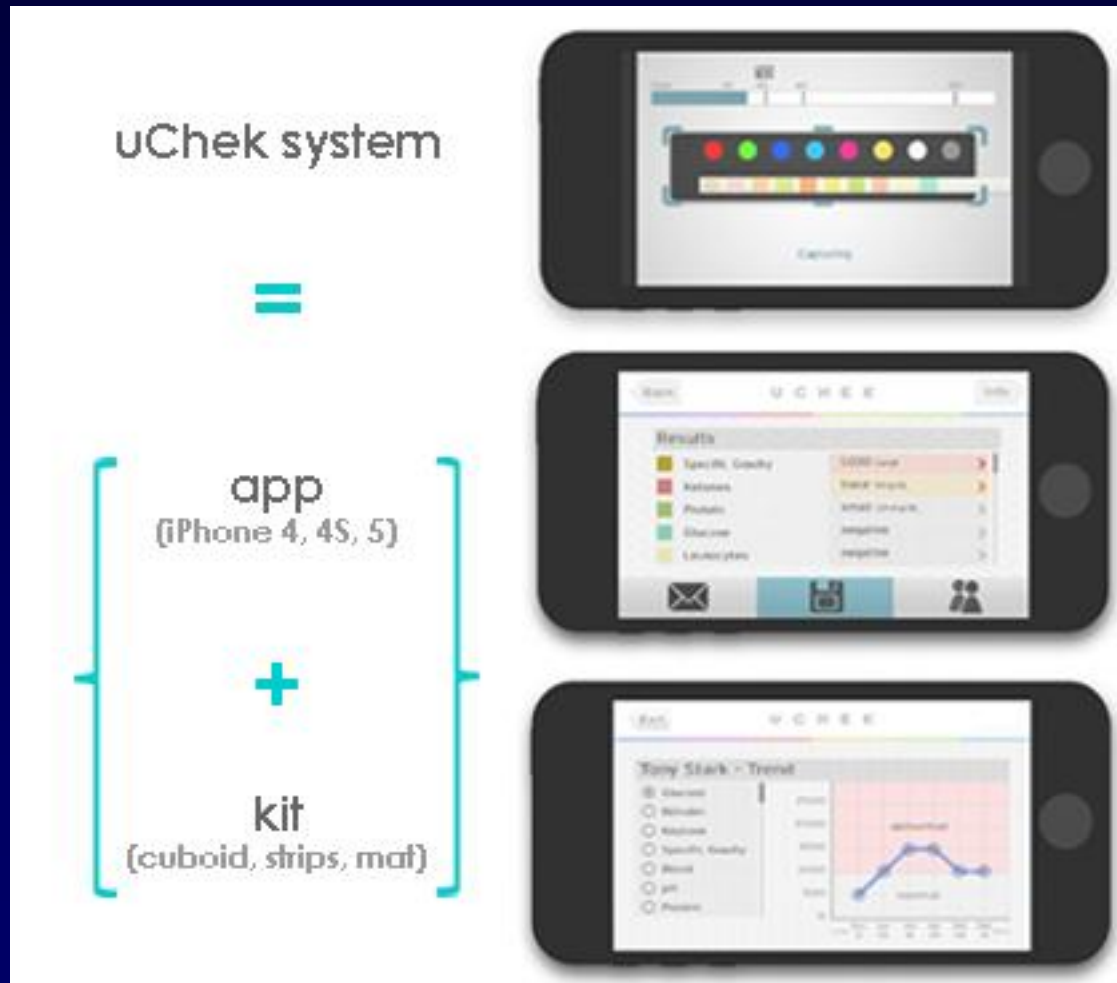
The role of POCT in modern medicine

*13th EFLM Continuous Postgraduate
Course in Clinical Chemistry and
Laboratory Medicine
Sverre Sandberg, Noklus / EFLM*

POCT is the fastest growing field in laboratory medicine

- ✓ There are many hospitals
- ✓ There are more wards and GP offices and nursing homes....
- ✓ There are more patients.....
- ✓ There are more healthy people.....

Urine strips



Glucose

Apple Store now sells Sanofi's iPhone glucose meter

By: [Brian Dolan](#) | May 2, 2012

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Point of Care

- a lot of possibilities -

New mobile phone to detect bad breath

Deviser uses tiny chip to warn of unpleasant odors

REUTERS 

Updated: 4:11 p.m. ET Sept. 22, 2004

BERLIN - A German telecommunications company said on Tuesday it is developing the first mobile phone that will alert users when their breath is bad or if they are giving off offensive smells.

advertisement

What will I speak about

1. Evolving technical possibilities
2. Developing countries and infectious diseases
3. Role of the laboratory people
4. A little bit about everything.

The NEW ENGLAND JOURNAL *of* MEDICINE

SOUNDING BOARD

**How Point-of-Care Testing Could Drive Innovation
in Global Health**

Ilesh V. Jani, M.D., Ph.D., and Trevor F. Peter, Ph.D., M.P.H.

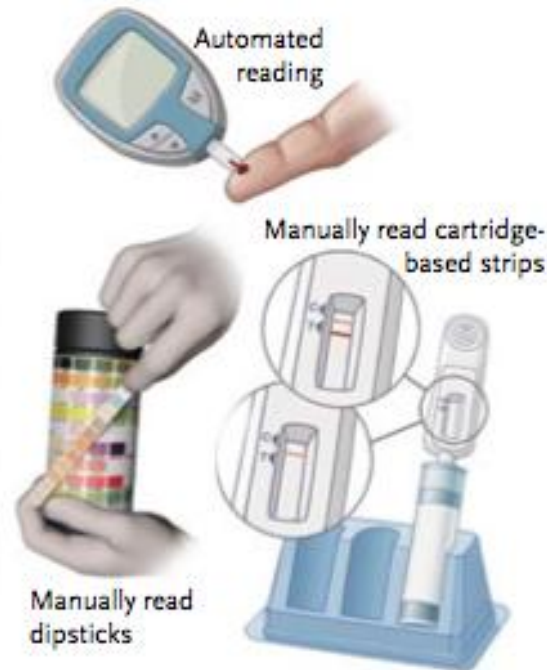
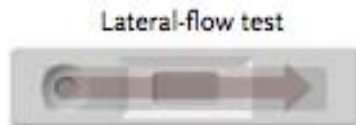
The first generation of point-of-care testing relies on easy-to-detect biomarkers, such as antibodies, antigens (HCG, infectious mononucleosis), and simple biochemical reactions (HbA1c, glucose, CRP, INR).

A First generation of POC diagnostic testing

Typical samples



Common test formats



Detection targets

Antibodies
Antigens
Simple biochemical reactions



Examples

Rapid test strips and dipsticks (HIV antibody and antigen, malaria antigen, urine biochemistry, and pregnancy tests)
Simple instruments (glucometers and hemoglobin meters)

On the horizon

Tests that can detect nucleic acids and cell-surface markers. The first applications of these technologies have e.g. included enumeration of CD4+ T cells, NAT-based diagnosis of tuberculosis and drug-resistance screening.

Thereafter “lab on a chip devices”, smaller devices, simpler to operate and potentially instrument free, enabling reliable home-based testing or self-testing.

Point-of-care testing can have a transformative effect on health care.
– especially in the developing world
and remote areas

Three of the most important diseases in the world:

- HIV
- Malaria
- Tuberculosis

HIV rapid tests

Rapid HIV tests increases the rates of case finding since you can meet the patients where they are, and in high prevalence countries they should be tested repeatedly over the course of their lives.

De Cock KM et al. N Engl J Med 2006;354:440-2.



Traveling HIV Tester and Counselor in Kenya.

Service providers come by bicycle to remote areas with poor roads. In isolated desert regions, service delivery by camel is being developed.

Malaria rapid tests

Malaria rapid tests have successfully raised testing rates in Africa for suspected cases from below 5% in 2000 to 45% in 2010 thereby reducing inappropriate antimalaria treatment and improving community-based management of fever and health outcomes.

Test treat track scaling up diagnostic testing, treatment and surveillance for malaria. 2012 (http://www.who.int/malaria/test_treat_track/en/index.html). Geneva: World Health Organization.

Tuberculosis

Rapid, cost-effective rapid testing for tuberculosis have increased the rate of case detection by up to 50% and reduced the time until treatment initiation by a factor of 10

Boehme CC et al. Lancet 2011;377:1495- 505.

However, the benefit of new point-of-care tests cannot be taken for granted.

Despite the availability of point-of-care testing for CD4+ T cells at primary health care clinics in Mozambique, 50% were not tested at all. Of those tested and eligible for antiretroviral therapy, 40% were lost to follow-up.

Jani IV et al. Lancet 2011;378:1572-9.

Thus

Innovation will be needed in the design, operation, and workflow of health care to ensure that testing is accessible and results are used in real time to guide treatment. Point-of-care testing may lengthen clinic visits and place extra demands on staffing and space.

So – where is the laboratory
people?



Are we disappearing in a hole

Future of the Laboratory World

Communication

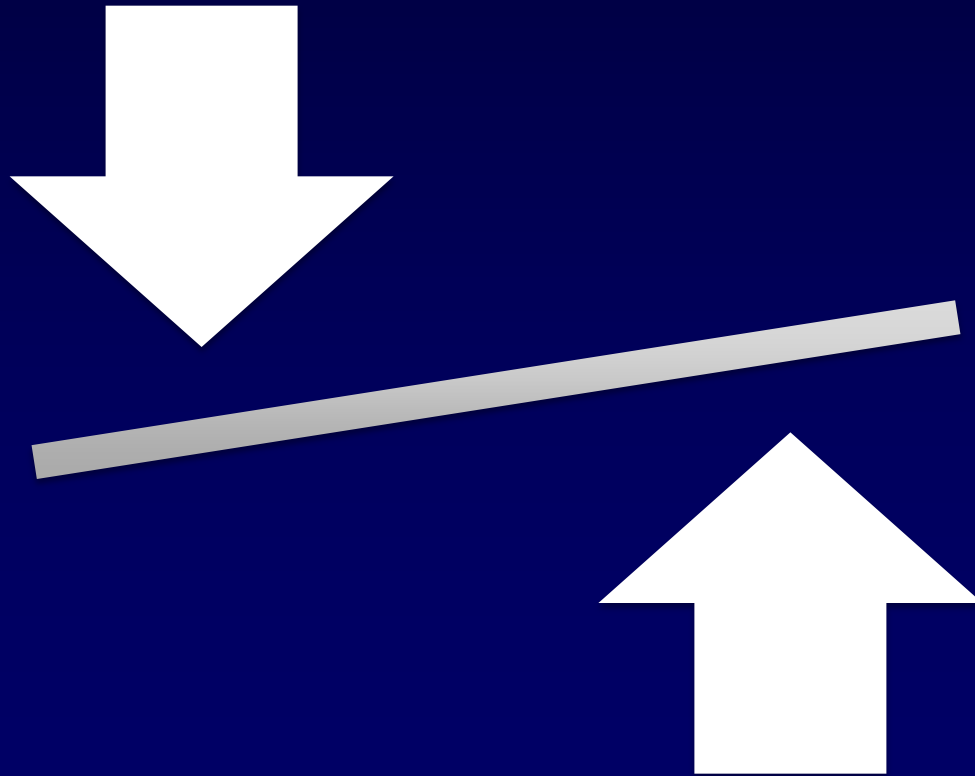
Automation / Core labs

*Point of Care
Testing*

Research

*Laboratories for
special analyses*

Most important question in laboratory medicine:
To use or not to use a test



Where should the test be done (and who decides)?

1. At the central laboratory
2. Other places at the hospital
3. Outside the hospital
 - doctors office / pharmacy
4. Self-measurement

POC

Better outcome for patients

Start with POC

?

Decreased costs
for society/clinician

Increased costs
for society/clinician
(Reimbursement)

?

Do not start with POC

Poorer outcome for patients

POC - in the hospital

We must agree (locally):

Which analytes are POC analytes.

How rapid must the result be provided

Analytical quality specifications

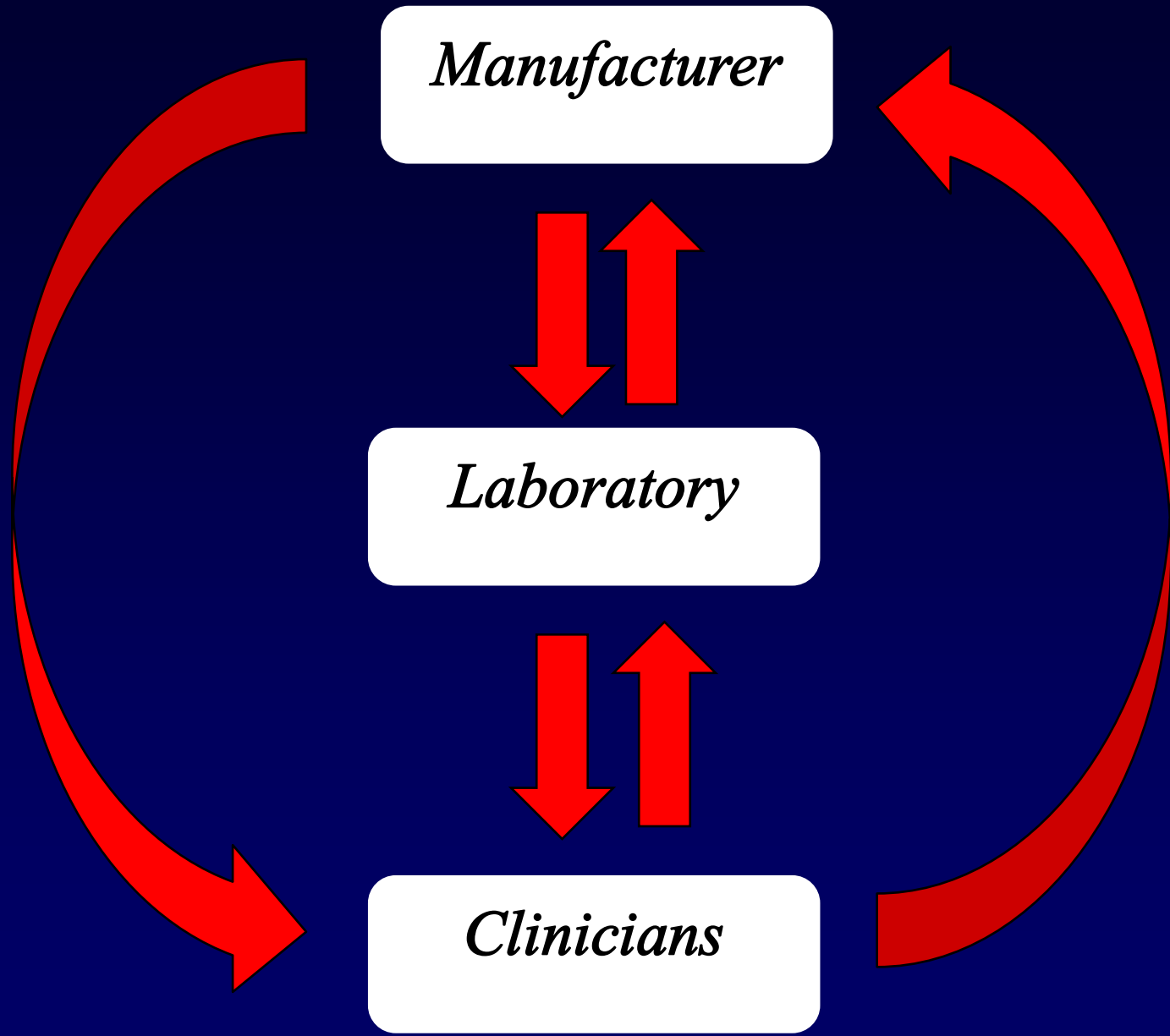
- other than in the central laboratory?

Education

Economy

- who shall pay?

Responsibility



POC instruments outside the hospital

What are the physicians and the patients interested in?

- Which constituents that shall be analysed.
- That the results are correct.
- To have someone to consult with when something goes wrong.
- Advices about what instruments to use.
- Correct interpretations of the results.

Can we provide this service?

Self-measurements

INR, glucose, creatinine and

It is about patient empowerment

INR: Strong evidence (e.g. Cochrane reviews) showing that self-measurement and dosing gives better results than ordinary practice.

Glucose: Much weaker evidence, especially in type II patients

Self-management Creatinine / BP

Kidney transplant patients

Results are loaded into a web page and automatic feed-back is given dependent on the results and trend analyses.

Patient empowerment!!

Paul van der Boog, Leiden

Decentralized at the Pharmacy??



Who has the responsibility?



Psychemedics PD
 Hair Drug Test
 Your Price: \$59.8



Home Access
 HIV Tests

Price: \$43.85



BIOSAFE PSA4
 Prostate Cancer Test
 Regular Price: \$39.95
 Special Price: \$34.95



Colon Test

- Drug Use**
- Urine Cards
- Urine Combos
- Saliva Tests
- Hair Tests
- Drug/Alc Packs
- Drug Date Rape
- Drug ID Sprays
- Test Supplies
- Treating Teens
- Alcohol Use
- Breath Tests
- Saliva Tests
- Breathalyzers
- Tobacco Use



DrinkSafe
 Date Rape Drink Tests
 Starting Price: \$1.75



Hormones & Minerals

- Female
- Male
- Mineral
- Stress
- AntiOxidant
- Performance
- Sleep

Reproduction

- Infertility
- Menopause
- Ovulation
- Pregnancy

Cancers

- Prostate
- Colon
- Skin/UV Ray

Disease & Infections

- HIV/Aids
- Thyroid
- Alzheimers
- Osteoporosis
- UTI
- Kidney/Bladder
- Hepatitis C

Test Kits

TOP 17 TESTS

- Alcohol Use
- Allergy/Mold
- Blood Type
- Cancers
- Cholesterol
- Diabetes
- Diseases
- DNA Genetics
- Drug Use
- Haz Chemicals
- HIV/Aids
- Hormones
- Infertility
- Menopause
- Thyroid
- Tobacco Use

Test Devices

- Body Fat Scales
- Breathalyzers
- CardioChek
- Cholesterol
- Diabetes Meters
- Carpal Tunnel
- UV Ray/Skin



This is a self-collected laboratory test that measures a substance called Thyroid Stimulating Hormone (TSH). TSH is a hormone that regulates your thyroid gland. If your TSH is high, it may indicate that your thyroid is under active and your health care professional may recommend you monitor an under active thyroid condition.

This will facilitate the
empowerment of the patients

But who looks after the quality

Who is evaluating POC instruments?

“What is missing in the EU is an independent institution that performs regular and critical evaluation of the quality of devices before and also after their market approval.”

Pre- and post-analytical quality assurance

- How to identify the patient?
- How to draw and send the sample?
- Stability, interferences?
- How to report the result?
- How does the physician, co-worker or patient interpret the result?
- What are their actions?

However

The benefit of new point-of-care tests cannot be taken for granted. Health systems have been designed around diagnostic testing performed in the laboratory and are not well adapted to the use of point-of-care testing (neither are we). The coming wave of such technologies therefore demands changes to health systems.

We have to be there

We should be active in “politics” and professional matters

Testing policies need to be updated. The World Health Organization (WHO) and other normative bodies should provide recommendations on how to use point-of-care tests (including guidance on risks, benefits, cost- effectiveness and quality assurance), how to select the right products, and where and how to apply new technologies in relation to existing tests.

Essential POC – testing questions

- ***political***: Do we have the power?
- ***organisational***: Can we do it?
- ***economical***: Can we afford it (or will it save money for the community)?
- ***analytical quality***: Is it good enough?

So the trends are

- ✓ POCT is used in more and more places
- ✓ POCT is better regulated
- ✓ POCT is important for patient empowerment
- ✓ Laboratory people should be more and more involved with POC testing wherever it is performed – and therefore

We have to move out of the laboratory



Thank you