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

Tags: Agamatrix Nugget | iBGStar Diabetes Manager | iPod touch glucose meter | Sanofi iBGStar | Smartphone diabetes management | WellDoc DiabetesManager |
Point of Care
- a lot of possibilities -

New mobile phone to detect bad breath

Devise 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.
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.
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).
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.

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.

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

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.

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

- Automation / Core labs
- Point of Care Testing
- Laboratories for special analyses

Communication

Research
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
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
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?
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