Point of Care Testing in Africa: Embrace rather than Resist
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Medical Devices and Health Technology Assessment: Resolving the Puzzle
Several Definitions of POCT

- Point of Care Testing (POCT) is diagnostic testing performed at or near the site of patient care.

- A test which will result in an action leading to an improved health outcome.
POCT – history

- POCT has been with us for ages.
- Indeed in India, the ancient physician Susrata used ants to diagnose and treat DM.
- An then the British physician tasted the urine of patients with diabetes.
In this work, Willis became the first person in Western medical literature to consider the connection between sugar and diabetes mellitus. "Why the urine of those who are sick with this ill smells so wonderfully sweet, or why it tastes like sweet honey...is a knot not easy to figure out"
ADVANTAGES AND DISADVANTAGES

**Advantages**
- Potential for improved clinical decision making with faster therapeutic turnaround time
- Small sample volume
- Unprocessed samples
- Ease of use
- Ability to rule out injury in preclinical studies
- Portable

**Disadvantages**
- Clinically focused operators
- Inappropriate unauthorized testing and overutilization (with increased costs)
- Regulatory compliance
- Semiquantitative results
- Problems related to urine volume
- Inadequate quality control and documentation
- Poor analytic performance
Despite the fact that the advantages of POC were known, POCT could not be implemented as many instruments were inaccurate and imprecise.

For many years POCT was restricted to glucose, cholesterol and INR.

Expensive with logistical issues.
Fasting growing sector in lab diagnostics due to ........

- Emphasis on primary health care
- Decentralisation
- Turn around time
- Portability of instruments
- Accuracy
- Small volumes

*Five-year compound annual growth rate
Abbreviations: POC, point-of-care; POL, physician office lab.
Source: Enterprise Analysis Corporation
Advances in Technology

- Nano technology and microfluidics are changing the POC landscape on a monthly basis
- Digital revolution and cell phone technology has led to improved connectivity
- Remote clinics can feed their results into the Lab Management Systems
Interoperability Platform

Point-to-point connectivity enables standardized electronic records, remote healthcare and diagnostics, remote clinical care, electronic medical records, and mobile healthcare.
An expanding menu and instruments

Troponins, Myoglobin, D dimer

DRUGS

Thyroid tests

Figure 21. BD FACSPresto™ Platform
Creating Value in the System

Customers Needs...
- Supporting a value-based purchasing strategy
- Shifting procedures to outpatient settings
- Reducing hospital-acquired infections (HAIls)
- Reducing readmissions
- Reducing unnecessary spend
- Others...

...Opportunities for Competitive Positioning
- Competitive differentiation
- Maintain relationships
- Generate new revenue
- Support price strategy
- Identify new customer needs and opportunities
- Others...
POCT Results

- Studies have shown that there is patient satisfaction with POCT.
- Patients prefer finger stick to venepuncture.
- Quality of results is as good as those obtained in the central lab.
- In certain clinics settings improvement in patient management has been shown.
Workforce: Less than 1 laboratory professional per 10,000 people.

Quality: Less than 500 laboratories accredited to international standards and 90% are in South Africa.


ASLM Seminar, 2014
A cycle of distrust
Long test turnaround time
Lost results and Lost samples
Tests disagree with clinical picture
Failure of laboratories

- Lack of personnel
- Brain Drain
- Lack of funds
- Infrastructure unavailable to conduct quality research
HIV is endemic in sub-Saharan Africa (SSA). Over 22.5 million people are living with HIV in the region, with 1.8 million new infections occurring in 2010.

TB

Interpersonal Violence

Non Communicable Diseases

*Lancet, 2013, 381, 113*
Diabetes in Africa

- In 2011, 14.7 million adults in the Africa Region were estimated to have diabetes.

- Over the next 20 years, it is predicted that SSA will have the greatest increase in diabetes prevalence of any region in the world due to rapid urbanisation.
What has changed in Africa

- African governments have been galvanised to improve healthcare by NGOs
- A good example is Treatment Action Campaign (TAC)
TAC was launched on 10 December 1998, International Human Rights Day. Zackie Achmat, whom The New Yorker calls "the most important dissident in the country since Nelson Mandela" Achmat also became famous for his pledge to not take antiretroviral medicines until all South Africans could obtain them.
Specific Factors driving POCT

- Loss of patient follow up
- TAT (main labs)
- Increasing accuracy
- Ease of use and operation by non-technical staff
- Burden of Disease and Changing Lifestyle
- Rural and rough terrain
POINT OF CARE TO THE RESCUE

Solution to this is Point of Care Testing

Point of Care instruments are now more accurate and precise
A Focus on Point of Care (POC) Diagnostics in Africa

The emergence of Point of Care (POC) technologies in recent years presents a significant opportunity to improve access to diagnostic testing in support of care and treatment programs for high priority diseases. However, the uptake of these potentially game-changing technologies has been slow due to the complicated regulatory landscape, the challenges of ensuring test quality as testing is decentralized to more remote settings, and the limited guidance to countries on how to effectively implement these new technologies. To address these issues, the African Society for Laboratory Medicine (ASLM) convened this POC meeting.
Some success stories from Africa

- Focused programs using POCT instruments have been actively pursued in a host of African countries.

- Promoted largely by NGO’s such as PEPFAR, Clinton Foundation in response to the AIDS and TB crisis.
POCT FOR MALARIA

Five percent of African children are killed by malaria, almost 3,000 each day, or the equivalent of seven jumbo jets full of children crashing every day. Up to 23 percent of African infants are born with the malaria parasite.
When the pilot began, waits for CD4 results were long and often fruitless.

Median time from enrolment to the start of treatment dropped from 98 days to 22 days.

50 per cent more patients on average are starting antiretroviral therapy (ART), and doing so more quickly after testing.
POCT as a means to strengthen Health Systems

- Resulted in policy change
- More patients could be screened at sites where it was previously offered
- Results were available immediately, taking 15 days at some centres
- Was integrated with the HIV screening program
- Systems approach which it allows the various building blocks of the health system to work together
- Reduce inequalities in access to health in low and middle income countries

Smart Phone: data and graphic uploaded to cloud for analysis

61 million active sim cards in SA
14 million smart phones

Capture sample
- Manual Entry
- Take picture of barcode

Take picture of rapid test

Enter result

Automatic upload to Cloud Server for analysis and Verification of result
POCT and Participatory Medicine

- Participatory medicine is a model of medical care, based on a team that includes the patient groups, specialized social networks and clinical researchers.

- POCT will play an important role in this rapidly developing form of care as Africa gets connected.
Challenges

- Training
- QA
- Improvement of supply chains so that the tests and treatment are continuously available
EQA

- Not available for all POC tests
- Or not available in a format that can easily be used at the POC setting.
- Novel approach: the Dried culture spot program for TB including web based result management.
- New concern: HIV rapid testing

Dried Culture Spot Program for External Quality Assessment (EQA)

Quality management of Mycobacterium tuberculosis molecular diagnostics

Dried Culture Spot (DCS) technology

DCS are manufactured using Mtb cultures grown in single cell format, followed by chemical and heat inactivation, quantification and spotted onto Muirhead TDN filter cards (LabM, Cape Town, SA). The DCS cards are barcoded and shipped by air at room temperature. Processing of the DCS on-site follows the Xpert MTB/RIF manufacturer’s testing protocol. The program involves two components: (1) verification (results gathered and (2) external quality assessment (EQA) results blinded).

EQA Result Reporting

DCS for EQA

Department of Microbiology, Johannesburg, South Africa


US patent 8,709,712.
Formation of Point of Care Research Network for Africa

- Advance the practice and knowledge of POCT
- Assess the quality of POCT instruments
- Develop training programs
- Carry out outcome based research
Conclusion

- Christopher Price, one of the greatest proponent of POCT described it as a health pathway disruptor.
- We will all have to embrace this change as Point of Care Testing is here to stay and growing annually by 7–8 %, with smaller and more accurate instruments.
Patient management and health systems will be changed forever
It’s a tsunami that we need to embrace and can’t stop
New possibilities are emerging everyday with advances in microfluidics and nanotechnology
Final Thoughts

- Point of Care needs to be exploited for earlier diagnosis and prevention of HIV, Diabetes and Cardiovascular risk, all of which contribute to the increasing burden of disease in Africa but we need to ensure that testing is carried out by trained staff who are competent and satisfy the regulatory environment.
We need to be innovative like this Whale Crier to address Africa’s burden of disease.