

Global Lessons on Access to Testing and Linkage

Rosanna W Peeling Professor and Chair, Diagnostic Research London School of Hygiene & Tropical Medicine Director, International Diagnostics Centre Professor, University of Manitoba



www.idx-dx.org

Land acknowledgement

I would like to acknowledge the Algonquin nation whose traditional and unceded territory we are gathered upon today



- The true meaning of leaving no one behind importance of empowering communities (social and technological innovation)
- Privacy and confidentiality concerns Dean Street model, MSM testing in China, self testing in rural Malawi
- Quality assurance and the power of connectivity
- The laboratory as a Command Centre
- The long road to adoption of new tests

Sustainable Development Goals (SDGs): A Global Pledge to Leave No-One Behind





WHO Sustainable Development Goals. http://www.who.int/sdg/targets/en/

ASSURED Tests to Improve Global Health



- A = Affordable
- <mark>S</mark> = Sensitive
- <mark>S</mark> = Specific
- U = User-friendly
- **R** = Rapid and robust
- E = Equipment-free
- D = Deliverable

- ✓ Affordability
- ✓ Accuracy
- ✓ Accessibility

Mabey D, et al. Diagnostics for the developing world. Nature Rev Microbiol 2: 231-40, 2004.



WHAT ARE SOCIAL INNOVATIONS IN HEALTH?

 a new and unconventional solution developed by various actors (communities, civil society, public sector, private sector) to a health care delivery challenge that enables health care delivery to be more inclusive, effective and affordable for all

• It has a positive effect on people's life beyond health (equity, dignity, empowering people)

A KEY ELEMENT IN THE GLOBAL DEVELOPMENT AGENDA 2030



- Vulnerable population
- People-centred
- Community-based
- Partnership-based
- Inter-sectoral
- Multidisciplinary
- Data-driven

LONDON SCHOOL@

- Adding social value?
- Political buy-in?
- Technologically sound?
- Sustainable?





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Addressing Privacy and Confidentiality Concerns



- **Dean Street Model**: an award winning HIV and sexual health NHS clinic in the heart of Soho supplying care that meets the needs of all patients regardless of sex, gender, sexuality or lifestyle. www.dean.st.
- Crowdsourcing video messaging to reach at risk populations to increase uptake of syphilis testing in MSM populations in China
- Kindness is infectious: Pay it forward model for STI testing
- Challenges of HIV self-testing in rural Malawi







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ISO 15189: Quality Standards for Medical Laboratories





Major Sources of Error:

- Proficiency of personnel
- Condition of the specimens
- Controls
- Reagents
- Equipment
- Interpretation of results
- Transcription of results
- Reporting of results

Quality Systems for Diagnostic Tests and Testing





Point-of-Care Tests: Training and Quality Assurance Challenges





The Need for Connectivity in Zimbabwe



MOH, QA Managers, Reference Labs, NPHL, SCM, Provincial Medical Directors, District and Provincial Hospitals



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Ensuring Quality: The Lab as a Command Centre





The Laboratory needs to take on the role of a Command Centre that provides:

- training, quality assurance and supervision of POC testing sites
- Collate surveillance data and turn data into intelligence for outbreak alerts and control interventions
- Conduct research into implementation

Ref: Boeras DI, Nkengasong JN, Peeling RW. Implementation science: the laboratory as a command centre. Curr Opin HIV AIDS 2017: 12:171–174.



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Explosion in Rapid and Accessible Diagnostic Technologies







STATDiagnostica PositiveID



Great Basin





BioFire

Curetis

Rheonix



Alere

Enigma



Spartan

QuantumDx

Roche



Cepheid

BioCartis





IdahoTechnologies

iCubate

Osmetech

Molbio



Atlas Genetics



Qiagen







Smartphone dongles performed a point-of-care HIV and syphilis test in Rwanda from finger prick whole blood in 15 minutes, operated by health care workers trained on a software app.

-Image courtesy of Samiksha Nayak for Columbia Engineering

Laksanasopin et al. A smartphone dongle for diagnosis of infectious diseases at the point of care. Science translational medicine 7 (273), 273re1-273re1, 2015



Priye, A. et al. A smartphone-based diagnostic platform for rapid detection of Zika, chikungunya, and dengue viruses. Sci. Rep. 7, 44778; doi: 10.1038/srep44778 (2017).



















Fluidigm

Dare to Dream NG-AMR POCT:





Source: US CDC Image Library

- 33, 431 ceftriaxone treatments are given annually In the UK for gonorrhoea (2014)
- Antibiotic susceptibility testing was performed on all available NG isolates
- A modelling study showed that if a 30 min AMR POC test:
 - for NG + penicillin resistance were available , 79% of current tx could be replaced by penicillin
 - for GC + ciprofloxacin resistance were available, 66% of current tx could be replaced by ciprofloxacin
- AMR POCT can:
 - √ reduce loss to follow up
 - V extend the life of current last-line treatment
 - √ be cost-saving

FDA Approval OraSure HIV Test in 2012: Accessibility vs Accuracy



Accuracy	Professional Use		Over-the-Counter	
	Minimum Recommended Performance: lower bound of 2-sided 95% Cl	Actual Performance	Minimum Recommended Performance for the lower bound of 2-sided 95% CI	Actual Performance
Sensitivity	98%	99.3% (98.4-99.7%)	95%	92.98% (86.6-96.9%)
Specificity	98%	99.8% (99.6-99.9%)	95%	99.98% (99.9-100%)

A risk-benefit model showed that in the first year of use:

- ~ 4,500 new HIV infections identified among those not aware of their HIV status
- ~ 2,700,000 who would test negative

~4,000 transmissions would be averted, outweighing the individual risk of ~1,100 false negative results The product would need to have clear messages on the implications of test results

Accelerating Access to Quality-assured Diagnostics





Thank you

- LSHTM/IDC: David Mabey, Peter Smith, Debi Boeras, Maurine Murtagh, Ben Cheng, Joe Tucker, Dan Wu, Noah Fongwen, Adrianna Gonsalves, Jack Butterworth, Carlos Gouvea, Helen Kelly
- Syphilis project: Adele Benzaken, Patricia Garcia, Xiang-Sheng Chen, Bill
 Pape, Dan Fitzgerald, Cathay Wilfert
- SystemOne: Natasha Gous, Brad Cunningham, Jeff Tackle
- Funding: Bill & Melinda Gates Foundation, Grand Challenges Canada, UNITAID, UK EPSRC, European Commission