PUTTING KNOWLEDGE (AND POWER) IN THE HANDS OF PEOPLE: A PARADIGM SHIFT FOR SELF-TESTS

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STRUCTURE OF MY TALK

• Why Empower people with dx tools and options?
• How did HIV self testing generate impact in ten years?
• Did Covid-19 help empower people with a self testing option?
• What’s the evidence on Self sampling for HPV, CT, GC and digital options?
• Why now- TB self sampling and self testing-
• Where do we go now?
PUTTING KNOWLEDGE IN THE HANDS OF PEOPLE: WHY NOW?

- Heightened sense of diagnostics consciousness in the world thanks to COVID-19
- Self testing has played a role in teaching lessons in proactivity, risk perception, preventing exposure, thanks to HIV/COVID-19.
- Overstretched health care systems - disappointed people - delays in service delivery of test results and failed to meet patient and community needs
- Time is ripe for expansion of people centered options!
- Best in class to meet this need/demand:
  - Self testing, self sampling options
To end the HIV epidemic by 2030, UNAIDS 95% individual living with HIV tested -95% treated -95% retained in treatment and care. So we needed to bring people to test and one of the ways to test was HIV self testing.
## SELF TESTING

**A solution that could plug gaps**

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<td>Connects self testers to counselling and care *</td>
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SELF TESTING:
LETS DEFINE IT

• Self testing is a self screening process whereby an end user (self tester) performs a self test on his/her own, collects his/her own sample, interprets, records self test results and proactively seeks linkages to counselling and care
  • Non-reactive results are considered negative.
  • Reactive or preliminary positive test results require a confirmation.

• Self tests in use for infectious diseases are most popularly avataars of RDTs, but with SARS COV-2, molecular tests are also available.
SELF TESTING STRATEGIES

2 Kinds of Strategies

Unsupervised or Unassisted self testing:
Testers understand pre-test information, conduct and interpret self test, and call the counselor for post test linkages.

Supervised or Assisted self testing:
Tester tests with the help of counselors, educators in a supervised setting, where the self testing process is conducted by the participant in a kiosk.
A short technical update on self-testing for HIV

2012: self test approved - technical updates followed and guidelines followed in
HIV Self-testing (HIVST) is the middle road to engagement of populations that are not traditionally served by conventional methods.

USP of convenience, confidentiality, affordability, and non-invasiveness

Minimal evidence of self-harm or domestic abuse consequent to self-tests across 250 studies

HIV ST does not stand to replace conventional testing but it did plug the gaps in service delivery that wasn't met by conventional testing.
HIV self testing in our lab: Since 2008-
Research and policy Gaps
WHO in 2018-2019

- Improve linkages to care post test - Service delivery
- Evidence for Innovations to support the process of testing and linkage
- Evidence for a Greater Use of peer workers in service delivery
- Evidence on Data on public health impact and cost effectiveness, scale up and sustainability.
HIVSMART!—2013

A GLOBAL DIGITAL STRATEGY FOR HIV SELF TESTING
HIV self-testing with digital supports as the new paradigm: A systematic review of global evidence (2010–2021)

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Modern diagnostic technologies for HIV

Nilesh Patel, Angela Karelis, John Em, Pavel Petro

Novel diagnostic technologies, including nanotechnology, microfluidics, omics science, next-generation sequencing, genomics big data, and machine learning, could contribute to meeting the UNAIDS 95-95-95 targets to end the HIV epidemic by 2030. Novel technologies include multiplexed technologies (including biomarker-based point-of-care tests and molecular platform technologies), biomarker-based combination antibodies and antigens technologies, dried-blood spot testing, and self-testing. Although biomarker-based rapid tests, in particular antibody-based tests, have dominated HIV diagnostics since the development of the first HIV test in the mid-1980s, targets such as nucleic acids and genes are now used in nucleoassays, however, nucleic acids and genes can be used in acute diagnosis of HIV. These novel technologies show promise as they are associated with ease of use, high diagnostic accuracy, rapid detection, and the ability to detect HIV-specific markers. Additional clinical and implementation research is needed to generate evidence for the use of novel technologies in a public health approach will be required to address clinical and operational challenges to optimize their global deployment.

Introduction

Diagnosis is crucial to achieve the UNAIDS 95-95-95 targets and control the HIV epidemic. An accurate and timely knowledge of an individual's HIV status is the first step towards control of the disease, because antibodies remain present at a high concentration following acute HIV infection. From a public health perspective, antibody-based rapid tests and laboratory-based tests complement each other well for the diagnosis of HIV infections in low-income and middle-income countries. (HIV)
US, UK, ITALY, NETHERLAND, LATVIA, FRANCE, CANADA have approved tests for sale in Kenya, Brazil, China, and Malta. South Africa has approved self-tests for use. 99 plus countries have HIV ST policies or programs in development. Global momentum on HIV self-testing 2020.
SARS COV-2 SELF TESTING
SARS COV-2 SELF TESTING

- Conventional lab testing:
  - Delays with RT PCR based service delivery - showing up to test, risking contagion, time to test results (2 days (lean season) to 3 weeks)
  - Delta wave: loss of lives because of lag in receipt of test results
  - Failure to honor rapid test results to admission

- Right to know your status: Demand from communities
  - Does not fundamentally harm the system
  - Issues with interpretation of self tests (ways to check on that)
  - Under reporting of test results (surveillance)
SARS COV-2 SELF TESTING : HIGH INCOME SETTINGS
BY FALL 2021

• Critical to know to protect and take an informed action
• Help in preventing onward transmission
• Increase uptake expanded access, especially in areas where affordability was an issue with RT PCR tests (when not free)
• Self testing evolved into a mainstream option for people in high income settings- decisions to attend school, work place, social gatherings, informed decisions were made based on results of self tests
• Self testing followed by self isolation, (if positive) and repeat testing (if in the asymptomatic period), helped contain infections at home. (anecdotal evidence
SARS COV-2 SELF TESTING

• Helped democratize access in high income countries.
• A Gateway to linkages to treatment and care
• Evolved into a risk management tool, and helped avoid exposure to others, and testing and isolation or treatment, helped prevent spread in communities.
• Can help level the inequity in access to dx tools (between high and low/middle income countries)
# Self Sampling for HPV, Chlamydia, Gonorrhea

Covid-19 has massively disrupted screening services for many infections including STBBI.

Communities desire a private option where the wait time in the clinics is reduced and sampling is less intrusive and convenient.

Private clinics offer a self sampling service (takes a week to get results)

Self sampling options for rural women have worked across LMICs

Same day test and treat strategies HPV are demonstrating an impact. ([Lancet, 2022](#))

Self sampling will help managing patient expectations for test results and linked services.
WHY TB?

- Dx - weakest link in TB
- Covid disrupted services for TB;
- Testing closer to home; is the preferred option for many
- Self testing is the best fitting option for home testing
- Reduces the stigma of receiving a Dx in a public setting, while offering privacy to test, at the testers pace, space and convenience,
- But it needs to be smartly executed.
TB: ITS 2022 -
POTENTIAL SOLUTIONS SELF SAMPLING AND SELF TESTING

• Self sampling: preferably oral sampling- simpler solution because HIV has already set the path for it in Southern Africa (60-70% of HIV patients have TB)

• Self testing:
  • Ideal, with digital supports (connected App platform-based instructions) for conduct and linkage if performed privately at home, office, private space, or kiosk.

• Samples:
  1) Oral, 2) Sputum, 3) urine

• Technologies:
  • LAMP and NAAT

• Ideally with Digital supports.
TONGUE SWAB + EXISTING & EMERGING NAATS
URINE SAMPLE + EXISTING & EMERGING RDTs
WHERE DO WE GO?

• Patients - center of engagement
  • Think along the lines of a patient’s journey in health navigation in their contexts
  • Understand their pain points-
  • Use Empathy as our compass

• Engage critical players to help understand the macro picture

• Create a community owned self testing solution that is sustainable and life changing with linked treatment options'

• Intent- thought- action are in alignment
Thank you! —UNITAID, NGOs and Sharon Ann

"Be the change you wish to see in the world."
~Mahatma Gandhi

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