Achieving the first “90”– and doing it right

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Increasing Access & Achieving Global Targets– with goal of 100% accuracy
Scale of HIV testing services (HTS) in low and middle income countries

• Over 150 million testing annually
• Over a billion tests done globally since HIV testing was introduced 30 years ago
• Over 16 million on ART
• HIV testing provided in:
  – Health facilities
  – Communities, mobile, out-reach, stand-alone sites
  – Households and homes
Who are we testing now?

- Pregnant women—testing rates in many African countries over 90%
- People who are motivated and seek testing
  - Traditional VCT or VCT in health facilities
- People living where mobile services reach
  - Community and home testing
- People who access medical services
  - TB, STI, OPD, in-patient wards
Camel testing services for nomads in northern Kenya
Who is getting too much testing?

• Low risk persons who test negative
  – “Window period” repeat testing messages still very common
  – Some HIV negative persons use repeat testing in place of behavior change

• Pregnant women in low prevalence settings
  – Is repeat testing later in pregnancy still needed?
Who are we missing now?

• Family members of ART patients
• Couples
• Men who feel healthy
• Children at risk
• Adults at high risk but afraid of stigma, discrimination
  – Key populations such as IDU, sex workers, prisoners
• High risk but not in a “key population” group
  – Divorced, widowed
• All patients before ART initiation
• Never tested before
  – May indicate fear of testing
Mass media targeting couples, men

“I am a loving father because I know my HIV status”.

CHANUKENI PAMOJA
VCT
VOLUNTARY COUNSELING AND TESTING CENTRES
Testing, counseling, ART, & a shampoo at a site for sex workers, MSM
Realities of point-of-care HIV testing under program conditions

• Testing often done by poorly trained lay providers
  – Too many messages

• Disorganized work space, unsafe practices

• Poor finger-prick or phlebotomy procedures
  – Kenya study found NO staff doing phlebotomy, including finger prick, followed all procedures correctly

• Testing algorithm and procedures not followed
  – SA study found only 3.4% of testing processes followed all 27 steps; lack of timer most common problem
    *Analysis of POCT/VCT performed at South African primary health care clinics. Strategic Evaluation, Advisory and Development Consulting. 2011*

• Hand written record keeping

• Inadequate supervision or quality assurance measures
I just spent 30 minutes talking to a pregnant young girl who tested positive and her partner refuses to get tested.

Oh? But did you manage to talk about...
..FP....
..STI s,
...Male condoms,
..Female condoms,
..ART,
..Disclosure,
....TB,
.....PMTCT,
..Nutrition
... malaria
... safe water and
..Positive living?
Disorganized Workspace

Cluttered workspace

Job aides often posted away from test area
Unsafe Practices

• Inconsistent use (or re-use) of gloves
• Sharps, test device and paper napkin all in one bin
• Open sharps containers
Batch Testing - ANC

Procedure Violations:
- Gloves
- Timer
- Switching test devices
- Recording of results
Poor Record Keeping: name of test, lot #, expiration date often not recorded

Use of un-official note books
Positive results are indicated by a DOT
Severe crowding in many sites

- Health workers overwhelmed with patients in OPDs, ANC
- Health workers making heroic efforts to serve their clients and patients
- But congestion has led to compromised testing practices
What do we know about the rate of mis-diagnoses with rapid testing?

- Very few studies conducted under field conditions
- Quality assurance or proficiency testing not systematically used for corrective actions or shared with testing site
- Anecdotal reports of patients on ART being found to be HIV-negative
Consequences of mis-diagnoses

• **If false positive:**
  – Person tested may be blamed, abandoned, rejected, suffer harm
  – Unnecessary ART
    • Expensive
    • Side effects of drugs?

• **If false negative:**
  – Person may transmit HIV unknowingly
  – Delayed correct diagnosis and treatment

• Potential for law suits and costly settlements
• Staff demoralized, lack of confidence in results
Death sentence

By DIPA GIGMAI and JULIA DAIA BORE

IN A landmark decision yesterday, the National Court at Waigani awarded more than K500,000 to a woman who was wrongly diagnosed as HIV positive and later subjected to sterilisation.

The woman, who did not wish to be named, said the diagnosis had felt like a “death sentence”, which had devastated her personal and family life.

Wrong HIV diagnosis shatters woman’s life

The plaintiff had initially named Dr Glen Mola, former Port Moresby General Hospital chief executive officer Dr Chris Marjen, and the independent State of PNG as first, second and third defendant respectively. She later removed Dr Mola from the list of defendants.

Justice Mark Sevua, in handing down his decision, said: “To me, this is a case of gross negligence and in my opinion, it amounts to the highest degree of culpability.” (See story on Page 2)

He ordered the defendants to pay the legal bills of the plaintiff, apart from the K567,884.02 in damages awarded to her by the court.

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MSF study results

• 2004 study in DRC, Burundi and Ethiopia
• Re-testing of persons in HIV programmes
  – Not all re-tested; not a random sample for re-testing
• 53 false positive patients identified
  – 6 were on ART
  – 2 women and their infants took ARV prophylaxis
  – Many suffered social harms
• Quality improvement measures improved performance
  but did not eliminate false positives in all sites
  – Performance significantly improved in some sites

Shanks et al. False positive HIV diagnoses in resource limited settings: Operational lessons learned for HIV programmes. PLOS One, March 2013, vol 8, issue 3
What can we do to improve accuracy of HIV test results?

- Require training in rapid testing by qualified lab personnel
  - No more “on the job” training
  - Regular refresher training; re-training if changes in test kits used
- **Enforce quality assurance measures**
  - Stop funding if QA not documented
- Encourage “second tester” to confirm results
- Encourage repeat testing if counselor or client unsure of accuracy
- Competency based certification program for testers and counselors
- **Require repeat testing** before starting patients on ART
  - 2013 WHO ART Consolidated Guidelines: “Retesting all people living with HIV before initiating ART is good practice to ensure correct diagnosis of HIV infection.” (page 89)
- Consider screening test in primary health care settings
Pay attention to clients and patients

• If results inconsistent with past testing or reported, offer immediate retesting
• Discordant couples: retest immediately
• If health worker or tester is unsure of results (faint lines), retest immediately
  – If uncertainty persists, retest in 14 days
• Ask another staff member to conduct sample collection and perform test
  – Concept of “second tester”
Should we stop confirmatory testing in primary health care, mobile programs?

• “Same day confirmed results” piloted in Malawi in 2000 when there were no ART sites and:
  – 2 week waiting period for confirmed results
  – 25% to 30% of clients did not receive confirmed results

• But do we still need this approach now?
  – Thousands of ART sites now available for confirmatory testing
  – Community screening with one test and referral for confirmatory to reduce complexity
Simple Procedure But in a Complex Process

~5 step-procedure

1. Perform A1
   - A1+: Report HIV-negative
   - A1-: Repeat A1

2. Perform A2
   - A1+ A2-: Report HIV-negative
   - A1- A2+: Repeat A1 and A2

3. Perform A3
   - A1+ A2-: Report HIV-negative

4. A1- A2-: Report HIV-negative (if A1 is 2nd or 3rd generation assay)
   - Report HIV-inconclusive (retest in 14 days)
   - A1+ A2-: Report HIV-positive (retest in 14 days)
Test for Triage

• One screening test in primary or outreach setting
• Immediate referral for any client or patient who tests reactive on first test
• Eliminates need to train testers in more than one test and stock 2 or 3 different tests
• 3 different tests now recommended by WHO for low prevalence settings
  – As more and more HIV+ identified, many testing sites observe low prevalence, even in high prevalence countries
• Re-testing everyone before ART initiation could also serve as point of confirmatory testing
Challenges of HIV Self-Testing

• Promising technologies and research results:
  – Accurate, low rate of social harms
• Challenges with implementation:
  – Accuracy in real-life situations unknown
  – If HIV+, not a confirmed diagnosis, rate of going for confirmation and enrollment in ART is unknown
• Opportunities:
  – Re-testing for high risk HIV-negative persons
    • Discordant couples, people on PrEP, key populations
  – Identify HIV+ persons early
• But: if HIV+, should people learn such a serious test result alone?
Summary—Getting to the First 90% with 100% accuracy

• Many millions already tested and on ART
• Challenge now is to find those who do not know current HIV status
• Window period repeat testing not needed unless high risk
• Mis-diagnosis occurs with profound consequences
• Test for Triage may simplify process and thus reduce errors
• Goal of 90% of HIV+ identified achievable
• Goal of 100% accuracy essential
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