HIV Point of Care Diagnostics & Monitoring Experience

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HIV PoC diagnosis and monitoring experience in MSF

• HIV RDTs
• CD4: PIMA
• Planned trials:
  - other CD4 PoC (Zyomyx, Daktari, Burnet etc.)
  - VL (SAMBA, Cepheid etc.)
  - EID (NWU, SAMBA etc.)
HIV RDT use in numbers in MSF

- 2011: > 1.2 million RDTs (Determine, Uni-Gold, ImmunocombFirm, Stat-Pak, SD Bioline etc.)
- 2012: >1.0 million RDTs (Determine, Uni-Gold, ImmunocombFirm, INSTI, Genie III, Stat-Pak, KHB)
- 2013 (1st half): > 650,000 RDTs (Determine, Uni-Gold, ImmunocombFirm, Genie III, Stat-Pak)
HIV RDT use in MSF

- Use: Screening of potential blood donors, classical VCT, PICT, ANC, PMTCT, HCT, community based testing etc.
- Mostly CT carried out by other actors – MSF focus on treatment provision in recent years
HIV RDT use – Barriers on uptake

- Lack of knowledge on HIV
- False perception of risk of being infected (not feeling sick)
- Fear of stigma (incl. VCT not confidential enough)
- Impact of positive results (socially, economical etc.)
- Accessibility of VCT services
- Poor planning of CT: stock ruptures, staff availability
- If PICT: patient often not counseled by physician who orders test > refusal testing (need for counselors)
HIV RDT use – Testing procedure

- Kit not properly stored
- Kit used after expiration date
- Identity of client not checked
- Deposit of blood directly on device (e.g. on Determine strip)
- Using wrong tool when measuring blood (i.e. wrong blood volume used)
- Buffer substituted with water, saline, water for injection etc.
- Not respecting incubation time (reading result when control band appears)
- No supervision of counselors when testing is carried out
HIV RDT use – Algorithm

• Many locations still using a serial algorithm with tie-breaker
• Tests used according to availability (test 2 used first when stock of test 1 low), or any test available bought locally but not pertaining of the national algorithm
• No tracking the results of the samples sent to the reference lab for confirmation
• Poor follow-up of indeterminates
HIV RDT use – Quality control and supervision

• No organized supervision of operators by local or national authorities
• Staff refusing to be supervised (e.g. a staff in charge of VCT refusing to be supervised by the head of lab of the hospital)
• HIV positive sero-status announced with only one positive test
• No regular internal QC (also lack of QC material!)
• No external QC enrollment
HIV RDT use – Linkage

• Positive status Test does not mean care
• Linkage to care is poor.
• Recent data from a project in South Africa (>15,000 tested with 5.2% pos rate) linked 42% to facility based care
  - mobile testing unit - 43%;
  - stand-alone fixed testing site – 36%;
  - home-based CT – 45%.
HIV RDT use – Actions taken

- Design & roll-out of supervision checklists
- Operational research & data analysis of routine programmes


*False positive HIV diagnoses in resource limited settings: operational lessons learned for HIV programmes.*

Shanks L, Klarkowski D, O’Brien DP.


*The evaluation of a rapid in situ HIV confirmation test in a programme with a high failure rate of the WHO HIV two-test diagnostic algorithm.*

Klarkowski DB, Wazome JM, Lokuoge KM, Shanks L, Mills CF, O’Brien DP.


*Evaluation of four rapid tests for diagnosis and differentiation of HIV-1 and HIV-2 infections in Guinea-Conakry, West Africa.*

PIMA use in numbers in MSF

- 2011: 24 analyzers and > 10,000 cartridges
- 2012: 2 analyzers and > 13,000 cartridges
- 2013 (1st half): 7 analyzers and > 20,000 cartridges
PIMA use

• Use: in centralized and decentralized settings - depending on number being monitored

• Limitations
  - No % for monitoring children,
  - Price 6 USD per cartridge
PIMA use - problems

- Number of rejected cartridges (13% average in recent analysis)
- Operating temperature: technical problems >30°C
PIMA – rejected cartridges & error analysis

- From 01-2011 to 06/2013 in 9 countries in sub-Saharan Africa in labs, mobile teams, clinics, laboratories
- 13% errors per device (2.2 – 28.3%); 92.5% of instruments had an invalid rate of > 5% (Alere’s rec)
- 12.2 % per user (in users ≥ 50 tests) 1.3 - 49.2%
- 62% on whole blood EDTA and 38% on capillary blood; error rate on capillary lower (12%) than whole blood (14%), p<0.0001
- Implications: increase price of > 20,000 USD (cartridge based), increases TAT and reduces testing throughput, re-sampling needed if capillary blood used, loss of confidence in test and frustration by end-user
What future PoC do we want?

- Instrument-free or handheld analyzer
- Transparency of manufacturer’s on cost and cost reduction overtime and with bulk procurement
- No monopoly
- Connectivity for proper data management, monitoring and troubleshooting
- ‘Quality assured’ production
THANK YOU

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