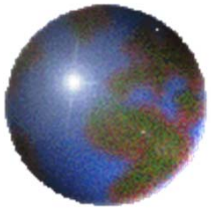

HIV Point of Care Diagnostics & Monitoring Experience

MEDECINS SANS FRONTIERES

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Leader Diagnostic Network

October 2013

HIV PoC diagnosis and monitoring experience in MSF

- HIV RDTs
- CD4: PIMA
- Planned trials:

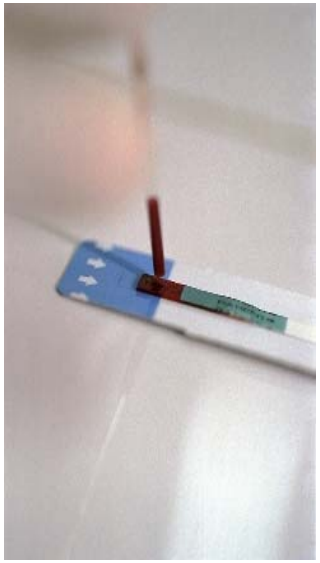
  - other CD4 PoC (Zyomyx, Daktari, Burnet etc.)
  - VL (SAMBA, Cepheid etc.)
  - EID (NWU, SAMBA etc.)

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

PLoS One. 2013;8(3):e59906. doi: 10.1371/journal.pone.0059906. Epub 2013 Mar 20.

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

Shanks L, Klarkowski D, O'Brien DP.

PLoS One. 2009;4(2):e4351. doi: 10.1371/journal.pone.0004351. Epub 2009 Feb 6.

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, Lokuge KM, Shanks L, Mills CF, O'Brien DP.

Trans R Soc Trop Med Hyg. 2010 Sep;104(9):571-6. doi: 10.1016/j.trstmh.2010.05.007. Epub 2010 Jun 17.

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

Chaillet P, Tayler-Smith K, Zachariah R, Duclos N, Moctar D, Beelaert G, Fransen K.

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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