Clinical Management Guidelines for HIV/AIDS - 2011

National HIV/AIDS Programme

Ministry of Health

August 2011

Background

- Only published guidelines done in 2003
- PMTCT guidelines updated in 2010
- PEP guidelines updated in 2010
  - Reflect non-occupational exposure
- T&C – updated in 2009
- Partner notification in 2008
- STI guidelines in 2005
- TB in 2011

Current HIV situation

- Decreasing trend for 2 years in a row
  - 33.8% decrease when compared to 2009 (2010)
- Total number of AIDS related deaths with few variations in total numbers
- Scale up in testing and in ARV treatment
- Expansion of services
- Budgetary increase
- Wider integration in regional activities with multiple stakeholder funding

HIV/AIDS Statistics 2010

- 244 new HIV infections
- 106 new AIDS cases
- 81 AIDS related deaths
- 29 cases of TB/HIV co-infection
- 93.2% coverage in pregnant women

PMTCT

- 53 documented cases in pregnant women
  - 33 were newly diagnosed
- 50 women received ARVs while pregnant
- 55 deliveries in 2010
- 54 received ARVs at time of delivery
- 100% coverage of babies exposed

ARV coverage

- End of 2010 – 1049 patients on ART
- At July 2011 – 1,228 patients on ART
  - 1,119 adults on therapy
  - 109 pediatric cases
- 10 adult regimens
- 2 pediatric regimens

ARV Regimens

- 482 patients on ZDV/3TC/NVP
- 93 patients on ZDV/3TC/IDV
- 19 patients on D4T/3TC/IDV
- 33 patients on D4T/3TC/NVP
- 347 patients on ZDV/3TC/EFV
- 39 patients on D4T/3TC/EFV
- 55 patients on FTC/TDF/EFV
- 36 patients on FTC/TDF/ IDV
- 11 patients on FTC/TDF/NVP
- 4 patients on FTC/TDF/ FPV

ARV pediatric regimens

- 95 cases on ZDV/3TC/NVP
- 14 cases on ABC/dDI/LPV/r

Prophylaxis

- Specific protocol for occupational and non-occupational exposure to HIV
  - ZDV/3TC or TDF/FTC
  - + (expanded) LPV/r or IDV/r
- Not in protocol:
  - Use of INH for HIV
- In PMTCT protocol:
  - Use of TMP/SMX in exposed babies

Treatment sites

- Corozal
- Orange Walk
- Belize City (BDF, KHMH, HHM, San Pedro, Kolbe Foundation) – other pharmacies
- Cayo (San Ignacio and Belmopan)
- Stann Creek
- Toledo

Funding

- In 2008-2010 funding was from MOH
- Donations are ad hoc
- In 2011, $200,000.00 is for ARVs
- Budget for 2011-2012 is around $700,000.00
  - We can probably buy ARVs for all patients in need with ~$350,000.00
  - Direct procurement from pharmaceutical company

Plan / Agenda

- In the pipeline for an extended period
- Technical assistance from PHCO and financial assistance from GF/UNDP
- Weekly plan that included:
  - Monday – Initial brainstorming and debriefing with CEO
  - Tuesday – wider stakeholders consultation (Arriaga, Osorio, Pacheco, Eck, Melhado, Anderson, Andrewin)
  - Wednesday & Thursday – Review of final document

Plan / Agenda

- Socializing with technical counterparts
- Specific deadlines for:
  - Feedback from technical partners
  - Final review
  - Approval of DHS
  - Printing
  - Sensitization with national stakeholders
    - University of Washington offer

Major changes

- Document is shorter – more succinct
- Concentrating on:
  - What and when to start
  - When to switch
  - HIV and co-infections
  - Prophylaxis for OIs
  - HIV and Co-morbidities
  - Pediatric & adolescent section

When to start

- Adults:
- CD4 count under 350 or with WHO stage 3 and 4 disease
- Adults under 500 will be considered:
  - If patients are ready, willing and understand the consequences of ARV initiations
  - Rapidly declining CD4 count (drop of 50/6 months) or high viral load

What to start

- 4 options for naïve treatment in adults (1st line)
  - AZT + 3TC + NVP
  - AZT + 3TC + EFV
  - TDF + FTC + NVP
  - TDF + FTC + EFV
- For those on current treatment regimens – will remain as is

Failure	Definition	Comments
Clinical failure	New or recurrent WHO stage 4 condition	Condition must be differentiated from immune reconstitution inflammatory syndrome (IRIS) Certain WHO clinical stage 3 conditions (e.g. pulmonary TB, severe bacterial infections), may be an indication of treatment failure
Immunological failure	Fall of CD4 count to baseline (or below) OR 50% fall from on-treatment peak value OR Persistent CD4 levels below 100 cells/mm^3	Without concomitant infection to cause transient CD4 cell decrease
Virological failure	Plasma viral load above 5000 copies/ml	The optimal viral load threshold for defining virological failure has not been determined. Values of >5 000 copies/ml are associated with clinical progression and a decline in the CD4 cell count

Patient switch – 2nd line

- Adults: same backbone (AZT/3TC or TDF/FTC) + LPV/r
- When: Clinical / virological / immunologic failure
- 3rd line / salvage therapy:
  - On an individual basis
  - Decided by a committee with specific recommendations to National Programme

Prophylaxis

- INH
- TMP/SMX

HIV & co-morbidities

- Specific recommendation/suggestion for pregnant women
- Specific recommendation for HBV
- Specific recommendation for TB
- The other OIs were aligned to our reality with medications available for Belize and with current reported more common OIs

HIV & co-morbidities

- Sickle cell disease
- Neuropsychiatric disorders
- Sickle cell disease
- Malaria
- Other STIs

HIV & Co-morbidities

- Metabolic complications in ART
- Renal disease
- Insulin resistance and diabetes
- Bone metabolism
- Chronic liver disease
- Elderly patients

Pediatric population

- 1st line therapy:
  - AZT + 3TC + NVP
- 2nd line option:
  - ABC + dDI + LPV/r

When to switch?

- Clinical failure is defined as the appearance or reappearance of WHO clinical stage 3 or stage 4 events after at least 24 weeks on ART in a treatment-adherent child.
- Virological failure is defined as a persistent viral load above 5,000 RNA copies/ml, after at least 24 weeks on ART, in a treatment-adherent child.
- Immunological failure:
  - CD4 count of <200 cells/mm3 or %CD4+ <10 for a child ≥2 years to <5 years of age
  - CD4 count of <100 cells/mm3 for a child 5 years of age or older