ART in Myanmar

Dr. Mar Mar Aye
Consultant Physician
Mandalay General Hospital ( MGH )
“Support needing populations through medical assistance and the transfer of knowledge to local medical practitioners.”

Our vision for the Medical Assistance & Medical Education (MAME) Programs
Antiretroviral therapy in myanmar

Dr Mar Mar Aye
Consultant Physician
Mandalay General Hospital ( MGH )
9.1.2015
Background
Milestones in HIV Medicine

- Discovery HIV virus
- First AIDS case Diagnosis
- HIV Diagnostic Test
- CD4 cell count
- First ARV AZT
- Viral Load Assay
- New ARVs for Multi-class failure
- Genotypic Resistance Testing
- HAART Triple ARVs
- Tropism Test
- Once daily HAART More tolerable More durable

9.7 million people on ART by end of 2012 - 1.6 million more than at the end of 2011

Actual and projected numbers of people receiving antiretroviral therapy in low-and middle-income countries, and by WHO Region, 2003–2015

WHO’s public health guidelines on ART: from “3 by 5 Initiative” to Universal Access
When to start ART: what is new since 2010?

• **Strong evidence** of the impact of ART on HIV transmission:
  - HPTN 052 study

• **Emerging data** on the impact of ART on HIV incidence at the population level

• **Increasing evidence** on clinical benefits of early ART initiation:
  - Observational studies showing impact on HIV mortality and morbidity
  - Scientific insights on HIV immunopathogenesis and on the effects of chronic inflammation associated with HIV infection

• **Better regimens**:
  - Better tolerable drugs
  - Better formulations
  - New classes
Increasing evidence that ART should be used earlier rather than later

Likely benefits of earlier initiation
– improves clinical benefits (AIDS & non-AIDS)
– decreases risk of TB
– offers medium and long term cost-saving opportunities

*but*
– could increase toxicities and risk of drug resistance
– increase up-front costs
– might limit preservation of treatment options
Risk of developing TB in HIV infected patients
Current Ultimate Goal of HAART

- **CD4+ T-cells**
- **Plasma HIV Viremia**
- **HAART**
- **Clinical outcomes**
  - No AIDS-complication
  - No non-AIDS-complication

Limit of detection

Relative Levels

Years After HIV Infection
Tools to Achieve Treatment Goals

- Optimizing of ARV regimen: right drug for right person
- Maximizing adherence
  - Compliance is very important!!!!
- Pretreatment resistance testing
- Discuss need for regular follow up
- People on ART still need to use condoms
Adherence versus Viral Load

Percent adherence to therapy

Undetectable viral load

From Peterson et al, 6th Conf ROI abstr #92
Adherence versus Viral Load

If you take 80-90% of your pills, only 50% chance of success.

From Peterson et al, 6th Conf ROI abstr #92
Adherence vs Response

HIV RNA below detectable * (%)  CD4 cell change (cells/mm³)

If you take 70-80% of your pills, CD4 count will go down.
Important messages when starting ART

Patients should understand

- that ART is suppressive therapy
- that ART is life-long
- that near perfect adherence is necessary to prevent ART resistance
- that there are possibilities of side effects
**Major Targets of Antiretroviral Agents**

**RT Inhibitors**
- **NRTI**: AZT, ddI, ddC, d4T, 3TC, ABC
- **NNRTI**: NVP, EFV, ETV
- **NTRTI**: Tenofovir

**Protease Inhibitors**
- SQV, RTV, IDV, NFV, AMV, LPV/rtv, ATV, fAMP, DRV

**Entry Inhibitors**
- CCR5: Maraviroc
- **Fusion gp41**: Enfuvirtide

**HIV**

1. **RNA**
2. **DNA**
3. **Integrate**
4. **Transcription**
5. **Genomic RNA**
6. **Protease**

**Spliced mRNA**

**Integrate inhibitors**
- Raltigavir
### Classes of ARVs – clinical practice

<table>
<thead>
<tr>
<th>NRTI</th>
<th>PI</th>
<th>NNRTI</th>
<th>Fusion inhibitors</th>
<th>Entry inhibitors</th>
<th>INSTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine</td>
<td>Saquinavir</td>
<td>Nevirapine</td>
<td>Enfuvirtide</td>
<td>Maraviroc</td>
<td>Raltegravir</td>
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<tr>
<td>Didanosine</td>
<td>Ritonavir</td>
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<tr>
<td>Stavudine</td>
<td>Indinavir</td>
<td>Efavirenz</td>
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<tr>
<td>Lamivudine</td>
<td>Nelfinavir</td>
<td>Etravirine</td>
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<tr>
<td>Abacavir</td>
<td>Lopinavir/r</td>
<td></td>
<td>Rilpivirine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenofovir</td>
<td>Atazanavir/r</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>Fosamprenavir</td>
<td></td>
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<tr>
<td></td>
<td>Tipranavir</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Darunavir</td>
<td></td>
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</tbody>
</table>
When to Start ART
When to start ART in Adults & Adolescents
Myanmar National Guideline 2011

• HIV positive **asymptomatic** ARV naïve individuals –
  CD4 \( \leq 350/\text{mm}^3 \)

• HIV positive **symptomatic** ARV naïve individuals –
  WHO stage 2 if CD4 \( \leq 350/\text{mm}^3 \)

  or WHO stage 3 or 4 irrespective of CD4 count
Starting ART in specific situations

- **HIV positive pregnant women** with CD4 ≤ 350/mm³ irrespective of clinical symptoms or WHO clinical stage 3 or 4 irrespective of CD4 count

- **HIV/TB co-infection** ARV naïve individuals – presence of active TB if CD4 < 500/mm³ (MDR TB, ART regardless of CD4 count)

- **HIV/HBV co-infection** – individuals who require treatment for their HBV infection regardless of CD4 count
When to start ART (WHO 2013)

- Threshold moved to ≤ 500 CD4
- Priority for reaching all HIV+ symptomatic persons and those with CD4 ≤ 350
- More CD4-independent situations for ART initiation (in addition to HIV/TB co-infection and HBV advanced liver disease):
  - HIV serodiscordant couples
  - Pregnancy

GL are a “tool” for countries to produce their own guidelines: they will adapt the new threshold(s) with operational / programmatic local context
WHAT ART REGIMEN TO START
Why always use three drugs

1991–1995: Dual nucleoside
1996–today HAART

Log change in HIV RNA from baseline

HAART + good adherence
First Line Antiretroviral Drugs in Myanmar (2011 National guideline)

3 drug combinations should always be used for antiretroviral therapy.

1. AZT +3TC + EFV (*)
2. AZT +3TC+ NVP (*)
3. TDF +3TC/FTC + EFV (*)
4. TDF +3TC/FTC + NVP
5. d4T*+3TC/EFV
6. d4T*+3TC+NVP

(*) Preferred First Line ART regimen
3 drug combinations should always be used for antiretroviral therapy.

<table>
<thead>
<tr>
<th>No</th>
<th>ART Regimen</th>
<th>Recommended Regimen %</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TDF +3TC (FTC) + EFV</td>
<td>77%</td>
<td>Preferred first line regimen</td>
</tr>
<tr>
<td>2</td>
<td>AZT +3TC + EFV</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>AZT +3TC+NVP</td>
<td>5%</td>
<td>Alternative first line regimen</td>
</tr>
<tr>
<td>4</td>
<td>ABC+3TC+EFV</td>
<td>7%</td>
<td></td>
</tr>
</tbody>
</table>

*(d4T* is phasing out gradually and will not be available beyond 2015)*
Number of PLHIV receiving ART

67,643 on ART for 2013... reports being compiled for final figures
HOW TO MONITOR AND WHEN TO SWITCH
Monitoring ART in those at higher risk of adverse effects

<table>
<thead>
<tr>
<th>ARV drug</th>
<th>Major toxicity</th>
<th>High-risk situations</th>
</tr>
</thead>
<tbody>
<tr>
<td>d4T</td>
<td>Lipodystrophy, neuropathy, lactic acidosis</td>
<td>Age &gt; 40 yr, CD4 &lt; 200/mm3, BW &gt; 75 kg, INH or ddI use</td>
</tr>
<tr>
<td>AZT</td>
<td>Anaemia, neutropenia</td>
<td>Anaemia at baseline, CD4 &lt; 200/mm3, BW &lt; 50 kg</td>
</tr>
<tr>
<td>TDF</td>
<td>Renal dysfunction</td>
<td>Underlying renal disease, age &gt; 40 yr, BW &lt; 50 kg, diabetes, hypertension, PI or nephrotoxic drugs</td>
</tr>
<tr>
<td>EFV</td>
<td>Teratogenicity</td>
<td>First trimester of pregnancy</td>
</tr>
<tr>
<td>NVP</td>
<td>Hepatotoxicity</td>
<td>Depression or psychiatric illness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HCV and HBV co-infection</td>
</tr>
</tbody>
</table>
## Monitoring

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC, CD4</td>
<td>Every 4-6 months</td>
</tr>
<tr>
<td>HIV viral load</td>
<td>Every 6-12 months</td>
</tr>
<tr>
<td>FBS, lipid profile, UA, Electrolyte</td>
<td>Every 6-12 months</td>
</tr>
<tr>
<td>SGOT, SGPT, Cr</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>HBsAg, Anti-HCV</td>
<td>At beginning</td>
</tr>
<tr>
<td>CXR</td>
<td>At beginning</td>
</tr>
<tr>
<td>Pap smear</td>
<td>At beginning and annually</td>
</tr>
</tbody>
</table>
# Recommendations: Monitoring for ART Response

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
<th>STRENGTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral load is recommended as the preferred monitoring approach to diagnose and confirm ARV treatment failure</td>
<td><em>Strong recommendation, low-quality evidence</em></td>
</tr>
<tr>
<td>If viral load is not routinely available, CD4 count and clinical monitoring should be used to diagnose treatment failure</td>
<td><em>Strong recommendation, moderate-quality evidence</em></td>
</tr>
</tbody>
</table>
Evolution of CD4 Count and Viral Load after Starting ART

- ART 1st line
- ART 2nd line
- Stop CPT
- Immuno failure
- Virological failure

CD4
VL
< 200 CD4/μl
< 50 cp/ml

Start CPT
Time

Virological failure
## ART switching criteria for failure

<table>
<thead>
<tr>
<th>Failure</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical failure</td>
<td>New or recurrent WHO stage 4 conditions</td>
</tr>
<tr>
<td>Immunological failure</td>
<td>Fall of CD4 to baseline or below or 50% fall from on-treatment peak or persistent CD4&lt;100</td>
</tr>
<tr>
<td>Virological failure</td>
<td>Plasma viral load &gt; 1000 copies/ml</td>
</tr>
</tbody>
</table>
WHAT ART TO SWITCH TO
### Summary of changes to recommendations: What ART to Switch to

<table>
<thead>
<tr>
<th>TARGET POPULATION</th>
<th>WHAT TO SWITCH IN ADULTS (PREFERRED REGIMENS)</th>
<th>2010 ART GUIDELINES</th>
<th>2013 ART GUIDELINES</th>
<th>STRENGTH &amp; QUALITY OF EVIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV+ ADULTS AND ADOLESCENTS</strong></td>
<td>If d4T or AZT used in first-line</td>
<td>TDF + 3TC (or FTC) + ATV/r or LPV/r</td>
<td>No change</td>
<td>strong, moderate-quality evidence</td>
</tr>
<tr>
<td></td>
<td>If TDF used in first-line</td>
<td>AZT + 3TC + ATV/r or LPV/r</td>
<td>No change</td>
<td>strong, moderate-quality evidence</td>
</tr>
<tr>
<td><strong>HIV+ PREGNANT WOMEN</strong></td>
<td>Same regimens recommended for adults</td>
<td>No change</td>
<td>No change</td>
<td>strong, moderate-quality evidence</td>
</tr>
<tr>
<td><strong>HIV/TB CO-INFECTION</strong></td>
<td>If rifabutin available</td>
<td>Same regimens as recommended for adults</td>
<td>No change</td>
<td>strong, moderate-quality evidence</td>
</tr>
<tr>
<td></td>
<td>If rifabutin not available</td>
<td>NRTI backbone plus LPV/r or SQV/r with adjusted dose of RTV (i.e., LPV/r 400mg/400mg BID or SQV/r 400mg/400mg BID)</td>
<td>No change</td>
<td>strong, moderate-quality evidence</td>
</tr>
<tr>
<td><strong>HIV/HBV CO-INFECTION</strong></td>
<td>AZT + TDF + 3TC (or FTC) + (ATV/r or LPV/r)</td>
<td>No change</td>
<td>No change</td>
<td>strong, moderate-quality evidence</td>
</tr>
</tbody>
</table>
Major opportunistic infections

1. Mycobacterium tuberculosis
2. Pneumocystis jiroveci pneumonia
3. Cerebral toxoplasmosis
4. Cryptococcosis
5. Systemic penicilliosis
## Optimal Timing to initiate HAART in Patients with Active OIs

<table>
<thead>
<tr>
<th>Active OIs</th>
<th>When to start</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| **Tuberculosis** | **CD4 <50**\(^\text{1,2}\)  
Within 2 weeks of the Diagnosis  
**CD4 higher**  
Within 8 weeks of the Diagnosis | **TB meningitis**\(^\text{3}\): is less certain  
Treatment at 2 wks had more severe AEs than at 8 wks of TB Rx |
| **Cryptococcosis** | **Less certain** | Early Rx (3 days) was associated with 2.85x risk of death vs 10 weeks\(^\text{4}\) |
| **Other OIs**   | **Within 2 weeks after OI diagnosis** |                                                                          |

\(^\text{1}\)Abdool Karim SS, et al. NEJM. 2011;365:1492-1501;  
\(^\text{3}\)To´ró´k ME, et al. CID. 2011;52:1374-1383;  
ARV Toxicities

- Initial problems tolerating therapy
- Hypersensitivity reactions
- Immune-reconstitution related
- Chronic toxicities
- Drug-drug interactions
Guiding principles in the management of ARV drug toxicity

1. Determine the seriousness of the toxicity
2. Evaluate whether the toxicity is attributable to ARV or non-ARV drug(s)
3. Consider other disease processes (e.g. viral hepatitis if jaundice)
4. Manage the adverse event according to severity
Guiding principles in the management of ARV drug toxicity: In general:

**Grade 4** (severe life-threatening reactions)
- Immediately discontinue all ARV drugs until the patient is stabilized
- Symptomatic and supportive therapy
- Introduce ARV drugs using a modified regimen when the patient is stabilized

**Grade 3** (severe reactions)
- Substitute the offending drug without stopping ART
Guiding principles in the management of ARV drug toxicity (continue)

**Grade 2** (moderate reactions)
- Consider continuation of ART as long as feasible
- If the patient does not improve on symptomatic therapy, consider single-drug substitution

**Grade 1** (mild reactions)
- do not require changes in ART
- Stress the maintenance of adherence despite toxicity for mild and moderate reactions
Single-drug switching for toxicity

- AZT intolerance (anaemia) → TDF OR d4T
- d4T intolerance (neuropathy) → AZT OR TDF
- Nevirapine intolerance (rash) → efavirenz
- Efavirenz intolerance (CNS toxicity) → Nevirapine
Potential Concern When Stopping Drugs With Different Half-lives

Drug Concentration vs. Time (Hours)

- Last Dose
- Day 1
- Day 2-weeks

Drugs:
- AZT
- 3TC
- NVP or EFV

Zone of potential replication

MONOTHERAPY

IC\(_{90}\)

IC\(_{50}\)

S. Taylor et al. 11th CROI  Abs 131
Discontinuation of ARV due to toxicity

- If ARVs are discontinued, stop all ARVs simultaneously unless the regimen includes an NNRTI.
- Long half-life of NNRTI may lead to effective monotherapy.
- Stop NNRTI and continue other ARVs (2 NRTIs) for at least 7 days (optimal time is not known) before discontinuing all, or substitute PI for NNRTI for a period before stopping all.
- To avoid NNRTI resistance.
Cotrimoxazole Preventive Therapy (CPT)
WHO Guideline

- In resource limited setting
- Start at CD4 \( \leq 350 / \mu l \), all symptomatic individuals including pregnant women
  (WHO clinical stages 2, 3 or 4)

- Prevent the PCP, Cerebral Toxoplasmosis
- Also prevent the bacterial diarrhoea & chest infection, malaria

- Skin reaction is the commonest side effect
Human Tuberculosis

• Infection with M.tb complex.
• 2 clinical states- (1) TB infection.
(2) TB disease (active TB)
TB Risk with HIV Infection

- Exceptionally high rate of reactivation of latent infection (7-10% per year)
- Rapid progression to TB following new infection
- Increased risk begins soon after HIV infection and increases as immunosuppression increases
- Increased risk is reduced but not eliminated by antiretroviral treatment
- Increased potential for reinfection after successful treatment for TB
Natural Course of TB Infection and interventions**

1. TB disease
2. Primary infection → Bacilli
   - **(2)**
   - **(4)**
3. Latent TB infection
   - **(5)**
   - 5-10% annual risk (PLHIV)
   - 5% life-time risk (normal)
   - TB disease: post-primary TB
   - **(2)**
   - Re-infection
Preventing HIV-associated TB

- Primary prophylaxis
- TB preventive therapy: treatment of LTBI
- Restore protective immunity: ART
Treatment of Latent Tuberculosis Infection (LTBI)

Isoniazid Preventive Therapy (IPT)
Isoniazid Prophylaxis Therapy (IPT)

- WHO has recommended at least 6 months of isoniazid prophylaxis therapy (IPT) for PLHA-Children and adults and those receiving ART
- Reduce the risk of developing TB by 33%
- Active TB can be excluded by the use of a simplified screening algorithm that relies on four clinical symptoms.
- symptoms of current cough, fever, weight loss or night sweats
IPT (Cont’d)

• dose of 300 mg/day for 6-9 months
• INH resistance is not significantly associated with providing IPT
• is being evaluated by the NTP in a pilot project in 9 townships for introducing it on a wider scale
Mandalay General Hospital

ART Supply Programme & HIV Care

Dr Mar Mar Aye
(MGH)
MU I OPD  – Started in May 2005
• Tuesday and Friday (Morning)

MU II OPD  – Started in April 2007
• Monday and Thursday (Morning)

MU III OPD(TB/HIV) – Started in August 2009
• Wednesday and Friday (Evening)

Pre-ART OPD – Started in March 2011
• Thursday (Evening)
  ➢ NAP Team Leaders attend OPD regularly
Human Resources in medical units OPD

• One physician, one Assistant surgeon and at least 4 HIV coordinators - attend to the IHC OPD

• 2 nurses & one manual worker of medical ward - drug dispensing

• PLWHA - 3 volunteers - help registration, patient flow

• One expert patient – for discussion, providing information, solving social problems of patients, etc
DA Counseling and defaulter tracing

- Drug adherence counseling three sessions was provided by the **medical social workers** from MGH as well as from the VD/STD clinic
Drug Delivery system

• Two Nurses from medical units are distributed the ARVs/ OI drugs and investigation request form to the patients at the day of OPD

• At the end of every month, the nurses provide the monthly drug report of the ward to the MS MGH as well as to the Union
Patients flow in Mandalay General Hospital

- STD clinic
  - Pre-ART pts
- Medical Unit I
  - Admitted pts
- Medical Unit II
  - Admitted pts
- Medical Unit III
  - Admitted pts
- TB OPD
  - TSHC (TB/HIV pts)

Entry point

IHC OPD

Care and Treatment

MGH

Transfer in/out

Other Sites

Decentralize to 7 townships
Outcome of MU I ART clinic

as of September-2014

Total patients (Enrolled+T/I): 4413
T/I: 3356
Death: 724
Defaulter: 629
Def retrieved: 251
Active F/U: 129

With or Without ART

Death rate on ART: 9%
Defaulter rate on ART: 5.6%
Outcome of MU II ART clinic

as of September-2014

<table>
<thead>
<tr>
<th>Enrollment</th>
<th>With or Without ART</th>
<th>With ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>T/O</td>
<td>3735</td>
<td>2634</td>
</tr>
<tr>
<td>Death</td>
<td>2361</td>
<td>312</td>
</tr>
<tr>
<td>Defaulter</td>
<td>245</td>
<td>201</td>
</tr>
<tr>
<td>Def retrieved</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>Active F/U</td>
<td>1047</td>
<td>880</td>
</tr>
</tbody>
</table>

Death rate on ART : 8%
Default rate on ART : 4.2%
Outcome of MU III ART clinic

as of September-2014

Death rate on ART : 10 %
Defaulter rate on ART : 5.8 %
Cumulative numbers of Patients Enrolled and Patients started on ART up to 2014(3rd Quarter) MU I, MU II, MU III

Total ART Started Patients
Total Enrolled Patients (Newly Enrolled + T/I From Pre-ART Clinic)
Total Patients ever started On ART Vs Active Follow up Patients on ART per year up to 2014 (3rd Quarter) MU I, MU II, MU III

- Total Patients Started On ART
- Active follow up patients on ART
DECENTRALIZATION (UP TO SEPT-2014)

MGH
IHC OPD

- MHAM (707)
- CATZ (529)
- CMTZ (724)
- AMTZ (667)
- PGTG (337)
- AMP (340)
- PTG (206)
- Madayar (122)

Peripheral Site
Current Regimens – first line ART
In Adult ART clinic (Active follow up)

First line ART

First Line: 1984 (91.89%)
Second Line: 175 (8.1%)
Present first line adult regimens for active follow up patients used in MGH IHC Clinic as of September 2014

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>D4T+3TC+EFV</td>
<td>67</td>
<td>3.38%</td>
</tr>
<tr>
<td>D4T+3TC+NVP</td>
<td>138</td>
<td>6.96%</td>
</tr>
<tr>
<td>AZT+3TC+EFV</td>
<td>426</td>
<td>21.47%</td>
</tr>
<tr>
<td>AZT+3TC+NVP</td>
<td>115</td>
<td>5.80%</td>
</tr>
<tr>
<td>TDF+3TC+EFV</td>
<td>1210</td>
<td>60.99%</td>
</tr>
<tr>
<td>ABC+3TC+EFV</td>
<td>28</td>
<td>1.41%</td>
</tr>
</tbody>
</table>
Current Regimens – second line ART
In Adult ART clinic (Active follow up)

First Line: 1984 (91.89%)
Second Line: 175 (8.1%)

2nd line ART

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF/3TC/LPV/r</td>
<td>125</td>
</tr>
<tr>
<td>ABC/3TC/LPV/r</td>
<td>23</td>
</tr>
<tr>
<td>TDF/AZT/3TC/LPV/r</td>
<td>13</td>
</tr>
<tr>
<td>AZT/3TC/LPV/r</td>
<td>12</td>
</tr>
<tr>
<td>D4T/3TC/LPV/r</td>
<td>2</td>
</tr>
</tbody>
</table>
Challenges

- Increasing enrolled patients
- Financial and transportation problems of patients from other township
- Difficulties in defaulter tracing
  - due to incomplete or wrong address and poor awareness about importance of continuous HIV care
- As for drug dispensing site, OPD responsible nurses are always changing
- Shortage of OI drugs
  - eg. Pyrimethamine, sulphadiazine, gancyclovir, foscarnet, dapsone
  - Antifungal drugs
Thank you

For further information please contact:

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UK charity number 1138412  US 501(c)(3) registered

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