MINISTRY OF HEALTH

No: 4139/QĐ-BYT

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom - Happiness

Hà Nội, November 02, 2011

DECISION

On revision and update of the "Guideline for diagnosis and treatment of HIV/AIDS" issued in accordance with the Decision No 3003/QĐ-BYT dated 19/8/2009 by the Minister of Health

THE MINISTER OF HEALTH

Pursuant to the Decree No 188/2007/NĐ-CP dated 27/12/2007 of the Government stipulating the function, task, authority and organizational structure of the Ministry of Health;

At the proposal of the Director General of the Vietnam Authority for HIV/AIDS Control and the Director General of the Medical Service Administration,

DECIDES:

Article 1. Revise and update the "Guideline for diagnosis and treatment of HIV/AIDS" issued in accordance with the Decision No 3003/QĐ-BYT dated 19/8/2009 of the Minister of Health (hereafter called the Decision No 3003) as follows:

1. Revision of Part A, section III, item 1, point 1.1 regarding "Indication for prophylaxis treatment using Cotrimoxazole" as follows:

- Criteria "People living with HIV in clinical stage 1, 2 with CD4 < 200 TB/mm^3" was revised as:

- "People living with HIV with TCD4 ≤ 350 cells/mm^3 regardless of the clinical stages".

- Other contents of this point remain unchanged as in the Decision No 3003.

2. Revision of Part A, section VI, item 2 regarding "Criteria for ARV initiation" as follows:

Criteria for ARV initation**:**

- People living with HIV with TCD4 ≤ 350 cells/mm^3 regardless of the clinical stage or

- People living with HIV with clinical stages 3, 4 regardless TCD4 count.

3. Revision of Part A, section VI, item 4 regarding "first line regimen" as follows:

4.1. Preferred regimens:

TDF + 3TC + EFV or TDF + 3TC + NVP

Indication: Use one of these two regimens for all new patients initiating ARV treatment.

As for regimen: TDF + 3TC + EFV: the dose of 3TC is set at 300mg once a day.

4.2. Alternative regimens

AZT + 3TC + EFV or AZT + 3TC + NVP

Indication: Use one of these regimens for patients with contraindication of TDF.

4. Revision of Part A, section VI, item 8, point 8.3.1 regarding "Choosing second line regimen" as follows:

<table>
<tr><th>First line regimen</th><th colspan="3">Second line regimen</th></tr>
<tr><td>TDF + 3TC + NVP/EFV</td><td>AZT + 3TC</td><td rowspan="2">+</td><td rowspan="2">LPV/r or ATV/r</td></tr>
<tr><td>AZT + 3TC + NVP/EFV</td><td>TDF + 3TC</td></tr>
</table>

- Other contents of this point remain unchanged as in the Decision No 3003.

5. Revision and amendment of Part A, section VI, point 9.2.1 regarding "ARV treatment for patients with hepatitis B" as follows:

- ARV regimen for patients with hepatitis B:

TDF + 3TC + EFV

- Other contents of this point remain unchanged as in the Decision No 3003.

6. Revision of Part A, section VII, item 1, point 1.1.1 regarding "ARV indication for pregnant women as follows:

Eligible criteria for ARV treatment for pregnant women who infected with HIV are similar with the criteria for adults with HIV as in item 2, Article 1of this Decision.

7. Revision of Part A, section VII, item 2, point 2.1 regarding "subjects for ARV prophylaxis for mother to child transmission prevention" as follows:

- **"**Pregnant women with HIV who don't meet criteria for ARV treatment for their own health (clinical stage 1-2 and CD4 > 250 cells/mm^3, clinical stage 3 and CD4 >350 cells/mm^3)**" was revised and changed to "**Pregnant women with HIV don't meet criteria for ARV treatment for their own health (clinical stage 1-2 and CD4 > 350 cells/mm^3)".

- Other remain unchanged as in the Decision 3003.

8. Revision of Part A, section VII, item 2, point 2.2 regarding "ARV prophylaxis for mother to child transmission prevention" as follows:

- Amended point 2.2.1 regarding "Preferred regimen AZT + single dose NVP" as follows:

Table 22: Mother to child transmission prevention regimen using AZT + single dose NVP

Mother	During pregnancy	AZT 300 mg x twice daily as early as week 14 of pregnancy or as soon as possible thereafter until the time of labor.
	Onset of labor	NVP 200 mg + AZT 600 mg + 3TC 150 mg Then AZT 300mg + 3TC 150mg in every 12 hours until delivery.
	After delivery	AZT 300mg + 3TC 150mg twice a day in 7 days.
Con	Shortly after birth	Single dose of NVP + AZT 4mg/kg twice a day
	After birth	Continued AZT 4mg/kg twice daily in four weeks

- Optional regimen: AZT + 3TC + LPV/r:

+ Mother: Taken daily from week 14 or as soon as possible thereafter until delivery. Stop after delivery if no breastfeeding. If the mother decides to breastfeed her child, continue the regimen until one week after completion of breastfeeding.

Dosage: AZT 300 mg/time, twice a day

3TC 150 mg/time, twice a day

LPV/r 400/100 mg/time, twice a day

+ Child: AZT 4mg/kg twice a day in four weeks.

- Other contents remain unchanged as in the Decision No 3003.

9. Revision of Part B, section III, item 1, point (b) regarding "Indication for primary preventive therapy" as follows:

Table 4: Preventive therapy using cotrimoxazole or HIV exposed children and HIV infected children

HIV exposed children	Children confirmed with HIV infection		
	Under 24 months of age	From 24 to less than 60 months of age	More than 60 months of age
- Indicating Cotrimoxazole preventive therapy (CPT) for children from week 4-6 after birth and continue until HIV infection is excluded. - If HIV is confirmed refer to the next column	Indicating CPT for all infected children	- Clinical stage 2, 3 and 4 regardless of CD4 count Or - % CD4 < 25% or TCD4 count ≤ 750 cells/mm3 regardless of clinical stage	- CD4 test available: +) **Clinical stages** 3, 4 regardless of CD4 count +) CD4 ≤ 350 cell/mm^3 regardless of clinical stage - CD4 test not available: Clinical stage 2, 3, 4

10. Revision of Part B, section VI, item 2 regarding "Criteria for ART initiation for children" as follows:

Criteria for ART initiation should be based on the HIV status, age, clinical and immune stages of the children.

2.1. Children diagnosed as HIV infection:

- Under 24 months of age: Start ART as soon as possible regardless of clinical stages and TCD4 count.

- From 24 to less than 60 months of age: start ARV treatment when:

+) Children with the percent of CD4 ≤ 25% or CD4 count ≤ 750/mm^3 whichever come first regardless of clinical stage.

+) Or children with clinical stages 3 or 4, regardless of CD4 count.

- From 60 months of age and above: ART is indicated as for adult with HIV as described in item 2, Article 1 of this Decision.

2.2 Children under 18 months of age whose have first PCR test with positive results: start ART treatment and as the same time performing second test of PCR. Stop ART if the child confirmed HIV negative.

2.3 Children under 18 months of age without diagnosis of HIV infection: Initiating ART if he or she is clinically diagnosed with severe HIV/AIDS.

11. Revision of Part B, section VI, item 4 regarding "First line regimen" as follows:

4.1. For children under 24 months of age who are exposed to NVP or EFV due to mother taking ARV for her own health or for mother to child transmission prevention:

AZT + 3TC + LPV/r

4.2. For children under 24 months of age without exposure to or unknown exposure to NVP/EFV:

AZT + 3TC + NVP

4.3. For children from 24 to 36 months of age:

AZT/d4T + 3TC + NVP

4.4. For children above 36 months of age:

AZT + 3TC + NVP/EFV

In case AZT cannot be used replace by ABC. In case of contraindication with ABC, use d4T as alternative.

4.5 For children > 12 years of age and infected with hepatitis B:

TDF + 3TC + EFV/NVP

12. Revision of Part B, section VI, item 8, point 8.3 regarding "Choosing second line regimen" as follows:

Table 10: Switching from first line ARV regimen to second line regimen

How to switch	
First line regimen	Second line regimen
AZT/d4T + 3TC + NVP/EFV	ABC + 3TC/ddI + LPV/r
ABC + 3TC + NVP/EFV	AZT + 3TC/ddI + LPV/r
AZT/d4T + 3TC + ABC	ddI + EFV/NVP + LPV/r

13. Adding in Part B, section VI, item 9 regarding "ARV treatment for children with TB" as follows:

9.3. Using the following regimen:

9.3.1. For children ≤ 36 months of age with TB:

AZT + 3TC + NVP or AZT + 3TC +ABC

9.3.2. For children above 36 months of age with TB:

AZT + 3TC + EFV or AZT + 3TC +ABC

Providing INH for TB prevention for children with HIV:

- Children living with HIV who are ≥ 12 months of age and with no evidence of active TB based on clinical symptom screening and have no contact with a TB case.

- Children < 12 months of age: only those who have contact with a TB case and are excluded from active TB. If the child is < 12 months of age without active TB and have no contact with a TB case then no IPT is provided.

- Dosage: 10mg/kg/day (max 300 mg/day).

- Duration: 6 months

- Providing vitamin B6: 25 mg/day during IPT.

Article 2. Other contents regarding diagnosis and treatment of HIV infection which are not mentioned in this Decision shall be remained as in the Decision No 3003.

Article 3. This Decision is applied for all health services providing treatment and care for people living with HIV.

Article 4. This Decision shall take effect since its date of signature for issuance.

Article 5. The Chief of MoH Cabinet, the Inspector General, the Directors of the Departments and Administrations of the Ministry of Health, Directors of Provincial Health Services and Heads of the Ministry's units and agencies are responsible for implementing this Decision./.

Copies to:
- As Article 5;
- The Minister (for reporting);
- Vice Ministers (for joint guidance);
- MoH Portal Gate;
- Website of the VAAC;
- Filed: Admin, MSA, and VAAC (2).

FOR THE MINISTER
VICE MINISTER

(signed)

Nguyễn Thị Xuyên