HIV/AIDS treatment and care  
Clinical protocols for the WHO European Region  

Protocol 11: Peadiatric HIV/AIDS treatment and care  

Update  
18 July 2008

Page 399, section 4 ART in infants and children, paragraph 2 the first sentence should read as follows:

Children of **12 months and older** should be started on ART when they have either an AIDS-defining illness or severe immunological failure (see Table 1).

Page 400, Table 2 second column should read **<12 months**, under this column it should read as follows:

**Treat all irrespective of CD4 level**

Table 2 should look as follows:

<table>
<thead>
<tr>
<th>Immunological marker</th>
<th>Recommended threshold levels for initiating ART</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;12 months</td>
</tr>
<tr>
<td>CD4 % and/or CD4 count</td>
<td>Treat all irrespective of CD4 level</td>
</tr>
</tbody>
</table>

* Starting at 5 years of age CD4 cell count is a more accurate indication for initiation of treatment.  
**Source:** adapted from WHO (30).

Page 400, after last paragraph subsection 4.1 insert the following text and Figure 2:
Figure 2 presents the algorithm for initiating ART for infants and children.

**Fig 2. Initiating ART for infants and children**

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### Source


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**Page 401, last paragraph before Table 3**

For non-exposed* infants and children the standard 2 NRTIs + NNRTI first-line regimen is recommended (see Table 3).

*Non-exposed infants are those who have **not** been exposed to NNRTI containing maternal ART or preventive ARV regimen.*

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**Page 401, Table 3**

The title of the table and first table note should read as follows:
Table 3. First-line ART regimens for non-exposed infants and children

<table>
<thead>
<tr>
<th>Age</th>
<th>ARV classes</th>
<th>ARV combinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3 years (or &lt;10 kg)</td>
<td>2 NRTIs + 1 NNRTI</td>
<td>ABC (or ZDV) + 3TC&lt;sup&gt;a&lt;/sup&gt; + NVP&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>≥3 years</td>
<td>2 NRTIs + 1 NNRTI</td>
<td>ABC (or ZDV) + 3TC&lt;sup&gt;a&lt;/sup&gt; + EFV&lt;sup&gt;b, c&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> The ABC + 3TC combination is very effective for ART-naive children. PENTA 5 follow up data clearly confirms the superiority of this regimen ([http://www.ctu.mrc.ac.uk/penta/trials.htm](http://www.ctu.mrc.ac.uk/penta/trials.htm) (32, 33). D4T should be avoided due to the increased risk of lipodystrophy (34, 35).

<sup>b</sup> EFV is not currently recommended for children <3 years of age or < 10 kg, and should not be given to post-pubertal girls who are either in the first trimester of pregnancy or are sexually active and not receiving adequate contraception. EFV is preferred over NVP in children older than three years.

<sup>c</sup> NVP should be avoided in post-pubertal girls (considered adults for treatment purposes) with baseline CD4 absolute cell counts >250 cells/mm³.

Page 401, subsection 4.4 the last sentence should read as follows:

The frequency of such transmission has not been well documented; however, direct and indirect data show compromised response to NVP based regimens after NVP exposure in infants; consequently, NVP-based therapy should be used only if protease inhibitors are not available, affordable or feasible.

Page 401, subsection 4.4.1 the last bullet point should read as follows:


Page 402, subsection 4.4.2 the last bullet point should read as follows:

- The PI/r-based first-line regimen (2NRTIs+LPV/r) is recommended, where available and affordable.

Page 402, at the end of subsection 4.4.2 insert the following text and figure:
Figure 3 presents the algorithm for selection of first-line ART regimens for infants.

**Fig 3. First-line ARV treatment regimens for infants**

1. **Infant (< 12 months) Needs ART**
   - Expedite treatment readiness for child & the caregiver

2. **No exposure to NNRTIs OR Unknown exposure to maternal or infant ARVs**
   - **Start Two NRTIs plus One NNRTI**
     - **One of these NRTIs:**
       - AZT or (NRTI) (NNRTI)
       - ABC or + 3TC + NVP

3. **History of any exposure to nevirapine**
   - Protease inhibitors not available or feasible
   - **Start Two NRTIs plus Lopinavir/ritonavir**
     - **One of these NRTIs:**
       - AZT or (NRTI) (NNRTI)
       - ABC or + 3TC + LPV/r

4. **Does the infant/child have any conditions requiring regimen or dosing modifications?**
   - **No**
     - Provide ongoing guidance & support to ensure ART adherence
     - Follow up with Routine Monitoring Visits
   - **Yes**
     - Modify dose / regimen
     - Follow these Cases with Intensive Monitoring

5. **Acute hepatitis:** Do not start ARVs until symptoms resolve, then avoid NVP
6. **Renal Disease:** Refer
7. **Severe anaemia:** Avoid AZT
8. **Severe neutropenia:** Avoid AZT
9. **TB:** Stabilize on TB therapy 2-6 weeks prior to starting ART