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The Florida/Caribbean AIDS Education and Training Center provides state-of-the-art HIV education, consultation, and resource materials to health care providers in Florida, Puerto Rico and the US Virgin Islands.

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Special Bulletin: Pediatric Guidelines Updated

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The Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children has updated its "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection" on February 23, 2009. The previous version of the guidelines underwent format and content changes. In the new format relevant tables and references for each section were incorporated into the body of the document. The key content changes to the different sections of the guidelines can be divided into five main categories and updated information is included here. Clinicians are encouraged to consult the full guidelines at <http://aidsinfo.nih.gov/contentfiles/PediatricGuidelines.pdf>

At present a total of 17 antiretroviral drugs have been approved for use in pediatric patients and 16 are available as pediatric formulation or capsule size.

I. What Drugs to Start: Updated information on darunavir included:

New pediatric dosing approved for **DARUNAVIR** (Prezista®)

- New 75 mg darunavir tablet formulation; only children who can swallow tablets should take darunavir
- Approved for pts 6 - 18 yrs of age; safety and efficacy of darunavir /RTV in pediatric pts 3 to < 6 yrs of age have not been established
- Dosing recommendations based on data from study TMC114-C212. Pediatric data limited to antiretroviral-experienced children (once daily dosing not recommended).
- Darunavir tablets should be taken with low-dose ritonavir for boosting twice daily with food.
- Because the currently available formulations require a high pill burden to provide adequate dosing for children weighing < 40 kg and several alternative options are available for initial treatment, darunavir is not currently recommended for initial therapy in children.
- Recommended dose for pediatric pts is based on body weight and is as follows:

Recommended Dose for Pediatric Patients (6 to < 18 Years of Age) for Darunavir (DRV) Tablets With Ritonavir (RTV)

(kg) - Body Weight - (lbs)		Dose
≥20 kg - <30 kg	≥44 lbs - <66 lbs	375 mg DRV (five 75 mg tabs) /50 mg (0.6 mL) RTV twice daily
≥30 kg - <40 kg	≥66 lbs - <88 lbs	450 mg DRV (six 75 mg tabs) /60 mg (0.8 mL) RTV twice daily
≥40 kg	≥88 lbs	600 mg DRV (one 600 mg tab) /100 mg (one 100 mg cap) RTV twice daily

Also the following PIs are not recommend as initial therapy in children because of insufficient data, data related to toxicity or potency, or inconvenient dosing:

- Tipranavir, darunavir, saquinavir, indinavir
- Dual (full dose) PIs
- Full dose ritonavir or use of ritonavir as the sole PI
- Unboosted atazanavir-containing regimens in children age <13 yrs and/or weight <39 kg

II. Antiretroviral Treatment Failure in Infants, Children, and Adolescents

- The former section "Management of the Treatment Experienced Child" has been completely revised into a more detailed section on management of treatment failure in infants, children, and adolescents. The most important aspects on this section are:
 - The goal of therapy following treatment failure is to achieve and maintain virologic suppression (i.e. undetectable plasma viral load)
 - When complete virologic suppression cannot be achieved, the goals of therapy are to preserve or restore immunologic function, prevent clinical disease progression, and preserve future antiretroviral options.
 - Not all instances of treatment failure require an immediate change in therapy (need to address relevant issues such as adherence)
 - Children who experience treatment failure should be managed in collaboration with a pediatric HIV specialist.
- Treatment failure (i.e. virologic, immunologic, and clinical) definition updated and clearly defined.
- A detailed discussion of discordance between viral, immune, and clinical responses has been added.
- Table on Assessment of Antiretroviral Treatment Failure has been added to provide more explicit guidance on evaluation of

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a child with treatment failure. This takes into consideration adherence, dosing and resistance testing.

- Revised sections on Approach to the Management of Treatment Failure and Choice of Next Antiretroviral Regimen for Treatment Failure with Evidence of Drug Resistance have been added. Overview of this sections as follows:
 - The causes of treatment failure need to be assessed and addressed.
 - When deciding how to treat a child with treatment failure, a clinician should consider the likelihood of achieving durable suppression based on several considerations.
 - Children who experience treatment failure should be managed in collaboration with a pediatric HIV specialist.
 - Antiretroviral regimens should be chosen based on treatment history and drug-resistance testing.
 - Ideally, use 3 fully active antiretroviral medications in the new regimen.
 - Interpretation of complex resistance test results should be made in collaboration with a pediatric HIV specialist. (*F/C AETC Resistance Testing Consultation Service available regionally – www.FCAETC.org/RT*)
 - Use of novel agents with limited available pharmacokinetic and/or safety data should be undertaken only in collaboration with a pediatric HIV specialist.
- A new section on the Use of Antiretroviral Agents Not Approved for Use in Children has been added. Most important aspects are:
 - If children need to use antiretrovirals that are not yet approved for their age range, the off-label use of them should always be done in collaboration with a pediatric HIV specialist.
 - “Off-label” use of antiretrovirals can be risky, as dosing recommendations have not yet been made.
 - Whenever possible, use of antiretrovirals that are not yet FDA-approved for children should be done in the context of clinical trials that can generate the data needed for pediatric approval.
- Table target trough concentrations updated with recommendations for maraviroc and tipranavir.

III. Antiretroviral Drug Resistance Testing - The section has been updated and includes tropism assays

IV. Appendix B: Characteristics of Available Antiretroviral Drugs

Updates have been added for the following drugs:

- Abacavir: 300 mg scored tablets with corresponding dosing information for pediatric pts ≥ 14 kg (about 30 lbs) approved
- Didanosine: Enteric coated didanosine (Videx EC[®]) was approved for use in pediatric pts ≥ 20 kg
- Lamivudine: 150 mg scored tablets dosing recommendations available for pts ≥ 14 kg
- Stavudine: Generic capsules and solution have been approved by the FDA for manufacture and distribution in the US
- Zidovudine (Retrovir[®]): Alternate dosing regimen (using mg/kg) was approved for twice daily dosing in pts 6 wks to <18 yrs old

Also minor changes regarding dosing, interactions or toxicities added to nevirapine, atazanavir, darunavir, ritonavir and maraviroc

V. Supplement I: Pediatric Antiretroviral Drug Information

Updates have been added to the overview, and to drug sections on abacavir, didanosine, lamivudine, zidovudine, efavirenz, darunavir, ritonavir, maraviroc, and raltegravir



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