

An estimated 2.6 million children currently live with HIV. But only about a third of those in need of treatment receive it. Without treatment, more than half of HIV-positive children will die before they turn two, and 80% will die before the age of five. The urgency to diagnose and treat children is high but challenges, delay the scale up of treatment.

Many babies born with HIV are not diagnosed and treated. The reasons for this include limited access to HIV testing for pregnant women and failure to keep HIV-positive mothers and babies in antenatal, post-natal, and HIV care. Also, current rapid tests do not detect HIV in infants and very young children. Test which need sophisticated laboratories for early infant diagnosis (EID) make this very difficult in resource-limited settings. We urgently need a simple, point-of-care EID test that can rapidly diagnose HIV in primary health care centers at the village level.

Even if EID is achieved, the lack of appropriate medicines for children makes scaling up treatment hard. Currently available antiretroviral (ARV) formulations for infants and young children taste horrible, contain alcohol, are difficult to store and transport, require refrigeration, have complex dosing requirements, and have interactions with tuberculosis medicines. Also, current ARV formulations do not meet the new World Health Organization (WHO) guidelines recommending the use of protease inhibitor-based first-line regimens for all children under 3 years of age.



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IMPORTANT CHANGES IN WHO GUIDELINES 2013

For several years now, the WHO has recommended early diagnosis and immediate treatment with ARVs for all children under two years, whatever their CD4 count. In June 2013, the guidelines changed to recommend immediate antiretroviral treatment (ART) for all children under five years of age. This means that 1.4 million two to five years year old children were in need of treatment in 2013.

WHO will also recommend that younger kids – meaning those under three years of age – be treated with an ART combination that includes a powerful class of ARVs called protease inhibitors, regardless of CD4 count and whether or not they have been exposed to ARVs through prevention of mother-to-child transmission (PMTCT).

This change in ‘when to start’ for children is because children who are not yet eligible for ART often are not brought back to the clinic for their HIV care and treatment. Providing ART to children with known HIV status earlier can keep them in care. Taking this into consideration, many countries were already introducing immediate ART for children less than five years old and some up to 15 years!

There are two important considerations when treating children:

1. The urgency to start treatment early. If the children are not treated, half will not live till the age of two.
2. Babies born with HIV have high viral load (more than a million copies/ml are very common in children). Many are exposed to ARVs during PMTCT by taking them directly (after being born) or through their mother (during pregnancy) thus already resistant to the NNRTI (eg. nevirapine or efavirenz) class. This calls for a strong class of ARV called the protease inhibitor to be used which is typically a second line for adults.

Myths about diagnosing and treating children with HIV

If treatment is started early, there will be no treatment option left when child grows up

- *It is critical to start treatment early in children as treatment gives them a chance to grow up healthy. Many children who start treatment late do not survive. A child can stay on the same regimen for some time if they take their medications all the time.*

- *My child is past 2 years, thus he/she does not have HIV. Without a proper diagnosis it is impossible to know if the child has HIV even if the child looks healthy. Because children infected with HIV have higher viral loads, when they get sick, it is often too late to save them.*

- *It is too complicated to treat a child with HIV. Treating a child with HIV is not very different from treating an adult with HIV. Doses of ARVs will need to be changed as the child grows and gains weight. A dosing chart for different weights guides this.*

- A child diagnosed HIV negative will never become positive again

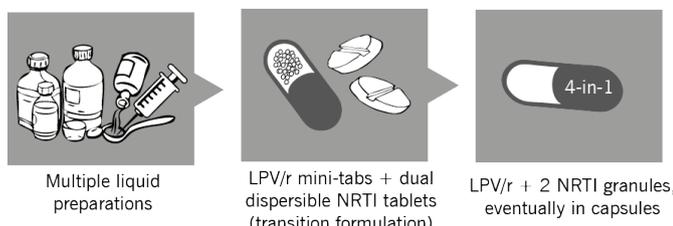
There are reasons why a child can become positive after an initial negative result. For example an HIV negative mother could be infected when she is breast feeding and does not know her status or get treatment. It is important to counsel mothers to bring their babies for retesting if there is a change in HIV status of the mother.

DNDi PROJECT AND IMPLEMENTATION STUDY (LIVING STUDY)

The Drugs for Neglected Diseases initiative (DNDi), a not-for-profit R&D organization created in 2003 by Doctors Without Borders/Médecins Sans Frontières (MSF) and five public sector research institutions.

DNDi is currently working with Cipla to develop two fixed dose combinations (FDCs) of ARVs for children; lopinavir/ritonavir/zidovudine/lamivudine (LPV/r/AZT/3TC) and lopinavir/ritonavir/abacavir/lamivudine (LPV/r/ABC/3TC) also referred to as 4-in-1. DNDi and Cipla will also develop a solid granule version of ritonavir which might be added to paediatric treatment when children are co-infected with TB, as additional “boosts” of ritonavir could do away with the negative interaction between the TB medicine, rifampicin and HIV medicines.

This new 4-in-1 paediatric formulation for infants and young children will be solid granules that fit into a capsule. Caregivers will be able to open the capsules and give the granules to children with soft food or breast milk. Unlike current liquid formulations, the capsules will not require refrigeration, will be “taste-masked” to do away with the terrible taste, and will be easy to dose across various weights. That is the goal!

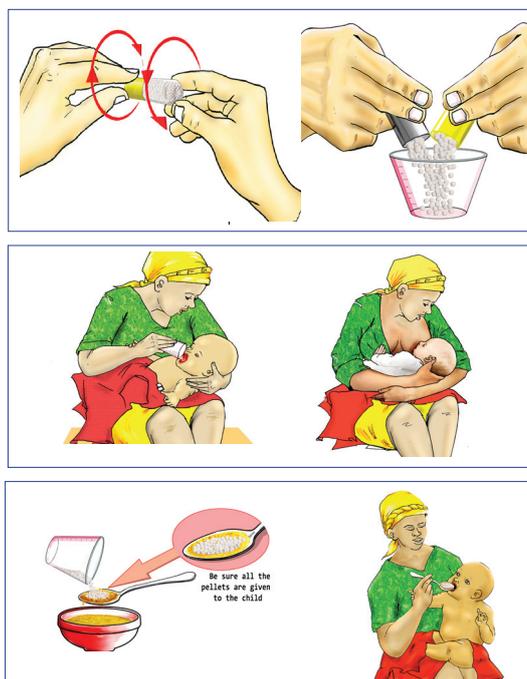


In order to get there, DNDi works with various programme implementers (governmental and non-governmental) and other research partners, particularly in countries highly affected by HIV, to test these products in infants and children with HIV as soon as possible.

All steps are taken to ensure that products are safe to be tested in children (for example, studies are conducted in HIV negative adult volunteers first). And the plans for developing these products are subjected to ongoing consultations with authorities which regulate and control medicines such as the United States Food and Drug Administration (US FDA) and WHO's prequalification programme. Of course, approvals for studies are sought from ethics committees in countries where studies are conducted as well as in Europe. All DNDi-supported studies are conducted in accordance to international standards for clinical trials to ensure patients' safety. DNDi is

firmly committed to ensuring communities are consulted before and throughout all these studies.

DNDi also recognizes that while there is a great urgency, the development of medicines takes time. Today countries are unable to adopt WHO Guidelines (2013) and use an improved treatment such as ones containing LPV/r for young children because of the refrigeration requirement of the syrups. For this reason, large implementation studies will be supported in order to facilitate rapid access to the LPV/r-based formulations for infants and children who need them. The information generated from these studies will be very helpful in assessing the feasibility (eg how to give to young children in various settings and environment) of rolling out this regimen more widely and lessons learnt will help programmes and countries to be better equipped to dramatically scale up treatment of infants and children with HIV/AIDS.



Administering the LPV/r pellets to an infant

ADVOCACY OPPORTUNITIES

The community can play an important role in building a support system for families affected by AIDS and in reaching out to more children at risk of HIV. Parents or caregivers are generally afraid to bring their children in for testing for many reasons including general low knowledge of HIV and treatment in children, a reliance on traditional healing methods, stigma in the community, long waiting time at the clinics etc.

This can change, as it did for adults. It is urgent that diagnosis and treatment reach children infected with HIV. Only knowledge can empower parents or caregivers to bring their children for HIV testing. Community health workers or volunteers can play an important role here to educate their community on the important of early diagnosis and treatment. Find them, treat them, retain them!