OPTIMIZING TREATMENT OPTIONS AND IMPROVING ACCESS TO PRIORITY PRODUCTS FOR CHILDREN LIVING WITH HIV

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BACKGROUND

Globally 3.2 million children were living with HIV in 2013. In the same year 240,000 were newly infected with HIV. Only 23% of children living with HIV receive treatment, compared to 37% of adults.

In July 2014, the global community reaffirmed its commitment to scale up antiretroviral treatment (ART) by supporting the 90-90-90 targets. These ambitious targets aim to reach 90% of people living with HIV with a diagnostic test, to start treatment for 90% of people in need, and to ensure that 90% of people on treatment achieve viral suppression, by 2020.

While these targets may be within reach for some services for adults living with HIV, the limited availability of reliable diagnostics and simple, effective antiretroviral (ARV) drugs for children and adolescents is a major challenge.

As of December 2013, only 23% of the 3.2 million children estimated to be living with HIV were receiving ART and in 2013 alone, 190,000 [170,000 – 220,000] children died of HIV-related causes.

The development and expanded use of more simplified, less toxic and more robust drug regimens are key priorities in ensuring that children and adolescents are not left behind in efforts to reach the new global targets.

WHO ACTIVITIES AND PROGRESS

Over the past two years, WHO has led a drug optimization programme that brought together academic researchers, clinical experts, programme managers, civil society and other partners to establish priorities for the development of paediatric HIV drugs.

This programme builds upon the WHO 2013 Consolidated guidelines on the use of antiretroviral drugs for treatment preventing HIV infection which promoted the use of more potent regimens for young children and a simplified, fully harmonized regimen for older children and adolescents.

The Paediatric ARV Drug Optimization (PADO) meeting was convened in late 2013 to establish a roadmap for streamlining access and uptake of paediatric ARVs and to identify medium and long-term priorities for the development of new drugs and formulations in response to the evolving paediatric HIV epidemic.
Key outputs of WHO’s drug optimization effort, undertaken with the technical advice of the Paediatric ARV Working Group (PAWG), include the development of revised drug information pages, a revised WHO generic tool to capture age-related differences in drug metabolism, new weight-based dosing for darunavir and boosted darunavir, and a collaborative pharmacokinetic modelling to establish the appropriate dosing for a new fixed-dose combination, including abacavir, lamivudine and efavirenz.

Development of this medication is a priority as it would allow use of a single once-daily pill for the treatment of all children aged 3 to 10 years.

Other priority work carried out by WHO and partners includes streamlining of forecasting, procurement and supply of paediatric ARVs. In particular, WHO and UNAIDS have worked together to develop more accurate modelling of future paediatric HIV treatment needs across different age groups in order to improve forecasting for paediatric formulations.

The first results of this work stemming from a technical consultation held in June 2014 will be implemented in early 2015, while additional work will continue to further improve estimates to inform forecasting and programme planning.

WHO’s collaborative paediatric drug optimization work also includes the development of the Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and their Children (IATT) optimal formulary list.

This tool, first developed in 2010 and revised in September 2013 in collaboration with other IATT partners, establishes the minimal set of optimal products needed to construct the currently recommended ARV regimens.

This will reduce market fragmentation and streamline procurement of paediatric products.

The Global Fund to Fight AIDS, Tuberculosis and Malaria has endorsed this list, which has also been widely disseminated through partners and key implementers in countries.

New challenges in the paediatric ARV market will emerge as transition from old to new regimens continues. In order to respond to these, WHO and partners developed a policy brief in August 2014 providing guidance to countries in overcoming the procurement challenges resulting from the phase-out of older drugs that are no longer recommended for use due to their higher toxicities, notably stavudine and didanosine.

WAY FORWARD

As part of WHO’s ongoing commitment to paediatric drug optimization, a second PADO meeting (PADO 2) was held in December 2014 to review existing drug recommendations and to update the list of priority products.

Additional engagement with research networks is being sought to ensure alignment between the research agenda and the normative guidance development process.

Finally, engagement with regulatory bodies is currently being strengthened with the goal of streamlining the pathway from drug and formulation development to regulatory approval and market entry.

WHO is fully committed to developing and contributing to catalytic projects that advance norms and standards for drug optimization, and foster collaboration and coordination needed for scaling up treatment for children and adolescents living with HIV.