

# MEETING REPORT

## Update to the optimal list of paediatric ARV formulations

11-12 Sept. 2013 | Geneva, Switzerland



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# Update to the optimal list of paediatric ARV formulations

## **The Interagency Task Team (IATT) on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children**

Child Survival Working Group and Supply Chain Management Working Group

11-12 September 2013, Geneva Switzerland

Publications of the IATT are available on the IATT website:

Website: <http://www.eMTCT-iatt.org>

Community of practice: <http://www.knowledge-gateway.org/eMTCT>

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# ACRONYMS

<b>3TC</b>	lamivudine
<b>ABC</b>	abacavir
<b>AIDS</b>	acquired immunodeficiency syndrome
<b>AMDS</b>	AIDS Medicines and Diagnostics Service
<b>ART</b>	antiretroviral therapy
<b>ARV</b>	antiretroviral
<b>ATV</b>	atazanavir
<b>AZT</b>	zidovudine
<b>PADO</b>	Paediatric Antiretroviral Drug Optimization
<b>CSWG</b>	Child Survival Working Group of IATT
<b>d4T</b>	stavudine
<b>ddI</b>	didanosine
<b>DRV</b>	darunavir
<b>EFV</b>	efavirenz
<b>ETV</b>	etravirine
<b>FDA</b>	United States Food and Drug Administration
<b>FDC</b>	fixed-dose combination
<b>FPV</b>	fosamprenavir
<b>FTC</b>	emtricitabine
<b>HIV</b>	human immunodeficiency virus
<b>IATT</b>	Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and their Children
<b>LPV/r</b>	lopinavir/ritonavir
<b>M&amp;E</b>	monitoring and evaluation
<b>MTCT</b>	mother-to-child transmission (of HIV)
<b>NRTI</b>	nucleoside/nucleotide reverse transcriptase inhibitors
<b>NNRTI</b>	non-nucleoside reverse transcriptase inhibitors
<b>NVP</b>	nevirapine
<b>PADO</b>	Paediatric Antiretroviral Drug Optimization meeting
<b>PAPWG</b>	Paediatric ARV Procurement Working Group
<b>PAWG</b>	Paediatric Antiretroviral Working Group
<b>PI</b>	protease inhibitor
<b>PMTCT</b>	prevention mother-to-child transmission of HIV
<b>RAL</b>	raltegravir
<b>R&amp;D</b>	Research and Development
<b>RTV</b>	ritonavir
<b>SCMWG</b>	Supply Chain Management Working Group of IATT
<b>SRA</b>	stringent regulatory authority
<b>TDF</b>	tenofovir disoproxil fumarate
<b>TPV</b>	tipranavir
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNFPA</b>	United Nations Population Fund
<b>UNICEF</b>	United Nations Children's Fund
<b>WHO</b>	World Health Organization
<b>WHO PQ</b>	World Health Organization Prequalification Programme

# EXECUTIVE SUMMARY

The complexity of HIV treatment in children is marked by a spectrum of issues, ranging from clinical management to market sustainability of antiretroviral (ARV) products. Children account for less than 7% of all patients on ART and despite the availability of multiple child-appropriate ARV formulations, demand for such products is relatively low and further fragmented across numerous, duplicative products. Consolidation of demand around a subset of optimal paediatric ARV formulations is essential to ensure a sustainable supply of drugs for children living with HIV.

In September 2013, the Child Survival Working Group (CWSG) and the Supply Chain Management Working Group (SCMWG) of the Interagency Task Team (IATT) on the Prevention and Treatment of HIV infection in Pregnant Women, Mothers and Children convened to update the existing optimal paediatric ARV formulary originally drafted in 2011. This list has served as guidance for national programmes, procurement agencies, funders and manufacturers. The working groups mapped out the process of revising the 2011 list, re-examined the existing selection criteria for rationalizing paediatric formulations, and evaluated all available products against these criteria.

The revision process for routine updating of the IATT optimized formulary list will be brought in line with the World Health Organization (WHO) treatment guideline revision process, while the list itself will reside within the WHO. The updated lists of optimal and limited-use products include both preferred and alternative drugs recommended in the WHO's 2013 Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection. A total of 10 optimal formulations for paediatric ART, including two syrups for infant prophylaxis in PMTCT, were selected. Stakeholders in the paediatric treatment landscape are encouraged to refer to these updated lists of formulations in guiding their decision-making for procurement.

# BACKGROUND

## The treatment landscape of HIV infection in children

The antiretroviral treatment (ART) of HIV infection in paediatric populations is associated with a complex set of clinical, operational, and procurement challenges, particularly in resource-limited settings. The reliable delivery of high quality, affordable, paediatric-adapted ARVs is a prerequisite for the timely identification, initiation, and treatment of infected children. Currently, children account for fewer than 7% of all individuals on treatment, and as a result, the global paediatric ARV market is both smaller and more vulnerable to supply disruptions compared to the adult ARV market.

Appropriate treatment of paediatric patients requires dosing across a range of regimens, ages and weight-bands. In recent years, new formulations that meet the unique administration needs of children have become available, such as dispersible fixed-dose combination tablets (FDCs), which can be dispersed in liquid before administration. These products have significantly improved the quality of paediatric HIV care in resource-limited settings; however the proliferation of these newer options, alongside the continued availability of older sub-optimal products has resulted in fragmentation of procurement orders across multiple, and often duplicative products.

WHO's 2013 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV infection (WHO 2013 Consolidated ARV Guidelines) provide clear guidance on regimen selection, but not on specific product selection. Notably, WHO strongly endorses the use of dispersible FDCs as a general principle to simplified dosing for providers and patients, and to improve adherence outcomes.

**TABLE 1:** Preferred and alternative first-line regimens for children adapted from the 2013 WHO Consolidated ARV Guidelines

Age Group	Preferred first-line regimens	Alternative first-line
Children < 3 years	ABC or AZT + 3TC + LPV/r	ABC + 3TC + NVP AZT + 3TC + NVP
Children 3 years to less than 10 years and adolescents <35kg	ABC + 3TC + EFV	ABC + 3TC + NVP AZT + 3TC + EFV AZT + 3TC + NVP TDF + 3TC (or FTC) + EFV TDF + 3TC (or FTC) + NVP
Adolescents (10-19 years) ≥ 35 kg	TDF + 3TC (or FTC) + EFV	AZT + 3TC + EFV AZT + 3TC + NVP TDF + 3TC (or FTC) + NVP ABC + 3TC + EFV (or NVP)

The guidance in this meeting report is complementary to WHO recommendations on supporting optimal ARV treatment options for children, however, the list is not intended to be definitive or all-inclusive. For example, although children are often treated using adult products, the list does not contain any adult formulations, as such products are not as vulnerable to market instability as paediatric products.

In addition, the list is restricted to products that are approved and available for procurement at the time of publication, and does not include products in the development pipeline. It is anticipated that this optimal list will be reviewed on a regular basis to allow old formulations to be withdrawn, and newly developed and approved child-friendly formulations to be added.

## Background on the IATT Optimized Paediatric ARV Formulary List

The IATT was first established in 1998. Initially, the IATT was composed of the five United Nations agencies working on HIV and health issues: WHO, UNICEF, UNFPA, UNAIDS and the World Bank. In 2003, the IATT expanded to include key global partners involved in the prevention and treatment of HIV infection in infants and young children. The IATT supports national scale-up of services for the elimination of mother-to-child transmission of HIV (EMTCT) and paediatric treatment, while providing a forum for global information sharing and consensus building on issues related to these two areas.

Due to its small volumes, the market uncertainty for paediatric ARVs has served as a disincentive for investment into future paediatric drug research and development (R&D). To address this issue, the CSWG (formerly known as the Paediatric Working Group (PWG)) of the IATT met in May 2011 to develop an optimal paediatric formulary list to serve as guidance to national programmes, procurement agencies, funders and manufacturers. This group defined the criteria for optimization and then evaluated all available paediatric products against these criteria. Out of more than 40 products reviewed, 14 formulations were identified for inclusion on a list of 'optimal' paediatric ARV products that would meet the needs of all children living with HIV and be aligned with WHO recommended first and second-line paediatric regimens. An additional 9 products were recognized to be of 'limited use'. The remaining formulations were recognized as 'non-essential'. The initial list was published online as part of a meeting report 'Developing an Optimized list of Paediatric ARV Formulations' and has been used as a reference for programmes in establishing their own optimized paediatric ARV formulary lists. ([http://www.who.int/hiv/pub/meetingreports/iatt\\_meeting.pdf](http://www.who.int/hiv/pub/meetingreports/iatt_meeting.pdf))

The process of consolidating paediatric ARV formularies around a subset of 'optimal' products remains critical to securing quality treatment for children living with HIV in resource-limited settings. Given the IATT's restructuring in 2012, this process is now under the direction of the Child Survival and the Supply Chain Management working groups. It has been recognized that the IATT optimal paediatric ARV formulary cannot be static over time and must evolve to accommodate updates to regimen recommendations and product availability. Members of the IATT are committed to a regular re-evaluation of this optimal list, and are responsible for finalizing the process map and selection criteria needed to revise this list.

# OBJECTIVE OF MEETING

The primary objective of this two-day meeting in Geneva, Switzerland was to reach consensus by a subcommittee of members from the CSWG and the SCMWG on a systematic process to revise the current optimized list of paediatric ARV formulations. In addition to finalizing the revision process and updating the current lists (which included optimal, limited-use, and non-essential formulations), the meeting involved discussions around the dissemination of the lists and the development of monitoring and evaluation (M&E) processes/indicators that would be important in determining country-level adoption.

The meeting is part of broader commitment on the part of stakeholders to improve access to paediatric HIV care and treatment and is in line with the Treatment 2.0 initiative and the Paediatric Antiretroviral Drug Optimization meeting (PADO), which took place in Dakar, Senegal in October 2013, aimed at identifying medium and long term priorities for developing paediatric drugs.

# METHODOLOGY

## Initiating review process

The participants agreed that the subcommittee of the CSWG and SCMWG will convene every six months to determine whether a major revision to the existing product list(s) is needed or if only a minor revision will be sufficient. A set of questions (Table 2) will guide the process to determine the extent to which revisions are necessary. For major revisions, the group agreed that, at a minimum, it would be important to link the revisions of the formulation list(s) to revisions of the WHO Consolidated guidelines which are anticipated to take place every two years. Furthermore, it was also agreed that while the members of the IATT will continue to lead the process for future revisions of the list, the WHO will include the list in the development and dissemination of normative treatment guidance. The group concluded that only currently available products should be considered during the process, while products currently in the R&D pipeline (new drugs and new formulations) would be excluded. Formal consideration for inclusion in the IATT list(s) will be reserved until such time as a given product becomes available.



**TABLE 2:** Questions for consideration to review current IATT formulation lists**Questions to initiate review**

Are there new WHO recommendations for paediatric ART?

Are there new paediatric ARV products available?

Have there been any shortages in supply due to supplier exit or changes in availability of products, or are any such shortages anticipated?

Have there been any significant shifts in HIV paediatric treatment practices?

Have there been any new paediatric drug/formulation approvals by a Stringent Drug Regulatory Authority?

Any notable ordering trends/use of list within last 6 months? If so, what are the implications of these trends on selection criteria for optimal products?

**Working definitions**

In an effort to guide the selection process, the participants recognized the need for clarity around the list categories (optimal, limited and non-essential) previously developed by the IATT in 2011. Working definitions for optimal, limited use, and non-essential paediatric ARV formulations are listed in Table 3.

**TABLE 3:** Working definitions for three separate lists of paediatric ARV formulations

List	Working Definition
Optimal	The paediatric ARV formulations that serve all currently recommended preferred and alternative paediatric first and second-line WHO regimens for all paediatric weight-bands (<35kg, see Table 1).
Limited use	Paediatric formulations that may be needed in limited supply during transition periods and/or for special circumstances.
Non-essential	Formulations not recommended for procurement (all remaining paediatric formulations not included on optimal and limited use lists).

## Selection criteria

Only formulations of drugs mentioned in the 2013 WHO Consolidated ARV Guidelines for paediatric use were reviewed. Adult formulations were not reviewed. Dosing recommendations from the 2013 WHO Consolidated ARV Guidelines and the United States Food and Drug Administration (FDA) were considered. A list of selection criteria against which each product should be evaluated was discussed and further defined. Table 4 lists the criteria for evaluation of paediatric ARV products.

**TABLE 4:** Working definitions for three separate lists of paediatric ARV formulations

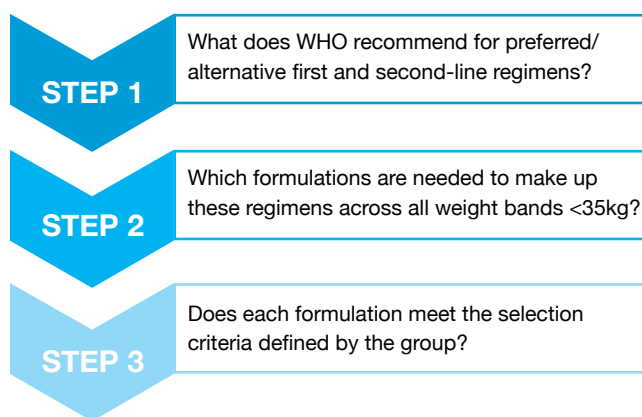
Criterion	Definition
Meets WHO requirements	<ul style="list-style-type: none"> <li>Included in the latest WHO guidelines for paediatric treatment</li> </ul>
Allows for widest range of dosing options	<ul style="list-style-type: none"> <li>Allows for flexible dosing across multiple weight bands and ages</li> </ul>
Approved by SRA/WHO PQ	<ul style="list-style-type: none"> <li>Availability of at least one SRA approved product</li> </ul>
User Friendly	<ul style="list-style-type: none"> <li>Easy for health care worker to prescribe</li> <li>Easy for caregivers to administer</li> <li>Supports adherence</li> </ul>
Optimizes supply chain management	<ul style="list-style-type: none"> <li>Easy to transport</li> <li>Easy to store</li> <li>Easy to distribute</li> </ul>
Available for resource limited settings	<ul style="list-style-type: none"> <li>Product is licensed/registered for use in resource-limited settings</li> <li>Reliable supply of product</li> </ul>
Comparative cost	<ul style="list-style-type: none"> <li>Cost should not be a deciding factor; however comparative cost of formulations of the same drug/drug combination should be considered</li> </ul>

## Steps for revision of optimal list

The group agreed that the process for choosing formulations for inclusion on the optimal list (Figure 1) would follow the sequence:

1. Start with list of all 10 preferred and alternative 1st and 2nd line regimens recommended by the WHO according to the latest guidelines.
2. Select a minimum number of non-duplicative products that will fulfill all 10 regimens across all ages and weight bands.
3. Review choices against selection criteria (Table 4).

**FIGURE 1:**  
IATT process for revising optimal list



## Steps for revision of limited-use list

The systematic process of determining which products would be placed on the limited-use list follows:

- 1 . Consideration of all remaining formulations
- 2 . Conceptualization of limited-use formulations in two categories:
  - a. Transition: drugs phasing in or out of use (e.g. phase-out of d4T)
  - b. Special circumstances (patient or situation specific, e.g. third line)
- 3 . Discussion of circumstances for use and anticipated demand for each product in addition to selection criteria.

## FINAL SELECTION

Table 5 includes the optimal, limited-use, and non-essential lists for paediatric ARV formulations, as determined by the subcommittee of the CSWG and SCMWG based on available products that align with recommendations included in the 2013 WHO Consolidated ARV Guidelines. At the time of the meeting there were no available three-drug dispersible FDC formulations to provide any of the preferred 1st or 2nd line regimens. [Post Meeting Note: Guidance for the development of such optimized formulations is addressed in the PADO medium and long term priorities for drug development for children.] There was also considerable discussion around the inclusion/exclusion of ddl, TDF, and d4T.

### *Didanosine (ddl)*

Of note, all ddl formulations were considered to be non-essential as they are no longer recommended by the 2013 WHO Consolidated ARV Guidelines for use in any preferred or alternative first or second line regimens. The group agreed that programmes should be encouraged to transition paediatric patients on ddl containing regimens to more optimal drugs (e.g. replacing ddl with 3TC in 2nd line regimens as recommended by WHO).

### *Tenofovir disoproxil fumarate (TDF)*

There was extensive discussion about the inclusion of paediatric formulations of TDF given its inclusion as an option for first line ART in children. At the time of the meeting, the only available paediatric formulations included TDF powder, 150mg tablets and 200mg tablets; all three formulations would be needed to meet dosing requirements across all paediatric weight bands. In addition, two separate single drug formulations (3TC and NVP, EFV or LPV/r) would be required in order to form a complete three drug regimen. Though TDF is now deemed safe and efficacious for use in children over two years, and products are available with FDA approval, these three formulations failed to meet all other criteria defined for product selection. However, as TDF may be needed for some patients, it was decided that the available formulations would be included on the limited-use list. When an optimal formulation for TDF becomes available (i.e. a paediatric TDF-containing FDC), the group agreed it should be considered for inclusion on the optimal list.

## Stavudine (d4T)

Despite efforts to phase-out d4T in programmes, data presented by WHO's AIDS Medicines and Diagnostics Service (AMDS) highlighted that a significant percentage of children remain on d4T-regimens. In 2012 an estimated 13.2% of children in sub-Saharan Africa were on a first-line regimen of d4T+3TC+NVP. A decision was made to exclude d4T from the optimal list, but include both the dual FDC and the triple FDC on the limited-use list. The inclusion of a dual FDC of d4T was based on the flexibility this formulation provides (under a 'special circumstance' indication). The inclusion of triple FDC of d4T was also included in the limited-use list as it is still being used by a significant number of children. The group noted that countries should be encouraged to use the current WHO first-line and alternative first-line regimens containing ABC or AZT. The group also underscored the need for more data on formulation-use and the volume of d4T stock currently available in countries to further inform guidance.

**TABLE 5:** IATT optimal, limited use, and non-essential lists of paediatric ARV formulations

Drug class (or FDC)	Product	Formulation	Dosage	Rationale for list
<b>OPTIMAL</b>				
NRTI	AZT	Oral liquid	50 mg/5 ml	For infant prophylaxis as part of PMTCT
NNRTI	EFV	Tablet (scored)	200 mg	
NNRTI	NVP	Tablet (dispersible, scored)	50 mg	
NNRTI	NVP	Oral liquid	50 mg/5 ml	For infant prophylaxis as part of PMTCT
PI	LPV/r	Tablet (heat stable)	100 mg/25 mg	
PI	LPV/r	Oral liquid	80/20 mg/ml	
FDC	AZT/3TC	Tablet (dispersible, scored)	60/30 mg	
FDC	AZT/3TC/NVP	Tablet (dispersible, scored)	60/30/50 mg	
FDC	ABC/3TC	Tablet (dispersible, scored)	60/30 mg	
FDC	ABC/3TC/AZT	Tablet (non-dispersible, scored)	60/30/60 mg	

Drug class (or FDC)	Product	Formulation	Dosage	Rationale for list
<b>LIMITED-USE</b>				
NRTI	3TC	Tablet (dispersible)	30 mg	To be used with TDF single formulation.
NRTI	TDF	Oral powder*	40 mg/scoop	For use in special circumstances when ABC or AZT cannot be used or for patients with Hepatitis B, until an appropriate FDC becomes available  *Product is administered as an oral powder, not reconstituted with liquids
NRTI	TDF	Tablet	150 mg	See above
NRTI	TDF	Tablet	200 mg	See above
NNRTI	ETV	Tablet	25 mg	Special circumstance in 3rd line where appropriate
NNRTI	ETV	Tablet	100 mg	See above
PI	RTV	Oral liquid	400 mg/5 ml	For boosting of non-co-formulated PIs and super-boosting PI during TB co-infection
PI	ATV	Solid oral dosage form	100 mg	Use in alternative 2nd line for children over 6 years old when boosting with separate RTV is available
PI	ATV	Solid oral dosage form	150 mg	See above
PI	DRV	Tablet <sup>1</sup>	75 mg	Special circumstances in 3rd line where appropriate, and when boosting with separate RTV is available
Integrase Inhibitors	RAL	Chewable tablet (scored)	100 mg	For use in 3rd line where appropriate
FDC	D4T/3TC/NVP	Tablet (dispersible, scored)	6/30/50 mg	Special circumstances where patients cannot be transitioned to a preferred or alternative NRTI.
FDC	D4T/3TC	Tablet (dispersible, scored)	6/30 mg	See above

<sup>1</sup> Inclusion of DRV liquid was discussed during the meeting to provide maximum flexibility for all weight bands however after further discussion it was determined that a 75mg tablet of DRV would be a more suitable option for inclusion on the limited use list as DRV is not approved for use in children <3 years and the 75mg tablet provides dosing for all weight bands >15kg.

Drug class (or FDC)	Product	Formulation	Dosage	Rationale for list
<b>NON-ESSENTIAL</b>				
NRTI	ABC	Tablet (dispersible and non dispersible; scored) as sulfate	60 mg	
NRTI	ABC	Oral liquid as sulfate	100 mg/5 ml	
NRTI	AZT	Tablet (dispersible and non dispersible; scored)	60 mg	
NRTI	AZT	Capsule	100 mg	
NRTI	AZT	Tablet	100 mg	
NRTI	3TC	Oral liquid	50 mg/5 ml	
NRTI	3TC	Tablet (non dispersible)	30 mg	
NRTI	d4T	Capsule	15 mg	
NRTI	d4T	Capsule	20 mg	
NRTI	d4T	Powder for oral solution	5 mg/5 ml	
NRTI	ddl	Capsule, unbuffered, enteric coated	125 mg	
NRTI	ddl	Capsule, unbuffered, enteric coated	200 mg	
NRTI	ddl	Tablet (buffered, chewable, dispersible)	25mg	
NRTI	ddl	Tablet (buffered, chewable, dispersible)	50 mg	
NRTI	ddl	Tablet (buffered, chewable, dispersible)	100 mg	
NRTI	ddl	Powder for oral liquid (buffered)	2g, 4g bottle	
NRTI	FTC	Oral liquid	10 mg/ml	
NNRTI	EFV	Tablet	50 mg	
NNRTI	EFV	Tablet (unscored)	200 mg	
NNRTI	EFV	Tablet (dispersible and non dispersible)	100mg	
NNRTI	EFV	Capsule	50 mg	
NNRTI	EFV	Capsule	100 mg	

Drug class (or FDC)	Product	Formulation	Dosage	Rationale for list
<b>NON-ESSENTIAL</b>				
NNRTI	EFV	Capsule	200 mg	
NNRTI	EFV	Oral liquid	150 mg/5 ml	
NNRTI	NVP	Tablet (dispersible)	100 mg	
PI	DRV	Oral liquid	500 mg/5 ml	
PI	DRV	Tablet	150 mg	
PI	ATV	Solid oral dosage form	200 mg	
PI	TPV	Oral liquid	500 mg/5 ml	
PI	FPV	Oral liquid	250 mg/5 ml	
Integrase Inhibitors	RAL	Chewable tablet	25 mg	
FDC	AZT/3TC	Tablet (scored)	60/30 mg	
FDC	d4T/3TC/NVP	Tablet (dispersible, scored)	12/60/100 mg	
FDC	d4T/3TC	Tablet (dispersible, scored)	12/30 mg	
FDC	ABC/3TC	Tablet (scored)	60/30 mg	

## NEXT STEPS

### Dissemination of lists

The optimized formulation list will be accessible online on the IATT website [www.emtct-iatt.org](http://www.emtct-iatt.org), and disseminated electronically to key stakeholders at the global and country level, including:

- Paediatric ARV Procurement Working Group of the Global Fund (PAPWG)
- All major agencies funding procurement of paediatric ARVs
- All major buyers of paediatric ARVs
- All stakeholders involved in the paediatric HIV treatment response
- WHO Prequalification and USFDA tentative approval programme
- Ministries of Health, including National Drug Regulatory authorities, National HIV management programmes and procurement offices
- Organizations of People Living with HIV (PLHIV) and other Community Based Organizations (CBOs)
- Manufacturers of paediatric ARVs

Advocating for the uptake of the optimal list in procurement decision-making will be critical, and the support of global partners is welcome. Along these lines, the list was presented at the PADO in Dakar, Senegal in October, 2013 and the International Conference on AIDS and STIs in Africa (ICASA) in Cape Town, South Africa in December 2013.

## Monitoring and evaluation

The group actively discussed whether there was a role for monitoring and evaluation (M&E) of adoption of the formulary list(s) by countries. The current AMDS survey on regimen-use may be amended to include a question on the use of the IATT list(s). The survey could serve as a proxy of how well the list(s) is/are being implemented (e.g. monitor if a country is over-procuring, or adding a question on whether a country is phasing out d4T use in children).

There was discussion on whether it would be beneficial to gather evidence on the impact of this list after implementation at the country level (e.g. is the IATT list preventing stock-outs, decreasing lead times, and supporting the phase-out of drugs not recommended for use by the WHO). It was also noted that through the PAPWG, trends in procurement could be observed. Similarly, the WHO Global Price Reporting Mechanism (GPRM) database (<http://apps.who.int/hiv/amds/price/hdd/>), which records international transactions of HIV, tuberculosis and malaria commodities purchased by national programmes, could also be an important resource for data collection.

## Country-level toolkit

As the IATT paediatric formulary lists are meant to be used as model lists, country-to-country adoption will need to be supported. Some countries may require additional guidance to adapt the list for their own needs. Country-level consultations and workshops will be conducted to support countries to make effective decisions on which formulation products meet their needs, while ensuring alignment with the most updated list. A country-level toolkit (including a stand-alone toolkit, coupled with a facilitator's guide) will be developed by the sub-committee in 2014 for use during national-level paediatric ARV formulary optimization workshops.

Guidance to countries will be particularly relevant in planning for transitions in treatment recommendations as the availability of paediatric ARV formulations must be considered in implementation planning. Country-level consultations/workshops will be most effective if key stakeholders and decision-makers are present, in addition to procurement agents who typically attend these meetings. These workshops could include a systematic overview of current formulations currently procured, regimens currently in use, and current treatment guidelines, in addition to information on global paediatric ARV market dynamics.

## Policy brief on currently available formulations

With a number of new paediatric treatment recommendations in place, WHO developed a policy brief to provide relevant stakeholders with up-to-date information on the availability of certain paediatric formulations of abacavir (ABC), tenofovir (TDF) and lopinavir/ritonavir (LPV/r) ([http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement\\_march2014/en/](http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement_march2014/en/))



## ANNEX 1: List of Meeting Participants (in alphabetical order)

Name	Organization	Role
Martin Auton	The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland	Senior Specialist, Lead
Arax Bozadjian	Médecins Sans Frontières, Switzerland	Pharmacist Specialist
Marianne Gauval	Clinton Health Access Initiative, United States of America	Paediatric Indication Manager
Dania Ghostine	The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland	Technical Officer, Sourcing and Supply Management Department
Raul Gonzalez	WHO, HIV Department, Switzerland	Medical Officer
Vincent Habiyambere	WHO, Switzerland	AIDS Medicines and Diagnostics Service HIV Technologies and Commodities
Shirin Heidari	International AIDS Society, Switzerland	Senior Manager
Ioannis Hodges-Mameletzis	Clinton Health Access Initiative, United States of America	Consultant
David Jamieson	PFSCM, USA	Deputy Director for Project Planning and Global Partnerships
Janice Lee	Drugs for Neglected Diseases Initiative, Switzerland	Project Coordinator
Clarisse Morris	The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland	Sourcing Specialist (Sourcing & Supply Management Department)
Boniface Dongmo Nguimfack	WHO, HIV Department, Switzerland	Clearing House Manager (Strategic Information Unit)
Atieno Ojoo	UNICEF, Denmark	Technical Specialist (Medicines and Nutrition Center; Supply Division)
Martina Penazzato	WHO, HIV Department, Switzerland	Paediatric HIV Treatment and Care Consultant
Nandita Sugandhi	Clinton Health Access Initiative, USA	Senior Clinical Advisor

## ANNEX 2: List of IATT Member Organizations (Alphabetical Order)

1. ANECCA (African Network of Children Affected by AIDS)
2. ANRS (French National Agency for Research on AIDS and Viral Hepatitis)
3. BIPAI (Baylor College of Medicine, International Pediatric AIDS Initiative)
4. CDC (Centers for Disease Control and Prevention)
5. CHAI (Clinton Health Access Initiative)
6. CMMB (Catholic Medical Mission Board)
7. Columbia University (ICAP)
8. DFATD (Department of Foreign Affairs, Trade and Development, Canada)
9. DFID (UK Department for International Development)
10. Earth Institute
11. EGPAF (Elizabeth Glaser Pediatric AIDS Foundation)
12. EngenderHealth
13. ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau)
14. FHI 360
15. GFATM (the Global Fund to fight AIDS, Tuberculosis and Malaria)
16. Global Networks of People Living with HIV (GNP+)
17. ICW (International Community of Women Living with HIV)
18. IPPF (International Planned Parenthood Federation)
19. IAS (International AIDS Society)
20. IntraHealth International
21. JHPIEGO
22. M2M (Mothers to Mothers)
23. MSH (Management Sciences for Health)
24. Office of the Global AIDS Coordinator (OGAC)
25. Population Council
26. Save the Children
27. UNAIDS (Joint United Nations Programme on HIV/AIDS)
28. UNFPA (United Nations Population Fund)
29. USAID (U.S. Agency for International Development)
30. UNICEF (United Nations Children's Fund)
31. WHO (World Health Organization)
32. The World Bank
33. World Vision

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2. Waning B, Diedrichsen E, Jambert E, Barnighausen T, Li Y, Pouw M, et al. The global pediatric antiretroviral market: analyses of product availability and utilization reveal challenges for development of pediatric formulations and HIV/AIDS treatment in children. *BMC pediatrics*. 2010;10(1):74.
3. 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. <http://www.who.int/hiv/pub/guidelines/arv2013/en/>
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