



FMOH

**Expanding Access to Pediatric HIV/AIDS
Care and Treatment in Ethiopia:
*Challenges and Prospects***



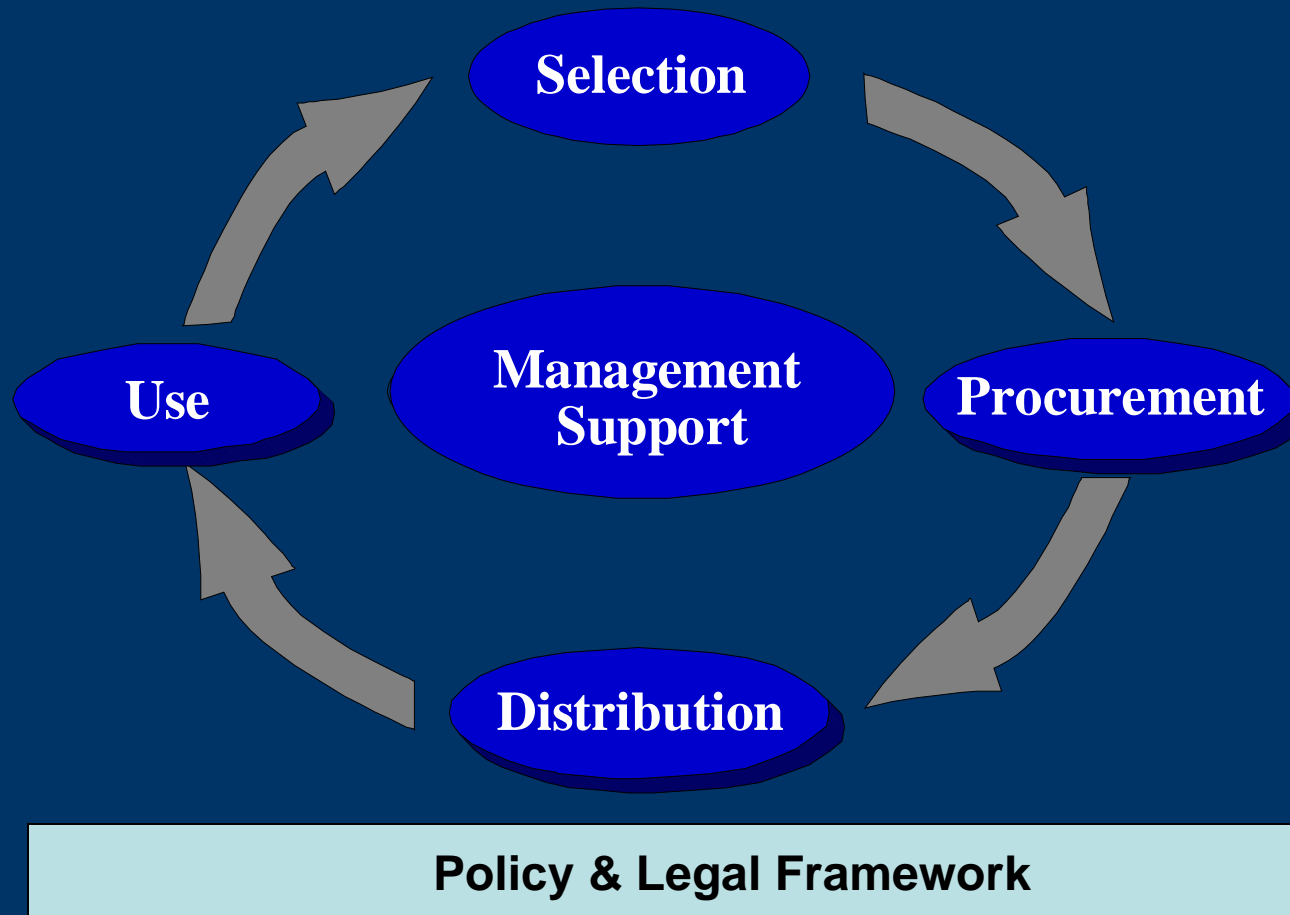
ICAP

**ARV Procurement:
The Ethiopian Experience**

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THE DRUG MANAGEMENT CYCLE



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1. Selection

- Based on the country's treatment guideline and the National Drug List
- Focused mainly on first line drugs with the anticipation that there will only be very few patients on 2nd line drugs
- Paediatric formulations has been very limited both in variety (3) and quantity ($\approx 4\%$).

Limitations:

- Limited previous experience
- Limited Information – Data only found from fee based supply chain (KENEMA and RED CROSS).
- Only few paediatric formulations were registered in the country

2. Quantification

- Based on several underlying assumptions

Adult:

- Combivir/D4T based regimen = 50% / 50%
- NVP/EFV based regimen = 70% / 30%
- D4T (30mg)/D4T(40mg) = 60% / 40%

Paediatrics:

- Quantification for paediatrics more complex and involved additional assumptions including:
 - Age (1-3, 3-6 and >6)
 - Weight
 - Body Surface areas
 - Paediatrics constitute only 4% of all patients on ART.

2. Quantification Contd...

- Paediatrics Assumptions (Age Vs Weight Vs BSA):

Age in Years	Weight in Kg	BSA	Proportion
0-3	11.5	0.51	20%
3-6	14.0	0.61	60%
Over 6	26.0	0.98	20%

2. Quantification Contd...

- Limitations:
 - Clinical practice didn't reflect assumptions in many of the cases
 - Only one regimen available to paediatrics
 - Limited variety of paediatric formulations
- Interventions:
 - Assumptions modified in the subsequent cycles of procurements to reflect the actual prescribing practice.
e.g. NVP/EFV (60/40%), Combivir/D4T (70%/30%), D4T 30/40mg (70%/30%).
 - Actual consumption data taken into account in subsequent quantification
 - Additional paediatric formulations included in the latest procurement.

3. Procurement

- Key Players on procurement in Ethiopia:
 - MSH/RPM Plus
 - MOH/PASS
 - NGO's (MSF – Holland, ENAHPA, etc)
 - The Private Sector

3. Procurement

- PEPFAR/E Products:
 - Procurement only from FDA approved manufacturers
 - IDA serves as procurement agent/dealer with manufacturers.
- GF Products
 - Procurement can be made from WHO certified manufacturers
 - MISSION PHARMA serves as procurement agent/dealer.
- Once order is placed, the status of the shipment is regularly followed and tracked all the time until received.
- After the shipment is received:
 - PEPFAR/E products are handled by PHARMID.
 - GF Products are handled by MOH/PASS

List of ARV Drugs in the Pipeline (Procurement)

<i>Drug</i>	<i>Supplier</i>	<i>Qty</i>
1. EFV 600mg, 30 caps	Aurobindo	28440
2. EFV 50mg, 30 caps	Merck/Bristol	11508
3. EFV30 mg/ml, 180ml	Merck/Bristol	2740
4. 3TC 150mg, 60 tabs	Aurobindo	88521
5. 3TC10mg/ml, 240ml	Glaxo	20230
6. LPV/r 80/20/ml, 300ml	Abbott	750
7. NFV 250mg, 270 tabs	Roche	4187
8. NVP 200mg, 60 tabs	Aurobindo	51919
9. NVP10mg/ml, 240ml	BI	30834
10. d4T 20mg, 56 caps	Merck/Bristol	4403
11. d4T 30mg, 60 caps	Aurobindo	64260
12. d4T 40mg, 60 caps	Aurobindo	18780
13. d4T 1mg/ml, 200ml	Bristol	6165
14. TDF 300mg, 30 tabs	Gilead	4154
15. ZDV 100mg, 100 tabs	Glaxo	4243
16. ZDV 300mg, 60 caps	Aurobindo	4151
17. ZDV10mg/ml, 240ml	Aurobindo	29912
18. ddI sol, 118ml	BMS	3200
19. IDV 400mg, 180 caps	Merck	1000

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Availability of Pediatric ARVs (PEPFAR/E)

Drug	Stock on hand	New PO
ZDV 50mg/5ml, 200ml syrup	21,600	29,912
ZDV 100mg, 100 tab	3319	4243
3TC 50mg/5ml, 240ml syrup	11,075	20,230
NVP 50mg/5ml, 240ml suspension	16,359	30,834
EFV30 mg/ml, 180ml syrup		2740
EFV 50mg, 30 caps		11508
LPV/r 80mg/20mg/ml, 300ml		750
d4T 20mg, 56 caps		4403
ddI sol, 118ml		3200

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Regimens for Paediatric Use

1. Liquids (Syrups)

- ZDV/3TC/NVP
- D4T/3TC/NVP
- ZDV/3TC/EFV
- D4T/3TC/EFV
- ZDV/3TC/Kaletra
- D4T/3TC/Kaletra

2. Solid

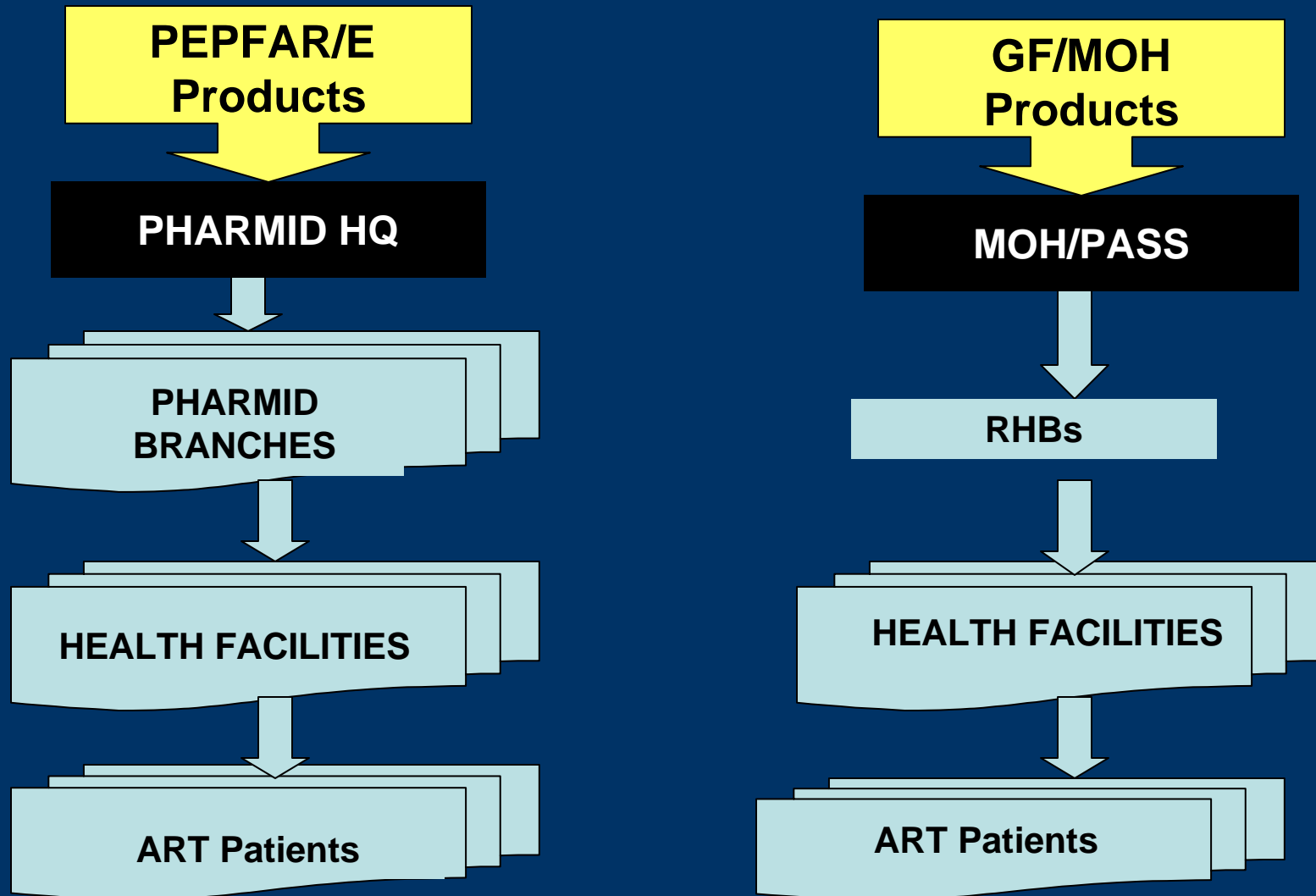
- ZDV/3TC/NVP
- D4T/3TC/NVP
- ZDV/3TC/EFV
- D4T/3TC/EFV

Comparison of the Monthly Cost of Adult and Pediatric 1st Line Regimens

		Cost in USD	Cost in Birr	Remarks
1	AZT/3TC/NVP	55.5	480.63	First Line, Adult
2	AZT/3TC/EFV	48	415.68	First Line, Adult
5	D4T/3TC/NVP	45.7	395.76	First Line, Adult
6	D4T/3TC/EFV	38.2	330.8	First Line, Adult
9	AZT/3TC/NVP	91.76	794.64	1st Line, Pediatric

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Supply Chain of ARV Drugs



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Challenges

◆ Product Related

- Limited suppliers and delay in delivery
- Requirement for special storage (security and refrigeration)
- Short shelf life
- Additional challenges for paediatric drugs procurement:
 - Variety of formulations suitable for children are fewer
 - Dosage more complex and change faster (based on wt., age, BSA)
 - Bulky (require more space for storage)
 - More expensive
 - Stringent storage requirements (more products need to be refrigerated)

Challenges Contd...

◆ Capacity Related

- Infrastructure – Limited storage spaces at many health facilities
- Equipment and/or Facilities: Refrigerators, Lockable cupboards, etc.
- Man power – shortage of trained man power
- Limited uptake of new patients especially paediatrics

Opportunities

- Adequate funding from donors
- Increased commitment of the government
- Accelerated registration of new products by DACA
- Availability of better information/consumption data
- Availability of better experience on procurement
- Availability of more paediatric formulations
- Possibility of procurement from WHO qualified manufacturers – significant reduction in cost.

Recommendations

- ◆ Coordinating the procurement at a national level
- ◆ Quantification to be based on real data
- ◆ Reporting accurate and reliable data from facilities on a regular basis
- ◆ Providing closer assistance and support to facilities
- ◆ Capacity building at the facility level:
 - ◆ Upgrading infrastructures/renovation
 - ◆ Supplying equipments/facilities
 - ◆ Training
 - ◆ Recruitment of additional staff
 - ◆ Strengthening ARV drugs MIS and encouraging regular and timely reporting.

For more information, please contact:

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THANK YOU!!

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