Forecasting pipeline ARVs for Paediatrics

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Medicines Patent Pool
Principles of the Model

- Currently does not include estimates of number of people who may need PrEP (e.g. number of IDUs at high risk of HIV acquisition) or TasP
- Borrows average usage forecast from currently available forecasts till 2018
- Borrows epidemiological estimates from available estimates till 2018
- Assumptions:
  - Linear regression on market share increase
  - Healthy and timely generic competition
  - Introduction of new drugs based on projected development timelines of generic manufacturers and estimated inclusion in WHO Guidelines
  - Price considerations: lower priced medicines would potentially have higher usage
  - Country inclusion: accounts for all low and middle income countries including those with well established ARV treatment programs such as Brazil
  - Accounts mainly for the public market
Introduction of 3 Scenarios

Considered three possibilities:

Scenario 1: Status Quo
- WHO Guidelines remain consistent with current guidelines
- New products when introduced show only a marginal uptake
- Use of Integrase Inhibitors (INIs) limited to 3rd line

Scenario 2: Likely Use
- WHO Guidelines accept and recommend new products using the treatment optimisation framework
- New products have a good uptake; assumed that new FDCs such as those containing DTG, TAF and heat stable DRV/r are made available as generics
- Use of INIs is recommended as preferred options in 2nd and 3rd line in initial years, and later progressing to 1st line use (when more safety data is available)

Scenario 3: Aggressive Adoption
- WHO Guidelines recommend aggressive use of new products
- Use of INIs as preferred option recommended in 1st line
Scenario 1: Status Quo

Guidelines remain consistent with current recommendations

In this scenario:
- **1st line:**
  - Continues to be NNRTI based
  - INI-based regimens used as an alternative, low uptake
  - Marginal use of LPV/r in children, only for <3yrs, due to lack of widespread availability of suitable formulations
  - DTG replaces LPV/r in 1st line
- **2nd line**
  - LPV/r is slowly replaced by ATV/b
  - ATV/b use increases due to its approval in CLHIV >3mos; QD dosing and the potential low cost
- **3rd line**
  - DTG slowly replaces RAL

This scenario is less likely, as generics are already developing low cost FDCs which may be compelling for potential use in developing countries.
Consistent with current Guidelines

- Uptake of ABC increases, becoming the main backbone in 1st line
- Due to higher use of ABC in 1st line, AZT becomes preferred option in 2nd line
- Minimal uptake of TAF for children <10 years
**Scenario 2: Likely Use**

INIs introduced in 1\(^{st}\) and 2\(^{nd}\) line from 2020 (post availability of data)

In this scenario:
- 1\(^{st}\) line
  - Continues to be NNRTI based
  - INI-based regimens used as an alternative
- 2\(^{nd}\) line
  - bPIs used with NRTIs (as per current Guidelines)
  - ATV gains market share from LPV due to low cost and QD dosing
  - INIs used as an alternative to PIs
- 3\(^{rd}\) line
  - Mainly RAL-based, as DTG is used in 1\(^{st}\) line

Some clinical trials are exploring some of these ARVs in naïve and experienced patients. This may be a likely scenario in the initial years.
Likely Use: Backbones

Introduction of INI in 1\textsuperscript{st} and 2\textsuperscript{nd} line

- Uptake of ABC increases, becoming the main backbone in 1\textsuperscript{st} line
- Due to higher use of ABC in 1\textsuperscript{st} line, AZT becomes preferred option in 2\textsuperscript{nd} line
- Low uptake of TDF and TAF
Scenario 3: Aggressive Adoption

INIs recommended in 1ˢᵗ line based on low cost and FDC availability

In this scenario:

- **1ˢᵗ line**
  - DTG is rapidly used in 1ˢᵗ line from year 2020, taking share from both NVP and EFV

- **2ⁿᵈ line**
  - bPIs used with NRTIs (as per current Guidelines)
  - DRV/b becomes one of the main options, along with LPV/r and ATV/r

- **3ʳᵈ line**
  - Mainly RAL-based, as DTG is used in 1ˢᵗ line

This scenario may be a reality in future once WHO gets more data with respect to INIs
Aggressive Adoption: Backbones

INIs recommended in 1\textsuperscript{st} line

- ABC replaces AZT in 1\textsuperscript{st} line, becoming the main backbone
- AZT becomes preferred option in 2\textsuperscript{nd} line
- Low uptake of TDF and TAF
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Thank You