Setting the scene:

Research & Development of HIV Diagnostics for Children

5 November 2020

Lara Vojnov, Diagnostics Advisor in the Global HIV, Hepatitis and STI Programmes, WHO
Despite high levels of PMTCT coverage, new child infections persist and infant diagnosis continues to scale-up slowly.
Call to action to re-prioritize HIV and paediatrics – Several challenges remain in diagnostics

<table>
<thead>
<tr>
<th>Research and development</th>
</tr>
</thead>
<tbody>
<tr>
<td>• High pricing of diagnostic products, requiring outright purchasing of devices and add-on costs</td>
</tr>
<tr>
<td>• Lack of transparency and consistency of pricing across countries, regions, and tests</td>
</tr>
<tr>
<td>• Limited availability and accessibility to novel interventions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Delayed national regulatory approvals</td>
</tr>
<tr>
<td>• Fragmented international and regional coordination of regulatory approvals</td>
</tr>
<tr>
<td>• Lack of funding to meet needs for international and national processes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Still missing a lot of children and weak linkage to treatment of those infected</td>
</tr>
<tr>
<td>• Delays in programmatic integration of diagnostics, particularly sharing of impactful devices</td>
</tr>
<tr>
<td>• Funding gaps to support novel case-finding approaches and procurement of impactful technologies</td>
</tr>
</tbody>
</table>
Improved identification and monitoring through collaboration

- More efficient case-finding
- Streamlined regulatory
- Clearer guidance
- Better, more transparent pricing
- Strengthen commitment to paediatric diagnostics
High-level diagnostic goals

- Suppliers
- Donors
- Countries and partners
- WHO
High-level diagnostic goals

- Suppliers
- Countries and partners
- Donors
- WHO

- Integrated, efficient system
- Multiplex technologies
- Enhanced case-finding
- Streamline regulatory
High-level diagnostic goals

Countries and partners

Suppliers

Donors

WHO

- Support national regulatory agencies
- Post-market surveillance guidance
- Additional guidance for key interventions
High-level diagnostic goals

- Suppliers
- Countries and partners
- Donors
- WHO

Support procurement and operations
Support competitive, healthy market
Research and development – technology pipeline

Available on the market

Centralized

POC

Pipeline products

- Technologies listed by WHO prequalification
- Multiplex/polyvalent technologies that can or will likely be able to test for HIV and another disease assay (i.e. TB, HCV, HPV, etc)
High-level diagnostic goals

- Consistent, transparent pricing
- All-inclusive pricing
- Service level agreements
- Clinical indeterminate range