Improving access to and appropriate use of medicines for newborn and child health for primary health care: amoxicillin and gentamicin

Child Health Task Force Commodities Subgroup

11 January 2022
Agenda

Moderator: Joseph Monehin, USAID

• Introduction (CHTF Commodities Subgroup chairs): Patrick Gaparayi, UNICEF

• Background on uptake of amoxicillin and gentamicin and role of the subgroup: Jane Briggs, USAID MTaPS program

• Prioritized bottlenecks and examples with discussion (Results for Development (R4D), GHSC-Procurement Supply Management (PSM), MTaPS, Promoting Quality of Medicines (PQM) Plus)

• How to contribute evidence: Jane Briggs, USAID MTaPS

• Questions/discussion: Joseph Monehin, USAID
Introduction

– Uninterrupted supply of efficacious, safe, quality and cost-effective essential medicines and other medical technologies are critical for preventing, diagnosing, treating and managing different health conditions that affect newborns and children among other age groups.

– A subgroup on newborn and child health commodities was created in 2019 within the Child Health Taskforce and is co-chaired by UNICEF and USAID.

– Our major aim is to raise awareness and promote collective efforts to improve the way commodities for newborn and child health are prioritized, financed and managed.

– This meeting is in line with some of our specific objectives:

  • To develop evidence-based strategies to improve access to and appropriate use of newborn and child health commodities

  • To share resources on recognized and emerging best practices and innovations as well as practical experiences from implementation in country programs for management of child and newborn health commodities.

– Your participation in different activities of the subgroup is key to continuing to advocate for improved access to and appropriate use of essential health commodities for newborn and children.
Background

• Children are still dying of preventable causes
  – Lower respiratory infections are a leading cause
  – Almost half of under 5 deaths are in newborns due to infections, including sepsis/pneumonia, pre-term complications and birth asphyxia

• Poor access to quality medical products contributes to morbidity and death

• Recent global changes in treatment of newborn and child health conditions still not widely adopted:
  – Amoxicillin DT was recommended in 2014 for pneumonia
  – Oral amoxicillin with gentamicin injection recommended in 2015 for treatment of PSBI where referral is not feasible
  – In sick young infants with fast breathing as the only sign of illness
    • under 7 days old refer and, if referral is not feasible, treat with oral amoxicillin
    • 7-59 days old treat with oral amoxicillin, referral not needed (IMCI 2019)

• Access to and appropriate use of amoxicillin DT and gentamicin for newborn and child health through PHC remains challenging – why?

• What is needed to further the advances already made and move the needle to improve access and appropriate use of amoxicillin DT and gentamicin?
Improving uptake of pediatric oral amoxicillin and gentamicin injection - role of the subgroup

- Engage stakeholders with a wealth of experience to come to consensus on solutions
- A series of 3 consultative meetings for country stakeholders, donors and implementing partners is proposed in early 2022 to:
  - Share the evidence on bottlenecks in uptake of medicines for newborn and child health at primary health care level for three prioritized areas
  - Discuss their root causes
  - Come to consensus on actionable solutions, including a research agenda, as needed, to improve access to and appropriate use of medicines for newborn and child health at PHC levels with clear roles defined for both countries and global partners
- Joint development of call-to-action paper following series of consultative meetings as a resource for country teams
- The members of this subgroup have a key role in compiling existing evidence and in defining the actionable solutions for countries to act on
Focusing our actions

- Three priority bottlenecks to access to and appropriate use (uptake) of amoxicillin and gentamicin are proposed:
  1. Inaccurate quantification at all levels and/or inadequate financing of pediatric amoxicillin and gentamicin formulations
  2. Quality of child health products not guaranteed
  3. Inappropriate use of medicines for treatment of pneumonia and PSBI by providers and caregivers
Prioritized Bottlenecks and Examples of Root Causes (I)

I. Inaccurate quantification at all levels and/or inadequate financing of pediatric amoxicillin and gentamicin formulations

- Examples of root causes contributing to the bottleneck
  - Inaccurate estimation of needs for amoxicillin and gentamicin: community often excluded, incomplete data, etc
  - Insufficient financing for procurement and distribution of these medicines at all levels
  - Inadequate budget lines for these low-cost high-volume medicines
  - Stock outs – weak inventory management and distribution challenges
Amox DT – need for robust quantifications

Challenge:
While global quantification guidance exists, the **ability to conduct robust quantification exercises is limited** due to constrained country-level resources (e.g. human capacity and funding for quantification exercises), lack of available quality data, etc. Lack of robust quantifications is one of many factors that may contribute to insufficient financing and procurement of amox DT. This ultimately leads to shortages and stockouts, such as seen in **Country A** where 68% of facilities were either out of stock or understocked in 2020.

Intervention and impact example:
**Country-level technical support** for quantification exercises – similar to that provided to other commodity areas, like HIV, TB, and malaria – can strengthen methodologies and assumptions. In early 2021, partners supported Country A to **revise its quantification** for amox DT. As a result, an improved methodology led to a **3x increase in quantified volumes**, avoiding continued underestimations of demand.

Country A: Amox DT volumes quantified for FY 20/21, pre vs. post TA (UOM = tablets)

<table>
<thead>
<tr>
<th></th>
<th>Pre TA</th>
<th>Post TA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Facilities</td>
<td>25M</td>
<td>69M</td>
</tr>
<tr>
<td>Community</td>
<td>16M</td>
<td>39M</td>
</tr>
<tr>
<td></td>
<td>9M</td>
<td>31M</td>
</tr>
</tbody>
</table>

**Technical support provided to:**
- **Align dosages** used in quantification methodology with treatment guidelines
- **Expand indications** included to account for conditions (beyond just childhood pneumonia) where amox DT is the recommended treatment
- **Align data assumptions and methodologies** across health system levels

Country A: Amox DT average HF stock status, January-June 2020

<table>
<thead>
<tr>
<th></th>
<th>Overstocked (&gt;4mos)</th>
<th>Adequate (2-4mos)</th>
<th>Understocked (&lt;2mos)</th>
<th>Stockout (0mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock status</td>
<td>27%</td>
<td>41%</td>
<td>15%</td>
<td>17%</td>
</tr>
</tbody>
</table>

2. Quantification volumes sourced from the Ministry of Health’s national RMNCAH Quantification.
Amox DT – insufficient financing

Challenge: Insufficient financing exists to meet demand for amox DT in high burden countries. Further, some high burden countries have been solely dependent on time-limited donor resources for amox DT. Thus, increasing domestically-mobilized resources – alongside donor support – has been necessary to reduce the funding gap and scale-up amox DT.

Intervention and impact example:

Over the past 5 years in a high burden country, alongside market shaping support and evidence-based advocacy, ~$1.5M in donor co-financing has catalyzed ~$1.1M in domestically-mobilized resources for amox DT. The co-financing agreement was designed to gradually increase government funding as donor funding decreases.

Each year, the government and donor coordinated to ensure the full funding need for amox DT was fulfilled. Flexibility in the co-financing agreement allowed the government to readjust targets and avoid wastage in response to amox DT utilization challenges.

Country B: Amox DT 250mg funding, 2016-2020 (USD, thousands)³

<table>
<thead>
<tr>
<th>Year</th>
<th>Donor co-financed</th>
<th>Domestically-mobilized</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>$459</td>
<td>$459</td>
</tr>
<tr>
<td>2017</td>
<td>$434</td>
<td>$246</td>
</tr>
<tr>
<td>2018</td>
<td>$486</td>
<td>$383</td>
</tr>
<tr>
<td>2019</td>
<td>$286</td>
<td>$302</td>
</tr>
<tr>
<td>2020</td>
<td>$302</td>
<td>$0</td>
</tr>
</tbody>
</table>

In 2018, gov’t delayed funding due to identified utilization challenges

³ Amox DT financing sources and amounts collected from the Ministry of Health
Assessment of the Availability of Quality Amoxicillin DT in Mali & Liberia - GHSC-PSM

• **Forecasting and quantification**
  – At the time of assessment Amoxicillin DT had not been quantified for facilities served by the national supply chain. (Mali and Liberia)
  – As of Sept 2019, no government financial resources were dedicated to the procurement of amoxicillin DT and so only available through partners sporadically. (Mali)
  – The guidelines do designate the DT formulation of amoxicillin for pneumonia treatment, but only oral suspension formulation forecasted and procured by government as of February 2020. (Liberia)
  – Amoxicillin DT classified on general essential medicines list and not included in specific government health area programs that receive elevated attention and resources. (Liberia)
  – Quantification process conducted with limited consumption data available and low-quality data. (Mali and Liberia)

• **Use**
  – Implementing partners supporting service delivery programs provided some commodities outside the national system (Mali)
    • Availability inconsistent without centralized leadership within the Malian government.
    • No data on consumption captured meaning a lack of visibility on consumption and stock status.
  – A large proportion of NBCH services are provided by community health assistants (CHAs). Amoxicillin DT provided by partner-managed parallel supply systems and bypasses the national health supply chain. (Liberia)
Prioritized Bottlenecks and Examples of Root Causes (II)

2. Quality of child health products not guaranteed
   • Examples of root causes contributing to the bottleneck
     – Selection of suppliers by procurement agencies not based on quality. Price criteria more widely considered
     – Technical specification for procurement of amoxicillin and gentamicin injection lacking or incomplete
     – Weaknesses and inefficiencies in registration of medicines
     – Suppliers of registered medicines don’t respond to national tenders
     – Manufacture of poor quality MNCH medicines- low capacity to follow GMP, regulatory authority inspection capacity insufficient
Examples of quality of child health products not guaranteed

Registration of amoxicillin & gentamicin (MTaPS study 2020)

- 2 of 9 countries studied had no amoxicillin DT products registered
- 6 of 9 countries had products of amoxicillin DT 125mg registered
- 6 of 9 countries had products of amoxicillin DT 250mg registered
- 8 of 9 countries had products of amoxicillin oral suspension registered
- 7 of 9 countries had a registered product for gentamicin 80mg injection but only 2 of 9 had a registered product for gentamicin 20mg injection

Example from Mali (PQM Plus): Post-marketing surveillance exercise from 2021 found, 100% of amoxicillin DT samples collected were NOT registered
Prioritized Bottlenecks and Examples of Root Causes (III)

3. Inappropriate use of medicines for treatment of pneumonia and PSBI by providers and caregivers

   • Examples of root causes contributing to the bottleneck
     - Country treatment guidelines not implemented in practice (translation of policy to practice)
     - Providers do not have access to treatment guidelines
     - Providers do not prescribe and dispense correct medicines for example because of:
       • Problems of availability
       • Unfamiliar with the STGs
       • Prefer to use another medicine
Examples of inappropriate use of medicines for treatment of pneumonia and PSBI by providers and caregivers

• Comparing relevant policies in place for pneumonia and diarrhea management (WHO survey 2019) and indicator coverage (last household survey) has shown that policies are a must but not a guarantee that all children will get quality service delivery at the last mile (UNICEF preliminary analysis).

• Amoxicillin not included in STGs and EMLs (Liberia and Mali GHSC-PSM 2020)

• Appropriate prescribing (per STGs) of amoxicillin for pneumonia increased from 13% to 86% in Ethiopia after 1 year (GHSC-PSM)
  – Root causes of problem - Lack of knowledge of STGs; lack of prescriber knowledge on childhood pneumonia; negative perceptions on the efficacy of amoxicillin; limited clinical monitoring
  – Interventions: Disseminated and improved awareness of guidelines, implementing order sheets for stock management, and conducted supportive supervision visits.

• Problem of adherence to administration of treatment with amoxicillin by caregivers (they forget, don’t understand etc.) With use of dispensing envelopes, 76% caregivers reported administering amoxicillin correctly (DRC SIAPS program)
How to contribute your evidence

• Ahead of the consultative meetings, evidence is being gathered on the 3 bottlenecks, their root causes, and any successful solutions or unsuccessful interventions (peer review literature & partner contributions)

• The evidence will be compiled into presentations for the meetings

• Please contribute by **January 26**, using this [Google Sheet](https://docs.google.com/spreadsheets)

• Find the appropriate tab on the google sheet (1 tab per bottleneck) and enter data on
  
  – Results and observations on any or all of the 3 prioritized bottlenecks from your country work
  
  – Data or evidence that shows the root causes of these bottlenecks
  
  – Descriptions of any successful (or unsuccessful) interventions you have used to mitigate any of these bottlenecks and results.
<table>
<thead>
<tr>
<th>Evidence of bottleneck (any data or descriptive information)</th>
<th>Source</th>
<th>Root cause(s) of bottleneck</th>
<th>Interventions implemented or recommendations</th>
<th>Results</th>
<th>Country</th>
<th>Organization</th>
<th>Contact person &amp; e-mail</th>
<th>Additional references</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>insufficient amox DT quantified</td>
<td>RAID</td>
<td>limited capacity and data challenges remain inability to quantify amox DT</td>
<td>Quantification TAs</td>
<td>TA has improved access to multiple SSA countries with high burden of childhood pneumonia. In one country in 2019, TA supported quant improvements amounting to 3x increase in volume of amox DT quantified (20mg to 60mg tablets)</td>
<td>SSA</td>
<td>RAID</td>
<td>Samantha. <a href="mailto:udock@gh.org">udock@gh.org</a></td>
<td><a href="https://www.ghsupplychain.org/how-supply-chain-improves-health-commodity-availability-liberia-and-mali">link</a></td>
<td></td>
</tr>
<tr>
<td>Funding gap for amox DT</td>
<td>RAID</td>
<td>insufficient domestic and donor resources mobilized</td>
<td>TA provided support to resource mobilization coordination. For example, in one country, RAID provided TA to create a system which MOH will use to identify funding commitments across govt and donors. The task committee also calculates remaining funding plan to support MOH in further resource mobilization</td>
<td>In one high burden country, since 2017, co-financing led to $1.1M allocated to amox DT (5.5X increase of courses of amox DT) and in 2019 for the first time the govt provided majority of amox DT funding</td>
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<td>Funding gap for amox DT at subnational level. In subnational surveys across 6 countries, the % of providers and DHMT members who agreed that funds are insufficient at the subnational level to support amox DT are as follows: Burkina Faso 15%, Ethiopia 12%, India 32%, Kenya 61%, Nigeria 17%</td>
<td>PATH Asset Tracker Subnational Survey</td>
<td>insufficient domestic and donor resources mobilized</td>
<td>Co-financing to provide donor funding while supporting govt to mobilize domestic resources for sustainable financing</td>
<td></td>
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<td>GHSC-PQM assessment of the availability of amox DT in Liberia in 2020</td>
<td>PATH Asset Tracker</td>
<td>limited of awareness of potential cost and supply chain management benefits of amox DT</td>
<td>Information shared with MOH Family Health Division and from the benefits of using amox DT formulation for treatment of pneumonia. Routine activity coordinated by the Ministry to adapt TAs.</td>
<td></td>
<td>Liberia</td>
<td>GHSC-PQM</td>
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<td>Recommendation to include amox DT in future procurement</td>
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<td>Liberia</td>
<td>GHSC-PQM</td>
<td>Jenn Chavez (<a href="mailto:jchavez@ghsc-pqm.org">jchavez@ghsc-pqm.org</a>)</td>
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<td>insufficient resources and attention</td>
<td>Recommendation to integrate essential commodities such as amox DT into the Reproductive Health Program</td>
<td></td>
<td>Liberia</td>
<td>GHSC-PQM</td>
<td>Jenn Chavez (<a href="mailto:jchavez@ghsc-pqm.org">jchavez@ghsc-pqm.org</a>)</td>
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<tr>
<td>GHSC-PQM included MCH/Innovations in country’s national health logistics management information systems (HNLMIS), developed standard operating procedures and trained 35 male and female logistics trainers in 4 states level</td>
<td>GHS-PQM</td>
<td>MCH/Innovations not included in</td>
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</table>
Data to compile

- **Evidence of bottleneck (any data or descriptive information)** - eg any data or observations that show that there is a problem of inadequate quantification or financing of pediatric amoxicillin or other CH commodities
- **Source** - Journal article, project report, MoH document, etc.
- **Root cause(s) of bottleneck** - describe here what the underlying cause of your example may be - eg lack of resources, lack of capacity, no tool, etc.
- **Interventions implemented or recommendations** - describe any intervention that you have put in place or any recommendations you have to address the problem
- **Results** - describe the results of what you implemented in previous column
- **Country**
- **Organization**
- **Contact person & email**
- **Additional references**
- **Comments**
Questions/Discussion
Resources

Engage with the co-chairs:

- Joseph Monehin: jmonehin@usaid.gov
- Ken Legins: klegins@unicef.org

Subgroup information, recordings and presentations from previous webinars and meetings are available on the subgroup page of the Child Health Task Force website: www.childhealthtaskforce.org/subgroups/newborn

*The recording and presentations from this meeting will be available on this page later today*

Check out the Task Force Child Health & COVID-19 web page for additional resources!

Suggestions for improvement or additional resources are welcome. Please email childhealthtaskforce@jsi.com.