Call to Action:

Improve access and use of quality medicines to save lives of children and newborns

CHILD HEALTH TASK FORCE

unicef

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Improve access and use of quality medicines to save lives of children and newborns

Each year, more than 700,000 children under the age of five[1] die needlessly worldwide from pneumonia and other treatable respiratory infections. Ninety percent of these children[2]—most of them newborns and infants—live and die in 40 low- and middle-income countries (LMICs), where nearly seven million babies under two months old experience episodes of possible serious bacterial infection (PSBI) every year. Without accelerated action, as many as 54 countries, mostly in sub-Saharan Africa, will not achieve their 2030 targets under Sustainable Development Goal 3 for reducing under-five mortality.[3]

It is in our power to prevent these tragic deaths

Inexpensive, widely available **antibiotic medicines—amoxicillin (in pediatric form of dispersible tablet or suspension) and injectable gentamicin—are proven effective at the primary health care level for treating children with pneumonia and newborns with PSBI.** It has been ten years since the UN Commission on Lifesaving Commodities (UNCoLSC) galvanized global and country efforts to improve access to and quality of these and other priority medicines. Yet, in many communities around the world, too many children and newborns continue to die because of inadequate access, inconsistent quality, and inappropriate use of these safe, effective medicines.

This **Call to Action** describes **practical, feasible, and affordable actions** that national governments, civil society, donors, and implementing partners should take to increase the use of these medicines to save the lives of children with pneumonia and newborns with PSBI. These recommendations were identified through a consultative process by diverse global and country-level stakeholders.

While it is not an exhaustive list of every action needed in every context, these recommendations address critical challenges that countries face in ensuring access to, quality of, and appropriate use of essential medicines and medical supplies for primary health care—specifically amoxicillin and gentamicin, the first-line medicines that WHO recommends for treating community- acquired severe pneumonia and PSBI in children and newborns.

Photo by GHSC-PSM

At a series of three consultations* in May 2022, the Newborn and Child Health Commodities subgroup of the Child Health Task Force (CHTF)—including technical experts from government agencies, global health institutions, NGOs, the private sector, and academic institutions—reviewed current evidence, identified root causes, and agreed on actionable solutions, including a research agenda, for improving access to and ensuring appropriate use of amoxicillin and gentamicin, as tracers/proxies for other essential child health commodities. This Call to Action sets out these recommended solutions, and describes the critical roles of country stakeholders, donors, implementing partners, and civil society organizations in driving purposeful action and saving children's lives.

[1] https://data.unicef.org/topic/child-health/pneumonia/#:~:text=A%20child%20dies%20of%20pneumonia,of%20these%20deaths%20are%20preventable [2] https://stoppneumonia.org/wp-content/uploads/2020/12/Every-Breath-Counts-Careseeking-Scorecard-1.pdf [3] Levels & Trends in Estimates developed by the UN Inter-agency Group for Child Mortality Estimation Child Mortality 2021 UN Inter-agency Group for Child Mortality Estimation https://data.unicef.org/resources/levels-and-trends-in-child-mortality/ *https://www.childhealthtaskforce.org/events/2022/05/improving-uptake-amoxicillin-and-gentamicin-three-part-consultation

The Problem:
Four Key Bottlenecks

While many bottlenecks impact access to and appropriate use of amoxicillin, gentamicin and other essential medicines for primary health care—such as governance and lack of coordination—four bottlenecks have been prioritized in this call to action.

Poor quantification of need

Weak health supply chains prevent medicines from reaching the children who need them. Quantification—the process of estimating needs for medicines and health supplies (forecasting) and planning procurement and deliveries —is essential for effective budgeting, resource allocation, resource mobilization, planning for procurement and delivery. Countries—from health ministries down to health facilities and community service points—lack the information, data systems, and capacities needed to accurately quantify how much medicine they need to procure, where it will be needed, and when it has to be there.

Insufficient financing

Sufficient and sustainable funding for newborn and child medicines is a complex challenge and remains a primary barrier to reliable product availability. Despite the low cost of amoxicillin and gentamicin, neither governments nor donors allocate sufficient funds to purchase and maintain necessary supplies. Significant resource mobilization is needed to alleviate both short- and long-term financing gaps.

Lack of quality assurance

An estimated 10% of medical products that reach users in LMICs are substandard or falsified.[4] Substandard antibiotics are ineffective and dangerous, resulting in prolonged treatment and growth of medicine-resistant microbes that make infections difficult or impossible to treat; ultimately killing children. Quality assurance—actions to ensure that medicines are safe, effective, and meet quality standards—requires compliance with good manufacturing practices, specification of proper packaging (e.g., blister packs for amoxicillin dispersible tablets and 1ml syringes, calibrated with 0.2ml markers for gentamicin administration to newborns), coordination among procurers and regulators, and appropriate storage, transportation, and product surveillance throughout the product lifecycle.

Inappropriate use

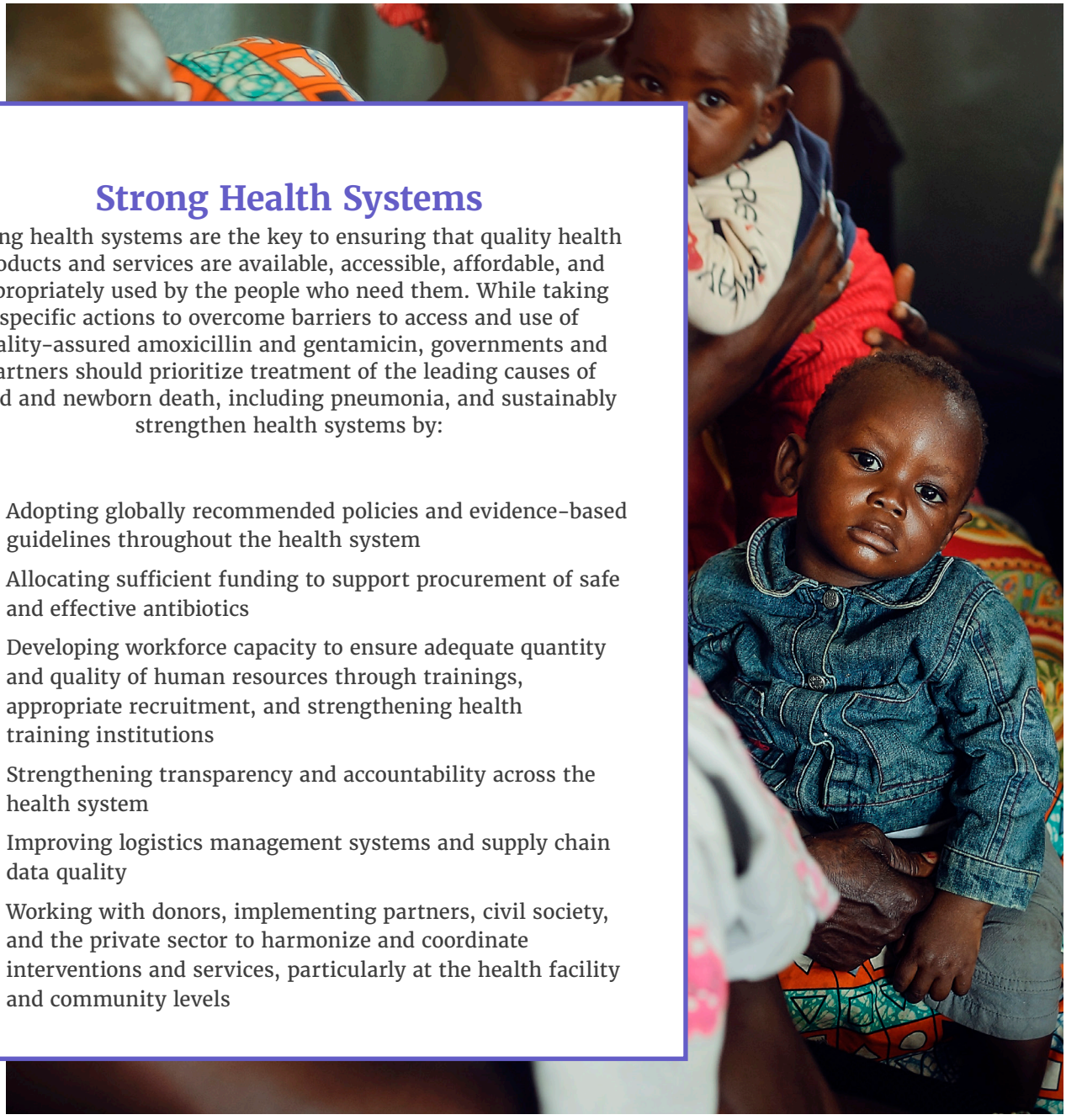
Worldwide, more than half of all medicines are prescribed, dispensed, or sold inappropriately. Patients often do not receive the most appropriate medicine for their condition or medicines are not prescribed and dispensed in the appropriate amount or administered in the appropriate dose, frequency, and length of treatment. Additionally, half of all patients fail to take medicines correctly, according to WHO estimates. Between 25% and 60% of children seeking care for pneumonia receive inappropriate treatment,[5] despite clear global treatment recommendations, for a range of reasons including caregivers' use of inappropriate health care providers, providers' failure to follow standard treatment guidelines, and product unavailability at facilities and in communities.

Photo by GHSC-PSM

[4] World Health Organization. (2017). A study on the public health and socioeconomic impact of substandard and falsified medical products. [5] Kruk, M.E. et al., 2018. High-quality health systems in the Sustainable Development Goals era: time for a revolution. The Lancet Global Health, 6(11), pp.e1196–e1252. https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30386-3/fulltext

Take Action Now:
Practical, Feasible, Affordable Interventions

By taking action now, countries can effectively address the bottlenecks inhibiting access to and use of quality-assured amoxicillin and gentamicin for management of childhood pneumonia and PSBI. Many of these recommended actions are not new: in fact, they are widely known but, a decade after UNCoLSC, are still not widely implemented. Countries are encouraged to design and own their own solutions to these bottlenecks, in collaboration with all stakeholders and partners.



Strong Health Systems

Strong health systems are the key to ensuring that quality health products and services are available, accessible, affordable, and appropriately used by the people who need them. While taking specific actions to overcome barriers to access and use of quality-assured amoxicillin and gentamicin, governments and partners should prioritize treatment of the leading causes of child and newborn death, including pneumonia, and sustainably strengthen health systems by:

- Adopting globally recommended policies and evidence-based guidelines throughout the health system
- Allocating sufficient funding to support procurement of safe and effective antibiotics
- Developing workforce capacity to ensure adequate quantity and quality of human resources through trainings, appropriate recruitment, and strengthening health training institutions
- Strengthening transparency and accountability across the health system
- Improving logistics management systems and supply chain data quality
- Working with donors, implementing partners, civil society, and the private sector to harmonize and coordinate interventions and services, particularly at the health facility and community levels

Photo by GHSC-PSM

Photo by GHSC-PSM

Strengthen Quantification

To strengthen quantification, including for primary health facility and community levels, countries should:

- **Coordinate forecasting and supply planning**—across governments, procurement agents, and partners—by improving transparency on types of commodities, quantities, timing, and intended recipients
- **Improve timeliness and accuracy of data collected at all levels of the health supply chain** through electronic logistics management information systems (eLMIS) and health management information systems (HMIS), linked to enable planners to model changes in demand and consumption
- **Build skills for data organization**, routine review, and analysis of consumption data and use established tools to conduct quantifications

Donors should continue to support countries in sustainably strengthening forecasting and supply planning through training on best practices and provision of financial resources.

Increase Financing

To increase financing for amoxicillin and gentamicin, countries should:

- **Build capacity to manage available domestic resources** efficiently and transparently
- **Improve transparency of financial commitments for procurement of medicines** and build accountability mechanisms for tracking budget allocations. Support civil society in developing capacities and tools (such as commodity and funding gap impact analyses) to engage, advocate, and monitor allocated funding for newborn and child health commodities
- **Include community-level requirements** for amoxicillin in grant applications to the Global Fund to Fight AIDS, TB, and Malaria, taking advantage of its recently announced intention to fund non-malaria commodities as part of a comprehensive package of commodities for integrated community case management of childhood illnesses (iCCM)

Donors should invest in co-financing agreements, support advocacy for increased domestic financing, and provide short-term supplies of medicine to bridge immediate gaps.

Photo by GHSC-PSM

Improve Quality Assurance

To improve quality assurance throughout the product lifecycle, countries should:

- **Strengthen national regulatory agencies** by streamlining product registration and supporting risk-based approaches such as Good Manufacturing Practice (GMP) inspections and routine post-marketing surveillance
- **Ensure that all procurers accurately specify quality requirements in tender documents and purchase only quality-assured products** (e.g., with WHO prequalification or national market authorization, approval by a WHO-listed regulatory authority, or acceptance by UNICEF)
- **Advance regulatory convergence and harmonization** through information exchange and work-sharing platforms that support regional inspections and market authorizations
- **Strengthen coordination mechanisms** (including between health and finance ministries) to eliminate constraints to procurement of quality-assured products, such as rules that do not take quality into consideration when requiring purchase of lowest price or locally manufactured products
- **Raise public awareness**—nationally and among communities and consumers—of the presence, consumption, and dangers of substandard and falsified products
- **Use long-term procurement agreements and tax and tariff waivers to incentivize local manufacture** using raw materials and finished pharmaceutical product (FPP) that meet quality standards
- **Ensure uninterrupted availability of quality-assured gentamicin and amoxicillin** at all health facilities and community service delivery points (including 1ml syringes calibrated with 0.2ml markers, needed for administration of gentamicin) through proper storage and planned, systematic distribution
- **Employ a multisectoral approach** to include pharmaceutical manufacturers, suppliers, retail and wholesale outlets to ensure quality throughout the supply chain
- Donors should deploy resources to strengthen regulatory practices and coordination, support improved procurement and supply chain practices focused on quality-assured products, and incentivize use of GMPs by local manufacturers.

Photo by GHSC-PSM

Enable Appropriate Use

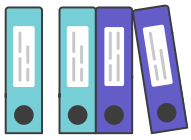
To enable appropriate use of amoxicillin and gentamicin for management of childhood pneumonia and PSBI, countries should:

- **Align national policies and guidelines with global recommendations** that promote appropriate use of these antibiotics, and disseminate them to all providers through pre-service and refresher training and across a range of media channels
- **Provide appropriate training for health workers,** not only on treatment protocols, but also on counseling patients on treatment adherence and administration of newborn IM injections
- **Provide electronic decision-making tools**, to support providers in complying with protocols and standards of care
- **Ensure effective supervision,** for mentoring, and coaching for all health workers
- **Set standards and indicators to monitor availability and use practices of providers and caregivers** for management of pneumonia and PSBI, promoting community participation in monitoring where feasible, and systematize continuous quality improvement and performance monitoring
- **Design and implement evidence-based, multifaceted interventions in addition to training.** Engage opinion leaders and civil society to target key root causes of inappropriate practices among providers and caregivers, link to messaging on reducing antimicrobial resistance and appropriate and timely care seeking, and respond to specific challenges relating to administration of gentamicin
- **Research the linkages between rational use of medicines, payment mechanisms, insurance schemes,** and best practices for engaging private-sector health care providers to support their adherence to quality standards (including appropriate use of amoxicillin and gentamicin)
- Donors should support implementation research and social and behavior change communication (SBCC) interventions that address the root causes of inappropriate use of amoxicillin and gentamicin by providers and caregivers.

Doing Your Part:

Roles of Key Stakeholders

Government



National Regulatory Agencies

Set product quality standards, facilitate and monitor compliance in the health supply chain

Ministry of Health

Set national health policy, develop strategic plans, deliver health services, drive implementation of all interventions, and ensure accountability

Ministry of Finance

Establish funding levels, release the necessary funds and ensure efficient utilization of resources

National Procurement Agency/ Central Medical Stores

Procure, store and distribute essential medicines for the country

To All Stakeholders

As countries and partners take focused action to drive progress and save children's lives, all stakeholders have critical roles to play.

Improved access to and appropriate use of quality-assured amoxicillin and gentamicin

Donors

Partner with national governments to invest in research and high-impact strategies that strengthen needed capacities and drive recommended actions

Implementing Partners

Provide technical support and capacity strengthening to enable implementation of recommended actions and further research where needed

Civil Society

Advocate, monitor, and hold governments, donors, and implementing partners accountable for taking recommended actions

Developed by the USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, the USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project, and the Promoting the Quality of Medicines Plus (PQM+) program with collaboration from Clinton Health Access Initiative (CHAI), PATH, Results for Development (R4D).