

# The pathway to **better medicines** for children

As the World Health Organization counts down to 2015 and the Millennium Development Goal to reduce under five-year-old mortality by two-thirds, we reflect on the achievements of the Better Medicines for Children project.

UN Photo/Sophia Paris



# Eight million reasons to do more

One statistic drives The Better Medicines for Children project towards success. **Every year, an estimated 8.1 million children die before their fifth birthday, many because they do not have access to simple, affordable medicines.**

Developing countries are most acutely affected. Even basic, low-cost treatments such as zinc and oral rehydration salts for diarrhoea are often unavailable. Yet these simple treatments could save millions of lives.

When child specific medicines are not available, healthcare workers are obliged to adapt medicine intended for adults. Tablets are crushed into imprecise portions or dissolved into unpalatable drinks that are difficult to administer and potentially ineffectual or toxic.

Treatment of chronic conditions, such as HIV/AIDS require a daily dose of several medicines over a long period of time. In such circumstances, fixed-dose combination products – a single pill which contains several drugs – are optimum. However, few fixed-dose combinations exist in child-size formulations.

The problem is compounded if a country's health system is further constrained by weak medicine regulatory and selection procedures, fragile medicine supply and distribution chains, and health facilities which are under-resourced and unable to meet the high cost of providing children's medicines.



UN Photo/Eskinder Debebe

## The top five health risks to children under five years:

**PNEUMONIA AND OTHER ACUTE LOWER RESPIRATORY INFECTIONS** are the biggest single cause of death among this age group. Every year an estimated 1.6 million children die from pneumonia.

**HIV/AIDS** — An estimated 370 000 children were newly infected in 2009. Most infections occur in sub-Saharan Africa and are the result of transmission from mother to child.

**MALARIA** — 40% of children live in malaria-endemic countries. More than 700,000 children die every year from malaria infection.

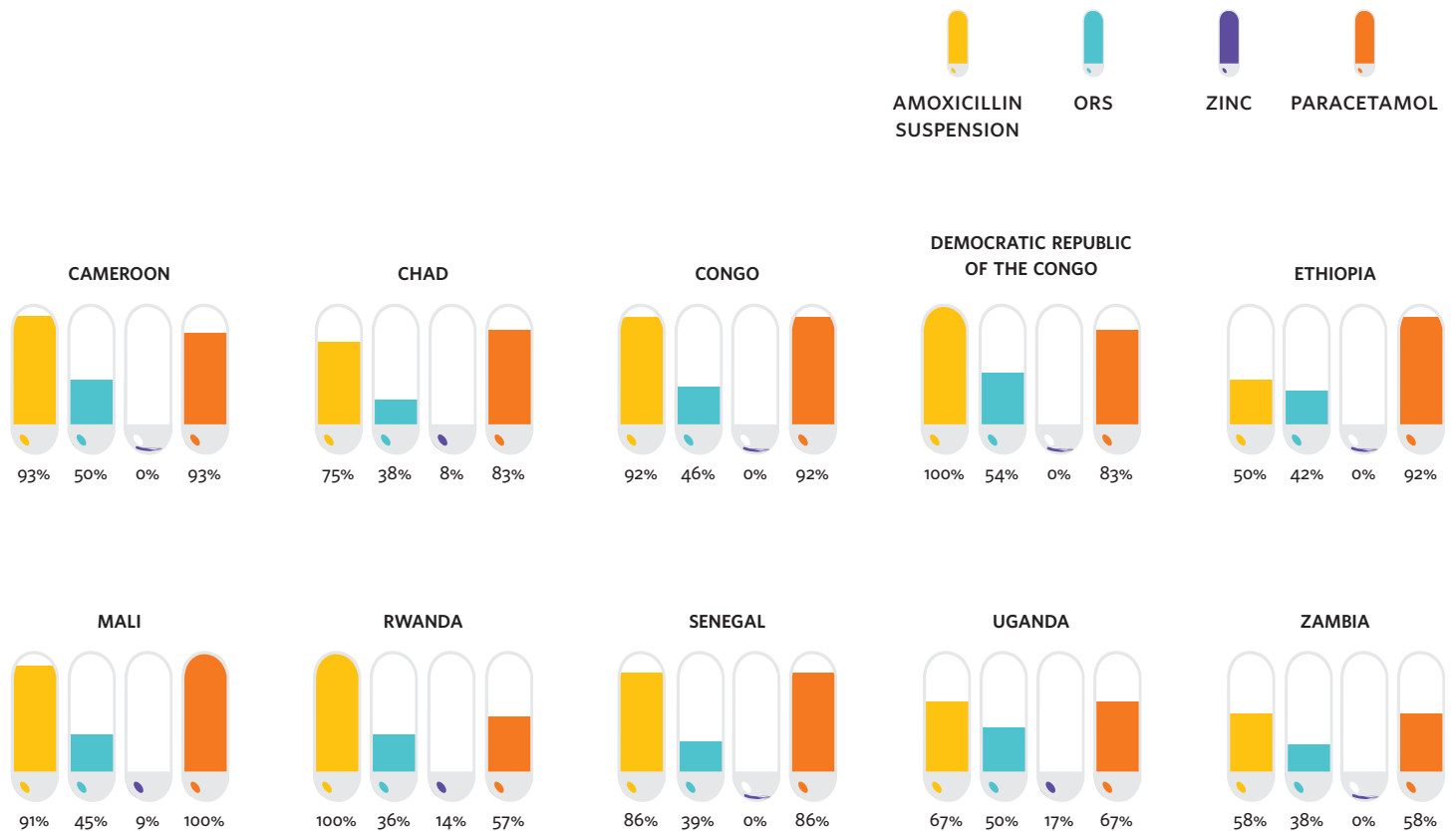
**DIARRHOEAL DISEASES** — An estimated 1.3 million children under five die each year from diarrhoea and related complications.

**NEONATAL SEPSIS** — One quarter of the estimated 3.6 million neonatal deaths around the world each year are caused by severe infections. Around half a million deaths are due to neonatal sepsis alone.

# Evidence for change

Almost three million children die needlessly each year from pneumonia and diarrhoea alone. The treatment of choice for pneumonia – amoxicillin – appears to be available in developing countries, however critically, not in the recommended dose and formulation. ORS and zinc is the recommended treatment for diarrhoea. Yet ORS is available in less than 50% of centres and zinc is not available at all in many countries. The consistent availability of paracetamol shows that procurement and supply systems are working well enough for children to have access to life-saving medicines.

## PERCENTAGE OF HOSPITALS, CLINICS AND PHARMACIES WITH MEDICINE IN STOCK



# What it will take

*'Success depends heavily on the integration of health programmes and the strengthening of underlying health systems.'* Dr Margaret Chan, Director-General of the World Health Organization speaking at the 128<sup>th</sup> session of the Executive Board.

A positive result requires investment in all of the health system building blocks: finances, workforce, information on which to base decisions, facilities and logistics to deliver medicines and technologies.

In addition, more research is required to develop child-size formulations and to learn more about their efficacy and safety. To this end, guidance is required to ensure that research is carried out appropriately and that the regulatory pathways exist to ensure rapid access. Research and development is also needed to determine appropriate packaging and labelling.

# From evidence to practice

An important step in improving paediatric health care is to assess the current availability and costs of essential medicines for children in countries. These assessments provide the evidence for change necessary for improving health outcomes in children. Three countries have been participating in the Better Medicines for Children project laying such foundations for the change in policy and practice that is required.

## India

The establishment of Essential Medicines Lists for children in two states, Orissa and Chhattisgarh is currently under way. The Indian Academy of Paediatrics is also reviewing a list for implementation at a national level. This will allow for better selection and procurement of child medicines based on specific needs. Pricing and availability studies of medicines for children in both states have been completed.

## Ghana

A literature review and baseline survey of available medicines for children have been carried out. Additionally, an assessment has been made of the local manufacturing capacity, and studies have been completed on quality of care, pricing and availability. Trainings for Drugs and Therapeutic Committees have been given on medicine selection procedures.

## Tanzania

In addition to quality of care, Tanzania has investigated drug pricing and the capacity to manufacture essential medicines locally. A survey of health care professionals, care-givers and children was carried out to provide insight into consumer opinion about medicines for children.

## In the pipeline for 2011

- 📌 The 2nd edition of the Pocketbook of Hospital Care for Children will be published and disseminated, providing countries with an updated essential care guide.
- 📌 Collaboration is under way with drug regulatory authorities to streamline registration and licensing procedures.
- 📌 Promotion of partnerships with researchers and advocacy to manufacturers to advance product development will continue.
- 📌 New guidelines for treatment of chronic pain, diarrhoea and pneumonia in children will be published to provide direction to healthcare professionals.
- 📌 The Model Formulary for Children, published in 2010 will be disseminated and its implementation monitored.



# Charting our success

The Better Medicines for Children project, launched in October 2008, has not only sought to promote better access to medicine for children – but to bring about better use of medicine.

To this end, WHO has made progress on several fronts: essential tools, such as treatment guidelines and information on the use of more than 240 essential medicines have been developed and published; relevant professional groups have been engaged; and key studies initiated.

## Highlights

### **May 2007: Resolution on Better Medicines for Children passed by the 60th World Health Assembly**

The resolution urges Member States and WHO to take action on the development of international standards and regulations to promote better access to essential medicines for children.

### **December 2007: Publication of the first ever WHO Model List of Essential Medicines for Children**

This list of more than 200 medicines, including HIV/AIDS treatment, vaccines, anaesthetics, hormones, vitamins and minerals serves as a reference for countries to develop National Essential Medicines Lists, according to their specific public health needs. The list is updated every two years and has been recognized as a powerful tool to promote health equity

**September 2008: The International Conference of Drug Regulatory Authorities** convenes to discuss regulation of medicines for children, including clinical trials.

### **January 2009: Publication of Sources and prices of selected medicines for children**

This guide offers up to date information on the availability and pricing of 612 different paediatric formulations selected from the WHO Model List of Essential Medicines for Children. The second edition was published April 2010.

### **April 2010: Publication of WHO Model Formulary for Children**

This guide provides information to health-care professionals on how to prescribe more than 240 essential medicines for children up to the age of 12.

### **March 2011: Publication of the priority medicines for mothers and children**

This list highlights the most important medicines for mothers and children that should be available throughout health systems.

## The right medicine

With support from a network of experts, new treatment and dosage guidelines for children with tuberculosis have been developed. In addition, research teams have successfully combined the essential active ingredients to form a dispersible solid oral medicine as recommended by WHO.

The task however, is not complete. The prototype is the size of a large coin, too big for a child to comfortably swallow. In addition, the taste is not pleasant. The challenge for scientists and the pharmaceutical industry is to work together to refine and transform it into a palatable medicine in the recommended formulation.



## Current needs

Since its inception, the Better Medicines for Children project has continued to discover new needs and fresh challenges. Our progress to date reflects the outstanding confidence, interest and commitment our partners and donors have expressed. To bring about long-lasting change, the momentum must continue. Our priorities are to:

- ✎ Expand the Better Medicines for Children project to other countries in need.
- ✎ Develop the appropriate fixed-dose combination for treatment of tuberculosis in children.
- ✎ Formulate standards for product development for medicines for children.
- ✎ Implement proven strategies to improve quality of care in Tanzania and Ghana.
- ✎ Support authorities in the development of capacity for regulation.
- ✎ Develop standard strategies for labelling and administration of medicines for children.

## A role for every stakeholder

- ✎ Governments have the means to expedite access to essential medicines through effective regulatory, supply and procurement mechanisms and to ensure that health care workers have the skills to facilitate the appropriate use of essential medicines for children.
- ✎ Health-care workers can ensure that children receive the right medicine in the right dose at the right time.
- ✎ The research community and pharmaceutical manufacturers have the expertise to address development gaps in the area of medicines for children, particularly in respect to dosage forms and clinical trials.
- ✎ Civil society, health-care providers and their affiliates play a pivotal role in raising awareness among policy makers about the need to improve access to appropriate pharmaceutical treatments for children.
- ✎ By becoming informed, individuals can stimulate public debate about this global need.

### Help make medicines child size

To find out more about Better Medicines for Children visit: [www.who.int/childmedicines/](http://www.who.int/childmedicines/)

To discover how you can contribute, please contact [pedmeds@who.int](mailto:pedmeds@who.int)



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