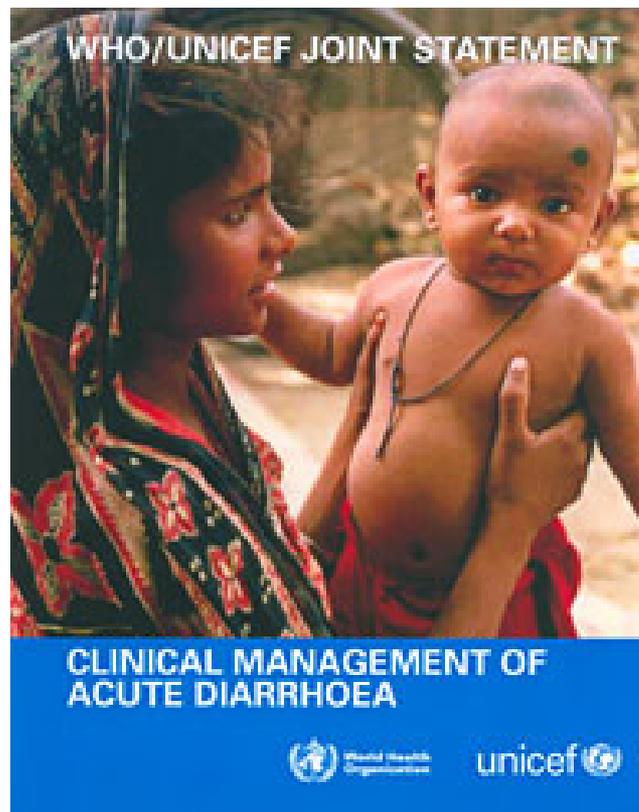


Zinc for management of diarrhoea

Consultation with Pharmaceutical Manufacturers
20-21 October 2008

WHO/UNICEF Joint Statement on Clinical Management of Acute Diarrhoea (2004)



JOINT STATEMENT

More than 1.5 million children under five continue to die each year as a result of acute diarrhoea. The number can be dramatically reduced through critical therapies such as prevention and treatment of dehydration with ORS and fluids available in the home, breastfeeding, continued feeding, selective use of antibiotics and zinc supplementation for 10–14 days.

These new recommendations, formulated by UNICEF and WHO in collaboration with the United States Agency for International Development (USAID) and experts worldwide, take into account new research findings while building on past recommendations. Success in reducing death and illness due to diarrhoea depends on acceptance of the scientific basis and benefits of these therapies by governments and the medical community. It also depends on reinforcing family knowledge of prevention and treatment of diarrhoea, and providing information and support to underserved families.

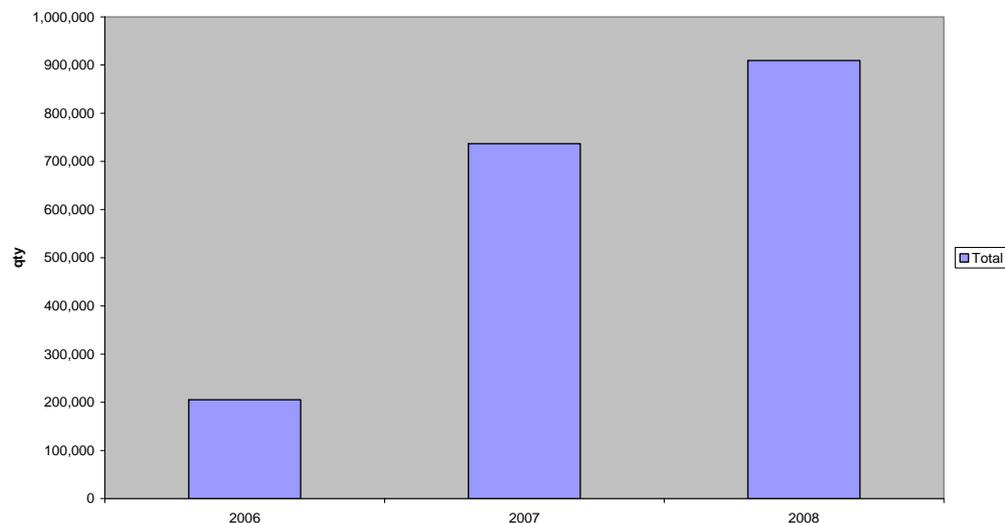
Follow up to the recommendation

- Following the publication in 2004 of the WHO/UNICEF joint statement on the clinical management of acute diarrhoea, recommending the use of zinc in the clinical management of acute diarrhoea, efforts to ensure the availability and use of suitable zinc products in countries were conducted by WHO, UNICEF, USAID and Johns Hopkins University.
- In 2005, a collaborative effort with the United States Pharmacopoeia (USP) helped establish monographs and reference standards for tablets and oral solutions, and led to the development of a document entitled Production of zinc tablets and zinc oral solutions: guidelines for programme managers and pharmaceutical manufacturers
- In addition, evidence on the efficacy and safety of zinc in the management of acute diarrhoea was collated and presented to the WHO Expert Committee on the Use of Essential Medicines in March 2005 to support the inclusion of zinc in the 14th revised edition of the WHO Model List of Essential Medicines in March 2005
- International Pharmacopoeia monograph in 2008

Follow up to the recommendation

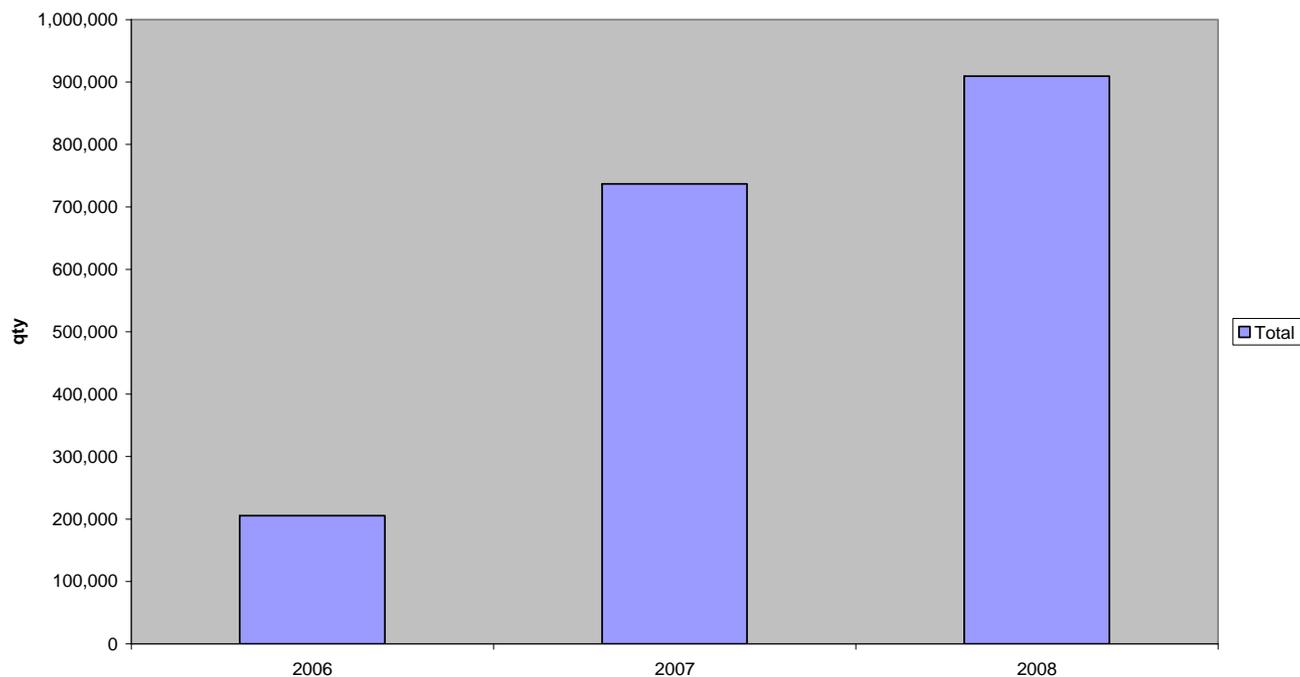
Procurement started in 2006 and has increased significantly since introduction (20 million tablets in 2006, 74 million tablets in 2007 and 91 million tablets in first three quarters of 2008). This translates in over 13 million treatments, which is still a low figure compared to the needs to treat diarrhoea.

UNICEF Procurement of Zinc 20mg tablets, pac 100, to date (qty)

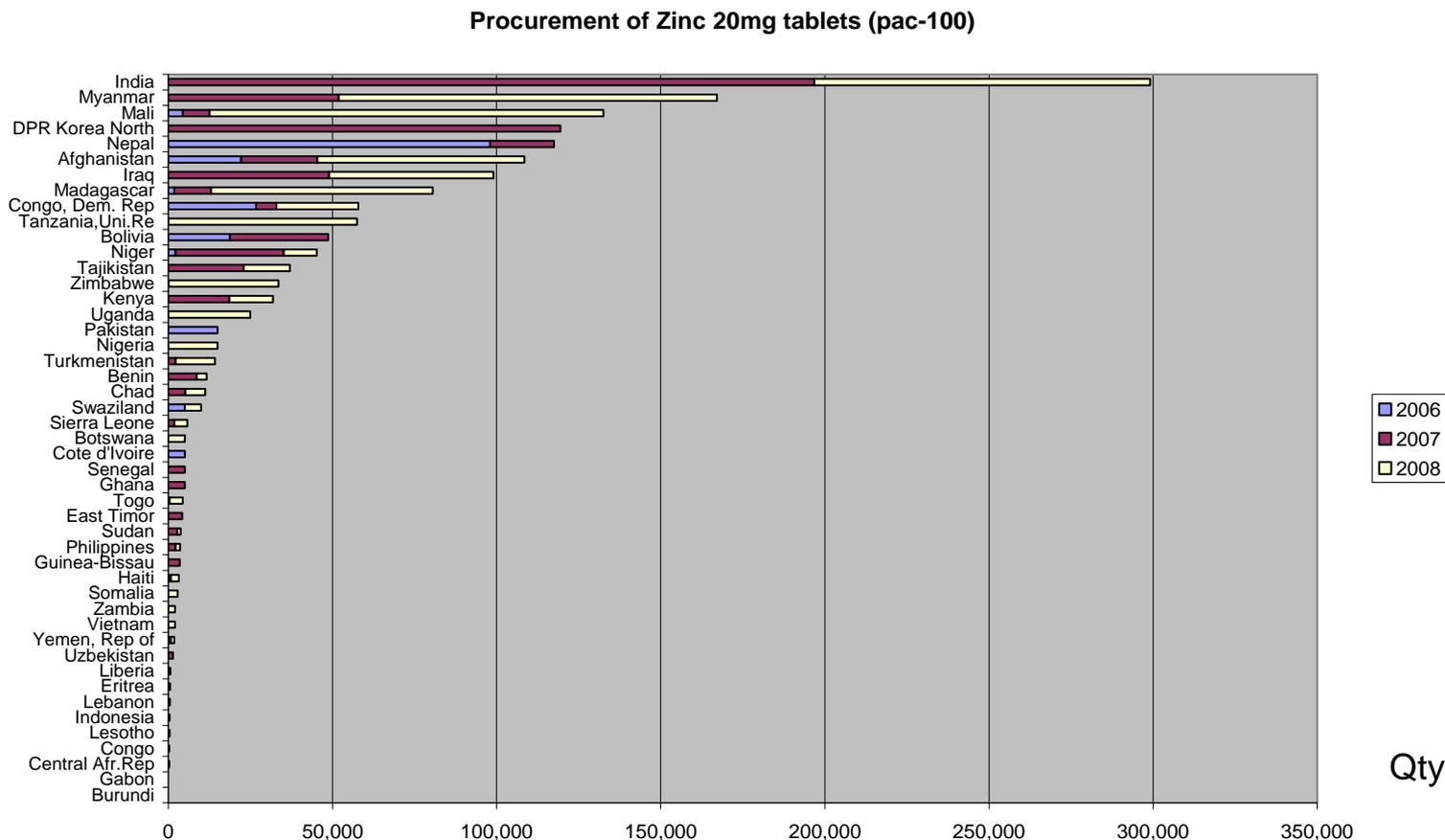


Procurement of Zinc tablets by UNICEF 2006-2008 (Sep)

UNICEF Procurement of Zinc 20mg tablets, pac 100, to date (qty)



Procurement of Zinc tablets by countries 2006-2008 (Sep)



The majority of funding for purchase of Zinc has been from UNICEF Regular resources (36%) and UNICEF National Committees (21%).

Procurement of Zinc tablets: efforts to increase access to programmes

Bottlenecks to access that have been identified include:

- Limited country adoption to date
- Still not incorporated as part of basket of essential drugs for Government purchase
- Difficulties in registration of first approved product due to regulatory status in country
- Evidence being generated in value of various distribution mechanisms (private/ with or without ORS)

A number of initiatives sponsored by members of the Zinc Task Force (WHO, UNICEF, JHU, USAID, Gates) are being developed to address these issues, including increased funding and evidence to support adoption of Zinc in countries

Tenders

First tender in 2006: One product qualified

Second tender in 2008: Two products qualified

Main reasons why products not approved:

- Insufficient stability data submitted
- Insufficient product documentation submitted

Some issues identified:

- Quality of leaflet information varied
- Lack of wide registration outside country of origin

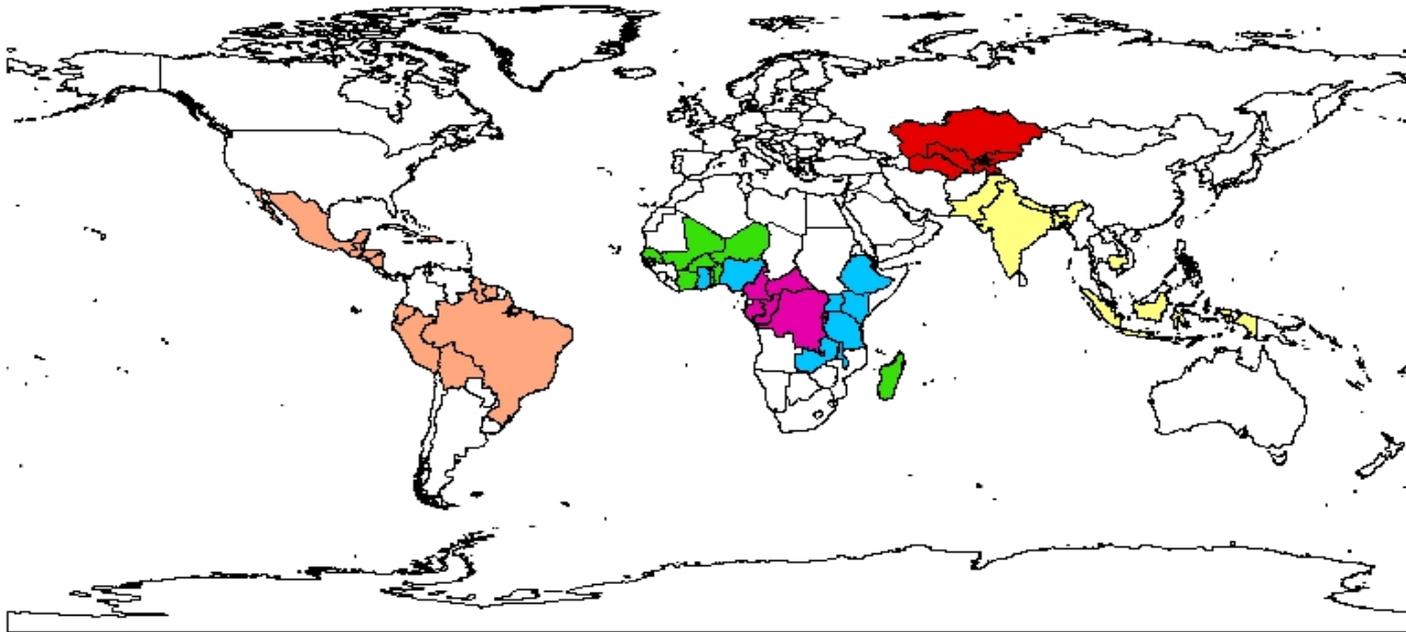
Steps initiated to include Zinc tablets in the WHO Prequalification programme

- 1 - WHO CAH request for zinc products for diarrhoea be included in the WHO PQP
- 2 - WHO PQP will make a workplan for activities required - including announcement of EOI for zinc products; identifying technical consultants that can assist with review of and technical assistance to manufacturers etc.
- 3 - UNICEF SD will contact manufacturers that offered to our 2008 bid informing them that WHO prequalification will be extended to cover zinc tablets. With the acceptance of the manufacturers, UNICEF will share technical documentation submitted to UNICEF 2008 bid with WHO PQP to allow for WHO PQP to identify of what activities they should consider first
- 4 - WHO and UNICEF will advocate for manufacturers to enter their products for prequalification

UNICEF has sought funding for short term support to increase product quality

- 1- Review of available technical information on products (Through 1Q 2009)
- 2- Review findings with manufacturers and discuss steps needed to achieve necessary product quality (1Q 2009)
- 3- Propose Technical Assistance needed, to be provided in coordination with current efforts by ZTF members
- 4- New tender in last part of 2009.

Countries where there have been zinc and I_o-ORS regional advocacy workshops in 2006-2007



THANK YOU

unite for
children

unicef 

