Technical Reference Team

Recommendation 4: Quality Strengthening

Background

The UN Commission on Life-Saving Commodities for Women and Children (the Commission) was formed in 2012 by the UN Secretary-General as part of the global Every Woman, Every Child (EWEC) movement. EWEC challenges the global community to increase access to and appropriate use of essential medicines, medical devices, and health supplies that effectively address the leading preventable causes of death during pregnancy, childbirth, and childhood.

Led by a wide range of high-level leaders from around the world, the Commission developed a framework for action on Reproductive, Maternal, Newborn, and Child Health (RMNCH) products that can be applied nationally and utilized in global RMNCH initiatives. The framework includes a priority list of 13 commodities, key barriers to access and use, and 10 cross-cutting recommendations to rapidly increase both access and use. By increasing access to and use of these 13 commodities, it is estimated that 6 million women and children can be saved by 2017.

Moving forward

To help carry forward the Commission's recommendations at the global and national levels, Global Technical Reference Teams (TRT) were established. One group was formed for each of the 13 commodities and 10 recommendations, and an advocacy working group is dedicated to advancing cross-cutting goals. The groups carry out their work through a variety of mechanisms, including guidance documents and tools to support countries in their efforts to implement recommendations and address global and regional bottlenecks. The TRTs are coordinated by a Strategy and Coordination Team hosted by the United Nations Children's Fund (UNICEF).

Spotlight on Recommendation 4

The TRT for Recommendation 4 focuses on ensuring that the quality, safety and efficacy of products meet the standards that clients should be able to expect from the health care system. Activities supporting Recommendation 4 include determining the actual quality problems experienced by the 13 types of commodities and implementing plans and providing technical assistance to manufacturers. The first steps are to identify the specific products available in the market of the 13 commodities and different presentations or delivery methods, then identify quality issues through surveys and physical testing of products found in the market place, followed by assistance to qualified manufacturers.

Limited amounts of quality products have been made available for clients in a rural health facility. Photo courtesy of Lisa Hedman, WHO.

Group membership

WHO and NAFDAC are co-conveners, with the Concept Foundation European Medicines Agency, PATH, Paediatric medicines Regulators Network (PmRN), UNFPA, UNICEF, USAID, and World Bank.

Progress to date

Policy: Revised guidelines for reproductive health, maternal, newborn and child care have been released by WHO in 2012 and 2013, highlighting appropriate use

of commodities such as chlorhexidine and neonatal resuscitation devices. The WHO Model List of Essential Medicines (EML) received and coordinated expert reviews of evidence-based applications to consider revisions to both chlorhexidine and dexamethasone.

Regulatory and quality surveys: The World Health Assembly (WHA) and an independent expert committee approved guidelines calling for countries to accelerate national registration products approved by the WHO PQ. Ten countries, including four pathfinder countries signed on to a memorandum of understanding to implement the guidelines (*Botswana, Ghana, Kenya, Namibia, Nigeria, Tanzania, Uganda, Zambia, Zanzibar and Zimbabwe).*

Key activities in the work on regulatory and quality status have begun through the development and testing of a survey tool as well as protocols for physical testing. A survey on regulatory and market status has been released to over 25 countries and preliminary data have been reviewed for 13 countries. For physical testing, country counterparts have joined in the process of sampling, testing, and managing a stringent protocol. Additional results are expected in the following months.

Standards: Standards against which country regulators can test products (monographs) were not available for chlorhexidine and dexamethasone, and have now been developed.

Upcoming activities

Policy: The 2013 WHO EML is expected to be released imminently, including updates on several commodities. Plans are in place to support countries in implementation of new guidelines, EMLs, and rational use of medicines. This support will be provided directly through funding from the RMNCH Fund as well as through partnerships with the Muskoka Initiative.

Procurers: Procurers, including international procurement agencies and country government procurers are proposed to review how to aggregate demand around the lifesaving commodities. The focus will be aligning procurers with regulators and how to consolidate demand around quality products.

Interagency lists: The interagency list of medical devices and medicines for reproductive, maternal, newborn and child health products is now being updated to include more specific definitions of products and a link to clinical interventions according to updated WHO guidelines.

Available resources

For updates on the WHO Model EML and the WHO Model EML for children, please see: http://www.who.int/medicines/publications/essentialmedicines/en/

For the meeting report and information on medical devices for the Commission please see: http://www.who.int/medical_devices/en/

Contact us

For more information or to request tools and technical assistance, please contact Lisa Hedman (WHO), (hedmanl@who.int).