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USP Creates New Global Health Standard to Help Fight Fatal Newborn Infections

First of new set of global standards will help ensure access to safe, quality chlorhexidine gel

December 12, 2016, Rockville, Md. — The United States Pharmacopeial Convention (USP) has published a quality standard for chlorhexidine gel, an antiseptic used to prevent life-threatening umbilical cord infections in newborns. This is part of USP’s new Global Health Standards program that supports the development of quality standards for medicines that are not approved or legally marketed in the U.S.

Each year, nearly [3 million infants](#) die in their first 28 days, and infections cause 15 percent of these deaths. Most occur in South Asia and Africa where [home births](#) are common. According to the [United Nations Commission on Life-Saving Commodities for Women and Children](#) and [Global Strategy for Women’s and Children’s Health](#), increasing the availability, accessibility, and proper utilization of chlorhexidine gel in these regions could help avert neonatal infections and save lives, and contribute to the Sustainable Development Goal of Universal Health Coverage—access to essential health services without financial burden.

“Mothers and babies in all parts of the world deserve access to medicines that they can trust,” said Ron Piervincenzi, Ph.D., USP executive vice president and CEO. “USP’s standard for chlorhexidine gel will help ensure these patients receive good-quality, safe medicines.”

Chlorhexidine digluconate topical gel is included in the [World Health Organization Model List of Essential Medicines](#) and recommended for umbilical cord care in regions with high rates of newborn deaths. USP estimates that 20 percent of the essential medicines on this list lack up-to-date, publicly available standards that governments, regulators, manufacturers, and other stakeholders can use to assure their quality. These quality standards are critical parts of the public health safety nets that make patients safer and health systems stronger.

“USP’s global health standard will help local regulators monitor and control quality to protect newborns from poor-quality versions of chlorhexidine gel, including incorrect dosage and unapproved formulations,” said Daniel Bempong, Ph.D., Director of USP’s Global Health Standards program. “It will also help local manufacturers ensure that the product is consistently produced to the same, high-quality standard globally.”

The USP Global Health monograph for chlorhexidine gel was developed to support collaborative efforts of the [Chlorhexidine Working Group](#), chaired by PATH, an international nonprofit. As part of this group’s work, the Promoting the Quality of Medicines program, funded by the United States Agency for International Development



and implemented by USP, shepherded the development and subsequent distribution of the standard in countries where chlorhexidine gel was first scaled and introduced, including Nepal, Bangladesh, Ethiopia, and Nigeria.

The monograph for chlorhexidine is available in the Global Health section of the most recent edition of USP's compendium of standards, [USP 40–NF 35](#).

Media inquiries may be directed to mediarelations@usp.org.

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The U.S. Pharmacopeial Convention (USP) is a global health organization that improves lives through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are used worldwide. For more information about USP visit <http://www.usp.org>.