Gentamicin in Uniject

Health need

The World Health Organization estimates that at least four million neonatal deaths (death during the first 28 days of life) occur around the world every year. Newborn infections are responsible for approximately one-third of these deaths. Case-fatality rates for severe bacterial infections are high in part due to not administering—or delaying the administration of—necessary antibiotics (including gentamicin). Treating infants in rural areas, where infrastructure is limited and where community health workers provide many essential services, presents a special challenge. To achieve maximum impact on neonatal sepsis rates, it is important that newborns with these infections receive immediate treatment.

Technology solution

Gentamicin in a prefilled syringe such as the Uniject™* injection system (gent-Uniject) can help ensure immediate delivery of lifesaving antibiotics in communities and peripheral health care settings. An accurate, premeasured dose is given in a nonreusable, sterile device (with minimal preparation and waste) when the signs of a neonatal infection are first detected. Community health workers can be trained to use gent-Uniject and a complementary antibiotic to extend accessibility and facilitate administration. The dose of gentamicin for neonates has traditionally been based on body weight. Since the Uniject injection system delivers a fixed dose, PATH collaborated in a study that identified safe and therapeutic fixed-dosing intervals. Based on those data, two fixed doses of gent-Uniject were developed for neonates in three common weight ranges.

Current status and results

Instituto BiologicoArgentino (Biol), an Argentine pharmaceutical manufacturer, and PATH produced a clinical trial lot that was used in the first field evaluation of gent-Uniject, which was conducted by PATH and John Snow International in Nepal in 2009. In the study, female community health volunteers and government health staff in five villages administered gent-Uniject to newborns with possible severe bacterial infections. Study results indicate that use of gent-Uniject, in combination with oral cotrimoxazole and an appropriate scale, is feasible and acceptable when delivered by female community health volunteers of various ages and literacy. In June 2010, PATH presented a rapid assessment of value at a United States Agency for International Development expert consultation on future programmatic opportunities for gent-Uniject. In response, PATH reviewed the range of possible product options to deliver antibiotics to treat neonatal sepsis in the community. Results showed that gent-Uniject was a favorable way to package gentamicin to simplify delivery and expand access to treatment. Currently, PATH is seeking opportunities to assess coverage and cost-effectiveness of gent-Uniject when used in community-based programming at the country level.

**Uniject is a trademark of BD.*

Penny Dawson

Prefilled, single-use injection device filled with gentamicin.

"...to further simplify the parenteral administration of gentamicin, the use of disposable syringes pre-filled with gentamicin, or a single-use simple Uniject device should be tested."

Bang AT, Bang RA, Baitule SB, et al. Effect of home-based neonatal care and management of sepsis on neonatal mortality: Field trial in rural India. *The Lancet.* 1999;354:1955–1961.

Availability

Uniject injection systems and the associated equipment for filling and packaging are available to vaccine and pharmaceutical companies from BD Pharmaceutical Systems, New Jersey, USA, Roderick Hausser, Tel: (201) 847-5185, Fax: (201) 847-4869.
For more information regarding this project, contact Patricia Coffey at pcoffey@path.org.

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