Nepal Family Health Program II
Technical Brief #21
(February 2010)

Gentamicin in Uniject to Treat Newborn Sepsis by FCHVs

A Female Community Health Volunteer (FCHV) assesses a sick newborn for possible severe bacterial infection. Severe infections are one of the major causes of neonatal deaths in developing countries.

BACKGROUND

According to the World Health Organization (WHO), an estimated four million neonatal deaths (i.e., deaths occurring during the first 28 days of life) occur around the world every year. Approximately 98% of these deaths occur in developing countries, and most are attributable to severe infection, asphyxia, the consequences of prematurity and low birth weight, and hypothermia. Overall, neonatal mortality accounts for nearly two-thirds of infant mortality worldwide, and approximately three-quarters of neonatal deaths occur during the first week of life.

In Nepal, the 2006 Nepal Demographic and Health Survey (NDHS) showed a neonatal mortality rate (NMR) of 33 deaths per 1,000 live births, which represented over 50% of the under-five mortality rate (61 per 1,000 live births). While the 2006 NMR represented a 33% decline in neonatal mortality over the 15-year period preceding the survey, this level of mortality is still unacceptably high, and is disproportionately borne by families living in rural areas, those headed by mothers with little education, and those from the lowest wealth quintiles.

The 2006 NDHS does not identify main causes of neonatal mortality, but there is some (limited) evidence to indicate that neonatal infections may account for around 30% of all neonatal deaths in the country. This figure is consistent with global estimates that infection (e.g., severe bacterial infections) accounts for an estimated one-third of all neonatal deaths.

The rate of neonatal deaths due to severe bacterial infections in developing countries is high, in part due to late or inadequate administration of necessary antibiotics. Signs of serious illness are difficult to recognize, especially in neonates, and diseases are often in an advanced stage by the time newborns are brought to the attention of a health worker. Given this, it is critically important that newborns with signs of severe infection receive immediate empiric treatment (even before an infectious agent is known), and that a strong emphasis is placed on the urgency of recognizing and managing newborn illnesses. When neonatal infections occur, many deaths can be averted if the signs are recognized early and the disease is treated promptly.

According to the 2006 NDHS, around 80% of babies in Nepal are delivered at home and less than 20% of all births are assisted by a doctor, nurse, or midwife. Within the first days of a newborn's life, contacts with formal health care providers are limited and/or non-existent. Signs of infections in newborns are most likely to manifest while an infant is at home, and families can be reluctant to seek care for newborns outside of the home, particularly at formal health care facilities, even when ill. Therefore an important strategy for reducing neonatal mortality is to improve the ability of caregivers in the family and community and of first-line health workers to prevent, recognize, and manage infectious diseases. In some settings, if treatment is initiated, and perhaps completed, right in the home, it may be possible to avert newborn deaths.

GENTAMICIN IN UNIJECT DESIGN STAGE TRIAL

The gentamicin in Uniject design stage trial was a program implemented in Morang district by the Nepal Family Health Program II (NFHP II/USAID) and PATH USA, under leadership from the Ministry of Health and Population (MOHP) Child Health Division (CHD). The trial was a non-experimental study aimed at assessing the feasibility of a gentamicin in Uniject device to treat newborn sepsis, when used by female community health volunteers (FCHVs) in a non-health facility-based setting. (For more information on the characteristics and functions

of FCHVs, see *NFHP II Technical Brief #1*.) Approval for the research was obtained from the MOHP, Nepal Health Research Council, and the PATH Research Ethics Committee.

The program was implemented for four months in five village development committees (VDC) of Morang district. These VDCs experience high incidence of possible severe bacterial infections (PSBI), and coincided with the implementation area of the then-ongoing Morang Innovative Neonatal Intervention program (MINI), which was begun in May 2005 and whose technical focus and modality were similar (for more information on MINI, see *NFHP Technical Brief #5*). The Uniject intervention was built on the ongoing MINI intervention, and the MINI team provided valuable technical support to NFHP II/PATH during this gentamicin in Uniject trial.

Implementation of the gentamicin in Uniject design stage trial was completed in June 2009 and evaluated jointly by PATH and NFHP II.

Gentamicin in Uniject Device

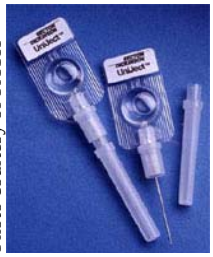


Photo courtesy of PATH

Uniject® prefilled, single-dose injection devices combine medication, syringe, and needle in a small, sterile package. The Uniject device was specifically designed to make injections safe and easy to administer. Uniject devices are an ideal delivery mechanism, not only within a health facility but also for minimally trained workers to administer injections at locations outside the health facility. Health workers with no previous experience using syringes have been able to easily learn to use the Uniject device correctly. Uniject devices, filled with different medicines including hepatitis B vaccine, oxytocin, and cylofem, have been used in different field trial settings. Use of Uniject devices filled with antibiotic gentamicin however was used for the first time in this study.

Uniject devices, prefilled with a single gentamicin dose, can be easily transported and used in a home or primary health facility when signs of neonatal infection are first detected. Health workers with minimal or no skills related to giving injections can be trained to use gentamicin in the Uniject device to increase accessibility and facilitate administration of antibiotics for early treatment of neonatal infections.

Advantages for administering gentamicin in Uniject for treatment of neonatal sepsis in Nepal include:

- *Convenience:* Uniject devices are small, easy to transport, and can be administered by minimally trained health workers, which may improve the timing of administering the first—and possibly subsequent—doses of antibiotics by improving accessibility within the home.
- *Sterile injections:* Uniject devices are nonreusable which ensures sterility of the needle and safety of the injection.
- *Accurate prefilled dose:* Uniject devices are produced with an accurate volume of a specified dose which reduces the possibility for a health worker to accidentally administer too much or too little antibiotic.
- *Stability:* Gentamicin is stable at ambient temperatures; gentamicin in Uniject does not need refrigeration and can be transported and stored at room temperature.
- *Logistical ease:* Since the antibiotic and syringe are incorporated in one device, logistical issues are simplified and stockouts due to insufficient supply of components such as syringes or medication may be minimized.

Research Questions

Nepal was selected as a site for this study for several reasons. The Ministry of Health and Population and developmental partners are committed to achieving Millennium Development Goal 4 related to reducing child mortality, and a National Neonatal Health Strategy was endorsed in 2004 which sanctioned community-based approaches to addressing the neonatal mortality problem. The design stage trial was designed to explore the following research questions:

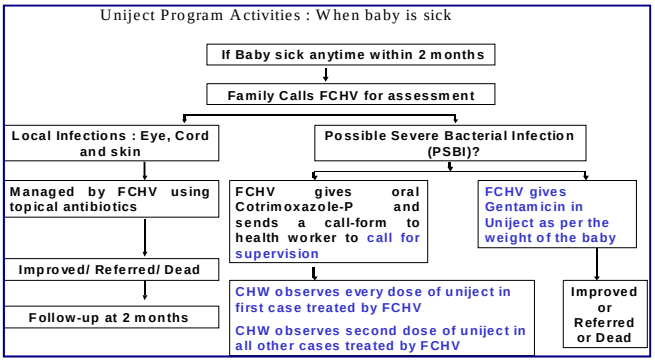
- Is gentamicin in Uniject, in combination with oral cotrimoxazole and an appropriate scale, a feasible option for the treatment of neonatal sepsis when administered at home by FCHVs?
- Are FCHVs motivated and able to continue to use this treatment modality in a program setting, as it will require a larger time commitment than their current responsibilities?
- Is the administration of gentamicin in Uniject by FCHVs as a treatment for neonatal sepsis acceptable to health workers and community members?

Study Design

This was a non-experimental post-test study

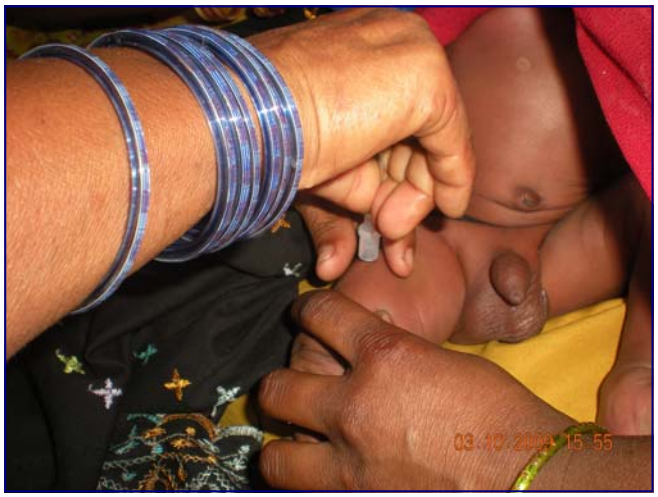
conducted in five VDCs (Hatimuda, Dianiya, Govindapur, Sorabhag, and Madhumalla) in Morang district, Nepal. These VDCs were purposefully selected based on the high prevalence of newborn infection identified in the ongoing MINI program. FCHVs were given four days training on the use of gentamicin in Uniject. All FCHVs were certified as competent to give gentamicin in Uniject using a checklist immediately after training. A second phase certification for their competency was done by their supervisors after observing the total doses of gentamicin in Uniject given by FCHVs in their first case after training. For the rest of the cases treated by each FCHV, supervisors observed the second dose of gentamicin in Uniject. All community health workers (CHW) in the five VDCs were also trained on the use of gentamicin in Uniject. Orientation about the study was also given to members of health facility management committees and to local community leaders.

In the ongoing MINI intervention, FCHVs conducted postnatal home visits to record information about recent births and to weigh newborns at home. All babies were followed up at the end of two months to identify their vital status. During the Uniject intervention period, the following activities were conducted if a baby became sick within two months of age:



FCHVs administered gentamicin in Uniject to newborns identified as having PSBI at home, according to the weight of the infant and the appropriate dosing regimen (see *Table 1*). Gentamicin in Uniject was paired with cotrimoxazole, which was given twice daily for five days, in a dosage based on the infant's age.

Before each treatment dose was administered by the FCHV to the infant, the FCHV was trained to reassess the status of the infant and decide if referral to a health facility was required. If not required, the FCHV continued to treat the sick infant in the home using cotrimoxazole and gentamicin in Uniject.



A baby receives a dose of gentamicin via a Uniject device.

FCHVs and CHWs recorded cases treated in pictorial registers developed for their use. At the end of the program, NFHP II collected evaluation data through: focus group discussions with FCHVs in each VDC; key informant interviews with community leaders in each VDC; in-depth interviews with CHWs; post-implementation FCHV competency certification; and post-implementation CHW and FCHV knowledge assessments.

RESULTS

A final report on the Uniject evaluation will be published by the end of March 2010. Preliminary findings from the evaluation and from regular monitoring data include:

- At the end of training, all 45 FCHVs were certified competent to give gentamicin in Uniject injections. Among them, 17 were illiterate/semi-literate with formal education less than class five.
- During the life of the trial, 422 births were identified in the five VDCs. A total of 94 possible severe bacterial infections (PSBI) were identified, of which 76 cases were treated using cotrimoxazole and gentamicin in Uniject by health workers and FCHVs. Of these, 67 cases were treated by FCHVs only. Twelve of 45

Table 1: Gentamicin in Uniject dosing regimen

Weight of Infant	Dose of Gentamicin and Timing	Duration	Total # Doses
< 2000 grams	10 mg every 48 hours	9 days	5
2000-2499 grams	10 mg every 24 hours	7 days	7
> 2500 grams	13.5 mg every 24 hours	7 days	7

FCHVs had no opportunities to treat PSBI during the trial.

- All doses of gentamicin in Uniject given by FCHVs in their first cases were observed by a CHW. All other cases treated by FCHVs were supervised by CHWs on the second dose of gentamicin in Uniject.
- All episodes of PSBI (n=76) improved after being treated with cotrimoxazole and gentamicin in Uniject.
- No cases developed local reactions (e.g., redness or abscess at injection site).
- All FCHVs, whether they had treated PSBI cases or not during the project period, were tested and found competent to give gentamicin in Uniject at the trial's conclusion.
- No FCHVs experienced needle stick injuries using the Uniject device.
- All Uniject devices used during the project were disposed of properly in safe disposal boxes.
- Among all caretakers interviewed (n=45) 98% had either "good" or "very good" impressions about FCHVs giving Uniject injections; the most common reasons for positive impressions were that the device was "easy" and "not frightening".

CONCLUSIONS AND NEXT STEPS

Preliminary results from this trial indicate that community-based management of neonatal sepsis, as implemented under NFHP II, is feasible and can contribute to improved neonatal health outcomes. Next steps include:

- Dissemination of study results at the national level through a workshop led by MOHP, NFHP II, and PATH.

A District Public Health Officer reviews a FCHV register and provides supportive supervision.

- Design of a pilot Uniject program for testing in one NFHP II community-based maternal/ newborn health (CB-MNH) core program district, located in Nepal's hill region.

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