Design-Stage Trial of Gentamicin in the Uniject® Device: A Feasibility Study

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[i] The Uniject device is a registered trademark of BD.

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Acronyms and abbreviations

AHW	auxiliary health worker
ARI	acute respiratory infection
BIOL	Instituto Biologico Argentino
CHW	community health worker
CMC	Christian Medical College and Hospital
cotrimoxazole-p	pediatric cotrimoxazole
DPHO	District Public Health Office
DSH	Dhaka Shishu Hospital
ENC	essential newborn care
FCHV	female community health volunteer
FGD	focus group discussion
GMP	Good Manufacturing Practice
GoN	Government of Nepal
HF	health facility
HIV	human immunodeficiency virus
MCHW	maternal and child health worker
MINI	Morang Innovative Neonatal Intervention
MOHP	Ministry of Health and Population
NFHP	Nepal Family Health Program
PATH	Program for Appropriate Technology in Health
PI	post-implementation
PSBI	possible severe bacterial infection
PT	post-training
SGC	serum gentamicin concentration
SHP	sub-health post
USAID	United States Agency for International Development
VDC	village development committee
VHW	village health worker

Executive summary

This design-stage trial was nonexperimental community research aimed toward assessing the feasibility of gentamicin in the Uniject®[i] device (hereafter referred to as gentamicin in Uniject) when used by female community health volunteers (FCHVs) in a peripheral care setting. The study was conducted in five village development committees (VDCs) of Morang district, situated in the eastern part of Nepal. The objectives of the study were to:

- Explore the feasibility of gentamicin in Uniject in combination with oral pediatric cotrimoxazole (cotrimoxazole-p) for treatment of neonatal infection when administered at home by FCHVs.
- Determine the level of motivation of FCHVs for the added responsibility.
- Explore the acceptability of administration of gentamicin in Uniject by FCHVs as a treatment for neonatal sepsis to caretakers and community members.

The study was conducted under the leadership of the Child Health Division of the Nepal Ministry of Health and Population (MOHP). It was a partnership between the Child Health Division, Nepal Family Health Program II/United States Agency for International Development (USAID), PATH, and the Morang Innovative Neonatal Intervention (MINI) program. Financial support for the program was provided by the USAID Nepal Mission, and the gentamicin in Uniject was provided by PATH. The study was approved by the Nepal MOHP, the Nepal Health Research Council, and PATH's Research Ethics Committee. The intervention activities and tools were designed based on ongoing MINI activities in Morang district. Most of the training materials used in the MINI program were adapted by technical experts from all the organizations involved in the study. A separate training module, classification card, color-coded weighing scale, color-coded thermometer, pictorial treatment register, call form, birth record form, safe-disposal box, and standard data collection forms were used in this study.

A local orientation about the study was conducted for community leaders and members in each VDC before the intervention began. A 2-day training session was provided to health workers about the use of gentamicin in Uniject, and the FCHV training curriculum was covered in 4 days. The trainings utilized participatory methods and opportunities for all participants to perform hands-on assessment and treatment. Fresh, whole eggplants were used to practice injection skills. A post-training questionnaire was administered to all trainees to evaluate the effectiveness of the training curriculum. All health workers and FCHVs took a competency certification test. Only those FCHVs who passed this certification were provided with gentamicin in Uniject to take home. All the FCHVs were again certified competent by their immediate supervisors after being observed giving all the doses of gentamicin in Uniject to the first sick newborn after the training. After completion of the study, the competency certification was again performed with all the FCHVs to assess the retention of skills in administering gentamicin in Uniject. The community health workers and caretakers were periodically interviewed using standard forms. At the end of the study, focus group discussions (FGDs) with FCHVs in each VDC, in-depth interviews with the supervisors of FCHVs in each community, and key informant interviews with two community leaders in each VDC were conducted. Consent was obtained for each type of activity.

[i] Uniject is a registered trademark of BD.

The MINI program in Morang trained and supported the FCHVs to visit homes in their villages within 24 hours of birth to weigh the newborn using a color-coded Salter scale, prepare a simple record of the birth, assess the neonate for any danger signs of infection, and alert the mother and caretakers to call the FCHV immediately for reassessment if any danger signs arose. The FCHVs also taught families about essential newborn care and additional care needed for low birth weight babies.

Through MINI, FCHVs in Morang have also been trained to identify and manage local bacterial infections and initiate management for possible severe bacterial infection (PSBI) in young infants. This gentamicin in Uniject design-stage trial continued the activities initiated by the MINI program. In this study, if an FCHV identified one or more danger signs, she obtained consent from the caretaker and initiated treatment for the sick infant. The treatment regimen consisted of two drugs—oral cotrimoxazole-p and gentamicin injection. The cotrimoxazole was given based on the age of the newborn. FCHVs administered gentamicin in Uniject based on the weight of the newborn, which was determined using the color-coded Salter scale. For sick infants weighing less than 2000 grams, red-colored Uniject devices containing 10 mg of gentamicin were given every 48 hours for 9 days by health workers. For sick infants weighing between 2000 and 2499 grams, yellow-colored Uniject devices containing 10 mg of gentamicin were given every 24 hours for 7 days. For sick infants weighing 2500–3500 grams, green-colored Uniject devices containing 13.5 mg of gentamicin were given every 24 hours for 7 days. For sick infants weighing more than 3500 grams, FCHVs referred families to a health facility and the health workers there administered gentamicin using a standard needle and syringe. The health workers also used gentamicin in Uniject to treat sick young infants when the infants were presented directly to them at the health facility.

The health workers supported and supervised FCHVs in the use of gentamicin in Uniject. FCHVs were certified and deemed competent to give gentamicin in Uniject at the end of the training. The call form that was used in the MINI program was also used in this trial, to request that the supervisor visit the home to observe the FCHV using the device in her first case. Supervisors used a skills checklist, which included all the correct steps for giving the injections, to certify competency. After the first successful completion of treatment, FCHVs were recertified as competent to use the device. For subsequent cases, they could give the first dose unsupervised to avoid any delays in initiating treatment and then called their supervisor to observe the second dose and verify that the technique and dosing choice were correct. A special disposal box was prepared for the used Uniject devices, which were placed in the safe-disposal box without recapping. One box was used for each sick newborn, and the boxes were then incinerated at the health facilities.

Special pictorial treatment registers were used by FCHVs and health workers to document all the relevant data about sick young infants. All the data were collected in standard MINI forms by project staff. Data cleaning, coding, entry, and analysis were conducted using SPSS statistical analysis software. For quantitative data, univariate and bivariate analyses of key variables were conducted. For qualitative data, coding was done following the translation of the transcribed data set. A set of codes was developed, and data were sorted and analyzed thematically.

Data were collected during the intervention period of January 1, 2009, through June 19, 2009. During the study period, a total of 422 live births were recorded by FCHVs. Of these, 94 were identified as PSBI; 87% were seen by FCHVs and 13% went directly to health workers.

Among 82 PSBI episodes first seen by FCHVs, 67 were treated by them with gentamicin in Uniject and 15 episodes were referred. Among the 67 cases treated by FCHVs, the completion rate was 100% for both cotrimoxazole-p and gentamicin in Uniject. There was no local reaction observed, and all 67 cases improved by the last day of treatment with gentamicin in Uniject. Among 45 FCHVs who participated in this study, only 33 had the opportunity to treat PSBI with gentamicin in Uniject. All 33 first cases treated by FCHVs were supervised every day for 7 days by their immediate supervisors, and the remaining 34 cases were all supervised for the second dose. In all 67 cases, the FCHVs disposed of the used gentamicin in Uniject devices correctly. A total of 82% of the sick young infants received their first dose of gentamicin in Uniject on the same day of contact with an FCHV or health worker. Elapsed time from the median day of illness to the first dose of gentamicin in Uniject was 2 days.

All FCHVs who treated PSBI demonstrated a high level of knowledge on danger signs, essential newborn care messages, correct dose of cotrimoxazole, and correct dose of gentamicin in Uniject. The knowledge level did not vary relative to literacy status or age of the FCHVs. Overall knowledge about the Uniject device was good among FCHVs regardless of their literacy status. There was an increase in knowledge about the Uniject device from post-training to post-implementation. The 13 FCHVs who had never treated PSBI were also certified competent during a post-implementation competency certification. Among the 45 FCHVs interviewed, 40 FCHVs (89%) reported that activation of the gentamicin in the Uniject device was easy, and the remaining 5 FCHVs (11%) found it acceptable. None of the FCHVs reported that activation of gentamicin in Uniject was difficult. Among 33 FCHVs who treated PSBI, only two reported that they had difficulty squeezing the bulb to inject the entire dose of medicine; these FCHVs also faced problems while trying to hold the baby in the correct position.

On average, FCHVs spent 8 hours per week on Uniject activities. Of the 33 FCHVs who treated PSBI, none perceived giving gentamicin in Uniject as an extra burden. Gentamicin in Uniject was acceptable to the FCHVs, health workers, caretakers, and communities. Of the 45 FCHVs interviewed, 44 liked the device. Ninety-two percent of health workers interviewed were satisfied about FCHVs giving gentamicin in Uniject. Ninety-five percent of caretakers interviewed expressed their satisfaction with the treatment provided through the FCHVs. Of the 45 caretakers interviewed, 36 reported they would prefer to use FCHVs for treatment with gentamicin in Uniject in the future. Out of ten key informant interviews with community leaders, all of them reported that FCHVs could correctly give gentamicin in Uniject to sick newborns. Nine out of ten community leaders thought the best treatment option for sick young infants was to be treated by FCHVs using oral antibiotics and gentamicin in Uniject at home. All the community leaders stated that they would be willing to accept an injection using gentamicin in Uniject if their newborns became sick in the future.

The FGDs with FCHVs in all five groups expressed confidence in the selection of the correct dose of gentamicin in Uniject. Many FGD participants stated that the presence of the supervisor helped them overcome their initial fear and anxiety related to giving the first dose of gentamicin in Uniject. Participants in four of the five FGDs agreed that in the future, supervisors should come at least once during the course of treatment—preferably on the first or second day of treatment.

Hence, the gentamicin in Uniject design-stage trial was successful in showing that FCHVs are willing to use gentamicin in Uniject devices to treat newborn infections at the community

level. They are competent in correct use of the device and safe disposal of the used device. The device was well-accepted by the caretakers, FCHVs, health workers, and community leaders, and the treatment of newborn infection with gentamicin in Uniject by FCHVs was well-accepted by the caretakers, community leaders, and health workers.

1. Introduction and rationale

Every year, four million neonatal deaths (death occurring within the first 28 days of life) occur around the world.[1] Overall, neonatal mortality accounts for nearly two-thirds of infant mortality worldwide.[2] Approximately 99% of these deaths occur in developing countries, and most are attributable to preterm birth (28%), severe infections (26%), and asphyxia (23%). Three-quarters of neonatal deaths happen in the first week, and the highest risk of death is on the first day of life.[1]

Neonatal sepsis is a significant public health concern, responsible for 10% of cause-specific mortality among children younger than 5, and between 8% and 80% of all neonatal deaths in developing countries.[3]

According to a review of 13 studies of community-acquired infections in developing countries, the major pathogens for neonatal sepsis within the first week of life are Klebsiella species (25%), *Escherichia coli* (15%), and *Staphylococcus aureus* (18%).[4] For the treatment of these bacterial infections, the World Health Organization recommends intramuscular injections of 7.5 mg/kg body weight of gentamicin (or another comparable aminoglycoside), divided twice daily for at least 10 days, and 50 mg/kg body weight of ampicillin (or a comparable penicillin) every 6 to 8 hours—depending on age—as the standard therapy.[3] Unfortunately, ampicillin and gentamicin should not be mixed in the same vial, because ampicillin will inactivate gentamicin to a substantial degree.[5]

Case-fatality rates for severe bacterial infections in developing countries are high, in part due to late or inadequate administration of the necessary antibiotics.[3] The chances of survival are slim for newborns with serious infections, whether hospitalized or in the community, with mortality rates of early-onset sepsis (<7 days) between 15% and 40% and of late-onset sepsis (>7days) between 10% and 20%.[6] Data from India suggest that approximately one-half of neonatal deaths in rural, resource-poor settings are due to infections.[7] A review of 32 studies identified that infections might have been responsible for 8% to 80% of all neonatal deaths and as many as 42% of deaths within the first week of life.[3]

The identification and treatment of newborns with infection is weak in many low-resource settings. Because sick newborns present with nonspecific signs and symptoms, diagnosing neonatal sepsis is difficult in even the most sophisticated settings. Many factors contribute to the high number of neonatal deaths from infection. These include under-recognition of illness, lack of access to appropriate treatment and trained health workers to administer it, delay in initiation of treatment, and inability to pay for treatment by families, if warranted.

Differential signs of illness severity are difficult to recognize, especially in neonates, and the disease is often in an advanced stage when the newborn is brought to the attention of a health worker. Therefore, it is important that newborns with these infections receive immediate empiric treatment, even before the infectious agent is known, and a strong emphasis must be placed on the urgency of recognizing and managing newborn illnesses.[5] When neonatal infections occur, many deaths can be avoided if the signs are recognized early and the disease is treated promptly.

Every year, an estimated 60 million women give birth outside health facilities—usually at home—and another 52 million births occur without the presence of a skilled birth attendant.[8]

The signs of infectious disease are most likely to manifest while the infant is at home, and families in many societies are reluctant to seek care for newborns outside the home, particularly at formal health care facilities, even when the infants are ill.[9-11] Therefore, an important strategy for reducing neonatal mortality will be to improve the ability of caretakers in the family and community and of first-line health workers to prevent, recognize, and manage infections.[12] In some settings, treatment will need to be initiated, and perhaps completed, right in the home. Moreover, as care-seeking behavior for newborn illness improves, it also will be important to provide effective and safe treatment at points of first contact with the health care system.

2. Background

2.1 Community-based management of neonatal sepsis in Nepal

Over the past two and a half decades, Nepal has been a pioneer in the successful implementation of community-based public health initiatives, which have been taken to scale through Ministry of Health and Population (MOHP)/Government of Nepal (GoN) programs. Examples include:

- Nationwide semi-annual distribution of high-dose vitamin A capsules to more than 90% of eligible children aged 6–59 months.
- Management of pneumonia with oral antibiotics and diarrhea with oral rehydration solutions and zinc at the community level, interventions which were originally implemented as extensions of the vertical acute respiratory infection (ARI) and control of diarrheal disease programs respectively, and later coordinated within the community-based integrated management of childhood illness program.
- Community-based distribution of polio and measles immunizations through campaigns in addition to the regular expanded program on immunizations program.
- Deworming for children combined with vitamin A distribution.
- Community-based distribution of oral contraceptives.

These, and many other health initiatives, have relied on the active participation of a large and unique cadre of workers—female community health volunteers (FCHVs). FCHVs are local, married women who have been selected by their communities and mothers' groups for health promotion through the MOHP. The FCHVs are volunteers; they receive no compensation for their services (although they do receive a small stipend for time spent in training). These local women, numbering almost 50,000 across the nation, volunteer their time to provide basic services and health education in their communities as the most peripheral cadre of health workers of the MOHP. In return, they receive training, supplies, and supervisory support from the GoN health facility (HF) staff in their areas. More recently, they have received additional support and recognition from their own local communities, village leaders, and the local government, as their contributions to the improved health status in the villages have been recognized and acknowledged.

In most districts of Nepal, there are nine FCHVs in each village development committee (VDC), and they provide their services to all those who live within their catchment area. As per GoN policy, there is one health facility in each VDC, and most often, this is a sub-health post (SHP) that is staffed by three health workers: the auxiliary health worker (AHW), the maternal and child health worker (MCHW), and the village health worker (VHW). They provide a variety of basic services in their villages, such as:

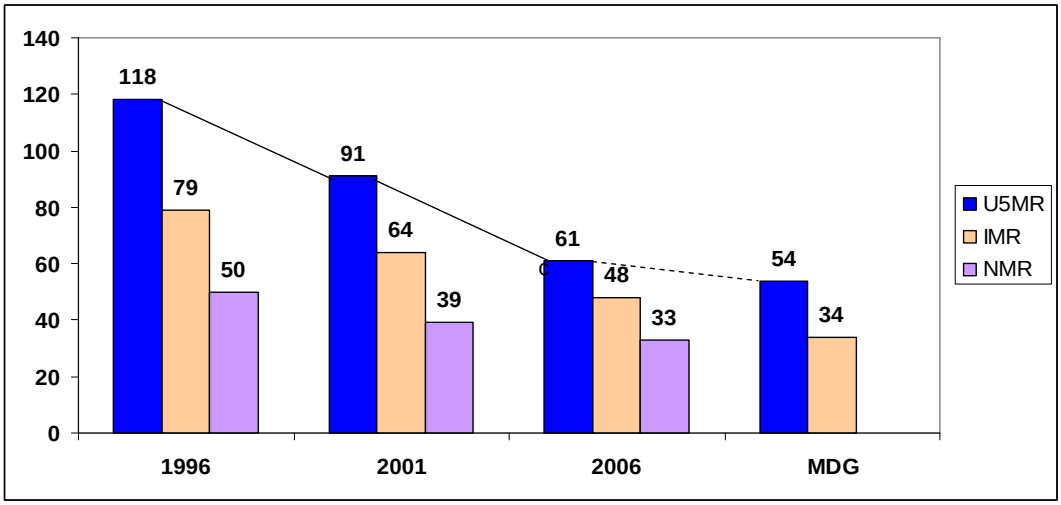
- Distribution of pills and condoms for family planning and provision of counseling on injectables and permanent methods.
- Semi-annual distribution of high-dose vitamin A capsules to children 6–59 months of age.
- Distribution of deworming tablets to children 1–5 years old.
- Provision of oral rehydration salts (and zinc in some districts) for diarrhea cases.

- Iron-folate tablet distribution for pregnant women.
- Provision of postpartum vitamin A.
- Advice on antenatal care, breastfeeding, and infant feeding.
- Immunization.
- General first aid.

The community trusts these health workers for advice on many health-related issues. The VHWs and MCHWs are the immediate supervisors of the FCHVs and support them in their work.

Nepal's successful community-based programs with dedicated volunteers and health facility staff, plus general systems strengthening within the MOHP, have contributed to a continued decline in the total fertility rate and under-five mortality indicators over the past 15 years, despite the political instability in the country (Figure 1). For the 5-year period preceding the 2006 Demographic and Health Survey, the under-five mortality rate (U5MR) was 61 per 1000 live births, the infant mortality rate (IMR) was 48 per 1000 live births, and the neonatal mortality rate (NMR) was 33 per 1000 live births. Therefore, the neonatal mortality rate represented more than one-half of all deaths of children younger than 5 years in the country.

Figure 1. Trends in child mortality in Nepal, 1996–2006.



MDG: Millennium Development Goal.
Source: 2006 Demographic and Health Survey.

These findings—along with earlier work for the preparation of a situational analysis of newborn health in 2002, the development of the National Neonatal Health Strategy in 2004, and other MOHP initiatives—helped consolidate the growing commitment within the government and among partners for improving newborn health and survival. In order to achieve Millennium Development Goal 4 (Reduce Child Mortality), it was apparent that the main killers of neonates (infection, birth asphyxia, and the complications of low birth weight and prematurity) must be addressed urgently.

In 2004, the MOHP introduced a community-based pilot program in Morang district, a large district in the eastern terai (flatland) of Nepal, to address the high mortality attributed to neonatal infections and sepsis. This initiative was implemented with technical support and

oversight from the John Snow, Inc. (known as JSI) Research and Training Institute and funding from the Saving Newborn Lives program of Save the Children with support from the Bill & Melinda Gates Foundation. The United States Agency for International Development (USAID) provided additional financial and technical support and facilitated later expansion of the program to the whole district through the Nepal Family Health Program (NFHP). It was implemented entirely through the existing public health system of the MOHP, under the direction of the District Public Health Office (DPHO).

This pilot program was called the Morang Innovative Neonatal Intervention (MINI). The public health services of Morang district are coordinated through the DPHO located in the district headquarters, Biratnagar. According to the national health policy of Nepal, each of the 65 VDCs of Morang have at least one health institution, and their distribution is as follows: 7 primary health care centers, 10 health posts, and 49 SHPs.

The FCHVs in Morang had also been previously trained on the assessment and management of children with pneumonia. Since 1995, FCHVs have treated children 2 months to 5 years of age with oral pediatric cotrimoxazole (cotrimoxazole-p) tablets for pneumonia. They are familiar with the use of a timer to count respiratory rate and assessment of young infants for danger signs. They have been trained to refer sick young infants younger than 2 months and those with “severe pneumonia” to the nearest health facility for further assessment and treatment.

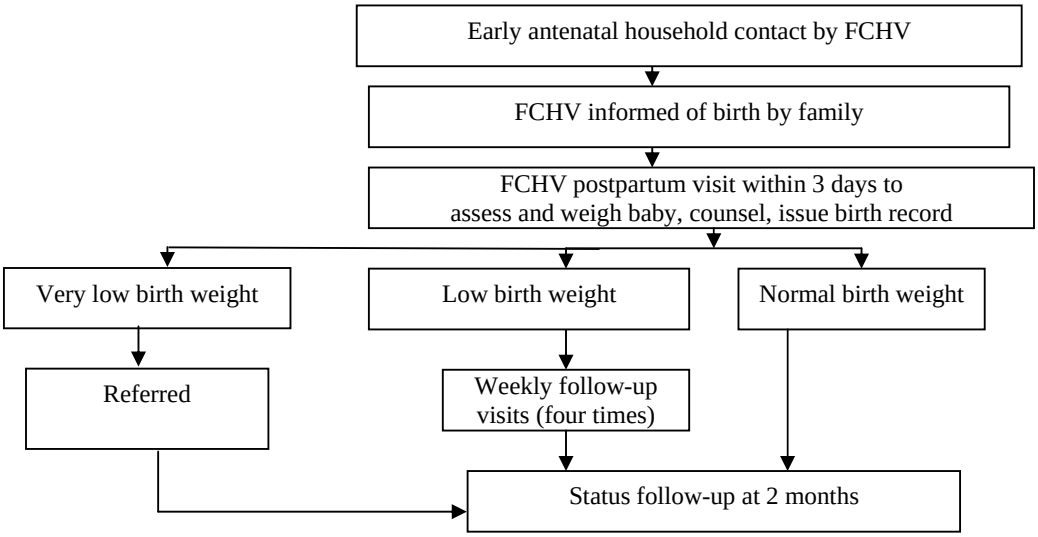
The MINI program trained and supported the FCHVs to visit homes in their villages within 24 hours of birth to weigh the newborn, prepare a simple record of the birth, assess the neonate for any danger signs of infection, and alert the mother and caretakers to call the FCHV immediately for reassessment if any danger signs occur. FCHVs also teach families about essential newborn care (ENC) and additional care needed for low weight babies. Through the MINI program, FCHVs in Morang have also been trained to identify and initiate management of both local bacterial infections and possible severe bacterial infections (PSBIs) in young infants (0–59 days of age).

While FCHVs are not asked to attend deliveries as part of the MINI intervention, they are aware of the pregnant women in their communities, as they maintain a pregnancy surveillance register and provide iron-folate tablets to pregnant women. During these antenatal contacts, FCHVs provide counseling on birth preparedness and recommend that women seek antenatal care from the health facility staff (including tetanus toxoid injections). In addition, through MINI, FCHVs talk about ENC practices and describe the danger signs of neonatal infections, and leave colorful information flyers with families that describe these danger signs. FCHVs also ask families to inform them immediately after the birth, so they can return to the home and conduct an initial assessment of the newborn.

When a family informs an FCHV of a birth, she immediately goes to the baby’s home and weighs the newborn using a color-coded Salter scale. This scale has three different categories of weight: red (less than 2000 grams), yellow (2000–2499 grams), and green (2500 grams or more). For babies who are in the “green” or “normal” weight category, the FCHV gives advice about ENC; for babies in the “yellow” or “low birth weight” category, she advises on ENC, with extra emphasis on keeping the baby warm, including skin-to-skin contact and frequent breastfeeding; and for babies in the “red” or “very low birth weight” group, she recommends that they go immediately to the nearest health facility for further advice and counseling. However, families may not be able to comply with the FCHV referral advice. In

such cases, she treats the newborns as low birth weight babies. For all babies in the “red” and “yellow” categories, the FCHV makes four follow-up visits, once per week within the first month of life to reassess the babies and support the families in providing care. She prepares a birth record and leaves one copy with the family to help facilitate formal registration of the birth with the VDC officials. She revisits all newborns at 2 months of age to document their status (dead/alive). See Figure 2 for activities conducted by FCHVs with all pregnant women and newborns.

Figure 2. MINI activities for all babies.



2.2 Identification and treatment of PSBI by FCHVs

For all newborns, regardless of weight, FCHVs conduct an initial clinical assessment, using an algorithm to identify any danger signs, as shown in Figure 3. The algorithm is depicted on a laminated classification card, carried in a shoulder bag along with other program materials. The ten danger signs are shown pictorially, as many FCHVs and mothers have limited literacy skills.

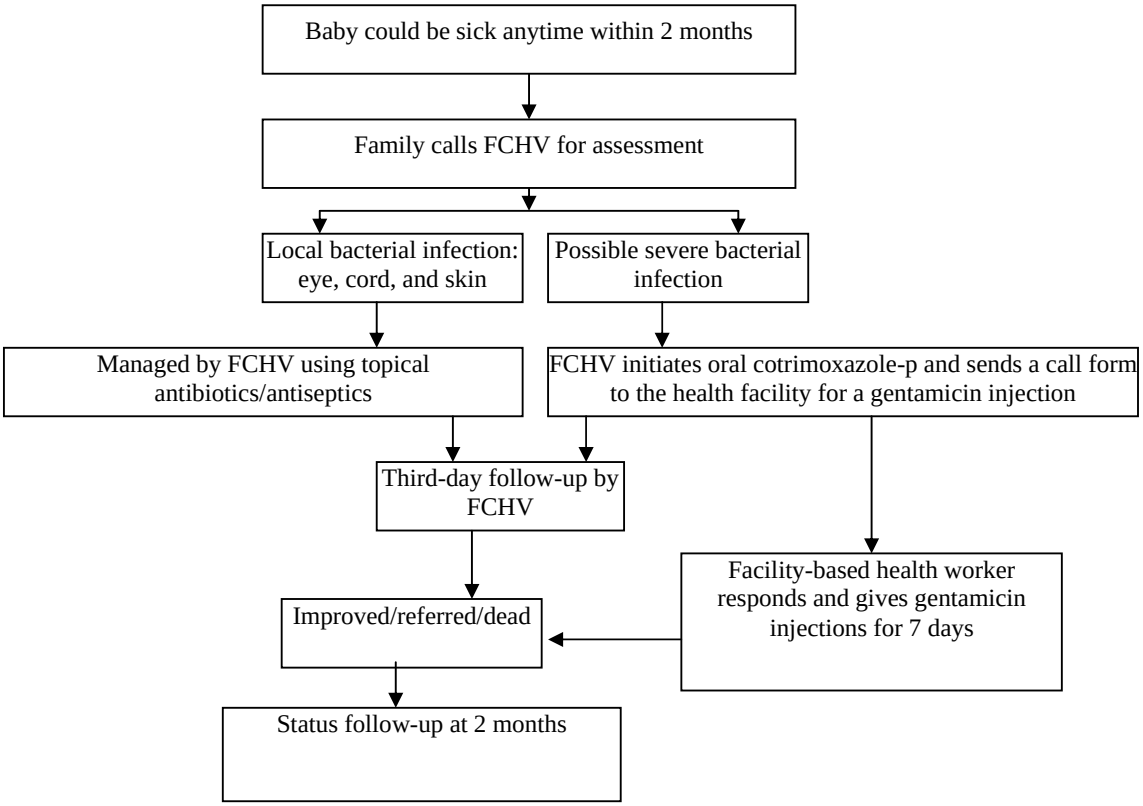
Figure 3. Danger signs of PSBI.

1. Unable to feed
2. Lethargic/unconsious
3. Fast breathing—respiratory rate of (or more per minute
4. Severe chest indrawing
5. Grunting
6. Fever (≥37.5°C axillary)
7. Hypothermia (≤35.5°C axillary)
8. More than ten skin pustules or one large abscess
9. Redness around the umbilicus, extending to the skin
10. Weak or absent cry

The FCHV uses a timer to count respiratory rate and a flat, mercury thermometer to assess temperature. If she finds any danger signs, she classifies the newborn as having PSBI and initiates treatment immediately. If no danger signs are identified, she advises the family to call her back immediately if any sign develops in the future.

When the FCHV assesses a young infant and finds any signs of PSBI, either on the initial assessment after birth or at any other time when she is consulted by the family, she obtains consent and initiates treatment immediately with oral cotrimoxazole-p (dissolved in breast milk). Then she provides the family with cotrimoxazole-p so that they can administer it twice daily at home for a total of 5 days. She also gives the family a call form to take to the next level of health worker (VHW, MCHW, or AHW) to ask them to come to the baby’s home to provide once-daily gentamicin injections for 7 days. See Figure 4 for activities conducted by FCHVs with sick babies.

Figure 4. MINI activities for sick babies.



The MINI model for treating PSBI appears to be effective in a flatland district where accessibility is reasonably good (usually less than a half-hour walk between the health facility and the home of the sick infant). It may be difficult or impossible to implement this model of care in the hill and mountain districts of the country and achieve similar coverage. Therefore, exploring the feasibility of alternative models of care, including the use of gentamicin in the Uniject®[i] device, in areas that are less accessible is of interest.

2.3 Use of the Uniject device for other medicaments

The Uniject prefill, single-dose injection device combines medication, syringe, and needle in a small, sterile package (Figure 5). The Uniject device was specifically designed to make injections safe and easy to administer.[ii] The device is an ideal delivery mechanism, not only within a health facility but also for minimally trained workers to administer injections at locations outside health facilities. Health workers with no previous experience using syringes have been able to easily learn to use the Uniject device correctly.[13,14] The Uniject devices filled with hepatitis B vaccine have already been proven safe and effective when used with newborns in home settings in Indonesia.[12]

Figure 5. Uniject prefill injection device.

[i] Uniject is a registered trademark of BD.
[ii] The Uniject device was developed and advanced by PATH under the USAID-supported HealthTech program. It was licensed to BD in 1996.

A wealth of experience in a variety of settings has been accumulated with the Uniject device to date (Table 1).[10-20]

Table 1. Summary of Uniject device studies.

Date	Drug or biological	Country or region	Site	Focus
1991–1992	Prostaglandin	Egypt	Hospital	Acceptability
1991	Prostaglandin	India	Hospital	Acceptability
1995	Tetanus toxoid	Bolivia	Homes	Acceptability, use by traditional birth attendants
1995–1996	Tetanus toxoid and hepatitis B vaccine	Indonesia	Homes	Acceptability, immunogenicity of hepatitis B vaccine
1995–1996	Cyclofem®	Brazil	Clinic	Acceptability
1997	Cyclofem®	Brazil	Clinic	Self-administration
1998–2000	Oxytocin	Angola	Hospital	Acceptability
1999–2000	Oxytocin	Indonesia	Homes	Acceptability, use by village midwives
1999–2000	Cyclofem®	Mexico	Clinic/homes	Introduction, self-administration
1999–2000	Hepatitis A vaccine	United States	Outpatient clinic	Provider acceptability, clinical equivalence with syringe
2000–2001	Hepatitis B vaccine	Indonesia	Clinic/homes	Introduction in two provinces
2000–2002	Tetanus toxoid	Africa	Outreach	Introduction
2004–2005	Oxytocin	Vietnam	Clinic/homes	Introduction

These studies occurred with the collaboration of pharmaceutical companies, which conducted pilot fills of drugs or biologicals into the Uniject devices and met regulatory requirements to release the products for clinical use. Early studies focused on the acceptability of using the Uniject device to deliver drugs in difficult situations (e.g., administration of uterotonic drugs to prevent or treat postpartum hemorrhage,[15,16] or administration of vaccine to women and children in their homes[10-12]). In the case of hepatitis B vaccine, the vaccine must be given as close to birth as possible to prevent perinatal transmission. Since home administration is essential in many areas where births take place in the home, facility-based health care, including immunizations, is often unavailable. A few studies focused on use of the Uniject device by individuals who do not normally give injections.[10,14] Results of studies thus far have revealed the following:

- The Uniject device was found to be easier to use and was preferred over a standard needle and syringe.[10,11,14,16]
- The activation step,[11,14,16] pressure required to collapse the blister,[14] and removal of the needle shield were found to be difficult by some users of early prototype devices. BD, the manufacturer of the device, has since improved the device to make these steps easier.
- As with any needle/syringe combination, users must be trained not to recap the needle of the Uniject device after use.[10,11]
- No significant differences were found in seroconversion rates or geometric mean titers of hepatitis B surface antibodies between three groups of infants receiving hepatitis B vaccine stored: (1) in the cold chain and delivered with standard needles and syringes, (2) in the cold chain in the Uniject devices, and (3) at ambient temperatures in the Uniject devices for up to 1 month.[12]

- The Uniject device is highly appropriate for use in outreach programs and for use outside the cold chain.[10,11]
- Individuals who have never delivered an injection are able to successfully do so with the Uniject device after minimal training.[10,17] Self-administration of injectable contraceptives using the Uniject device is a viable option.[12]

2.4 Gentamicin in the Uniject device

Uniject devices prefilled with a single gentamicin dose may be easily transported and used in a home or primary health facility when the signs of a neonatal infection are first detected. Health workers may be trained to use gentamicin in the Uniject device (hereafter called gentamicin in Uniject) to extend accessibility and facilitate administration of antibiotics for early treatment of neonatal infections. Thus, if gentamicin in Uniject is used safely, properly, and efficiently for infants with severe bacterial infections, then Uniject devices may make significant contributions in reducing neonatal mortality in developing countries.

The idea of introducing gentamicin in a simple, mono-dose injection device, such as the Uniject, has been received with optimism from several international experts on neonatal infections and treatment. In a 1999 *Lancet* article, Abhay Bang, Director of the Society for Education, Action, and Research in Community Health, wrote: "To further simplify the parenteral administration of gentamicin, the use of disposable syringes prefilled with gentamicin, or a single-use simple Uniject device should be tested."[21]

There are many identifiable advantages for administering gentamicin in Uniject for treatment of neonatal sepsis in developing countries. Some of those advantages include the following:

- **Home use may improve timing.** Uniject devices are small, easy to transport, and can be administered by minimally trained health workers. These features may improve the timing of administering the first dose—and possibly subsequent doses—of antibiotics by improving accessibility within the home or first-line health facility. To decrease the case-fatality rate, it is critically important to deliver the first dose of antibiotics as close to the onset of infection as possible. Often, waiting until the infant reaches the referral center may be too late.
- **Sterile injections.** The Uniject device, a nonreusable injection device with a fixed needle, eliminates the possibility of reuse. The design of the packaging also decreases the likelihood that the device will become contaminated before the injection is administered. These design features will help ensure sterility of the needle and safety of the injection, thereby eliminating risk of transmission of blood-borne agents—notably HIV, hepatitis B, and hepatitis C—while minimizing risk of local infections at the injection site.
- **Accurate prefilled dose.** Uniject devices are produced with an accurate volume of a specified dose. This reduces the possibility for a health worker to accidentally administer too much or too little antibiotic. However, the preset dose would make it more difficult than using standard syringes to calibrate and deliver the exact dose per body weight.
- **Stability.** Because gentamicin is stable at ambient temperatures, gentamicin in Uniject does not need refrigeration and can be transported and stored at room temperature (the stability of gentamicin packaged in the Uniject device was verified in a pilot study prior to initiation of the field study).
- **Simplified logistics.** Since the antibiotic and syringe are incorporated into the Uniject device, logistical issues are simplified and stockouts due to insufficient supply of

components such as syringes or medication are minimized. Furthermore, the inclusive design of the Uniject device also means that no other equipment—except for a safety disposal box—is required to administer injections in the field or at the health facility.

Home-based and primary health facility use of gentamicin in Uniject is considered highly feasible based on PATH's experience in introducing the Uniject device in various developing countries.[12-14,17-20,22]

2.5 Dosing for gentamicin in Uniject

PATH, in collaboration with Johns Hopkins University, undertook a pharmacokinetic study with funding from Saving Newborn Lives to determine safe and effective dosing regimens of gentamicin for use in the Uniject device to treat neonatal sepsis in developing countries. In the study, neonates with suspected sepsis in the neonatal intensive care unit at Christian Medical College and Hospital (CMC), Vellore, India (n=49), and Dhaka Shishu Hospital (DSH), Bangladesh (n=59), were administered gentamicin intravenously according to the following regimens: (1) 10 mg every 48 hours for neonates who weighed less than 2000 grams; (2) 10 mg every 24 hours for neonates who weighed in the range of 2000–2249 grams; and (3) 13.5 mg every 24 hours for neonates who weighed 2500 grams or more. Serum gentamicin concentration (SGC) at steady state and pharmacokinetic indices were determined. Renal function was followed while under treatment, and hearing was examined 6 weeks to 3 months after discharge. Peak SGCs ($\geq$4.0 and <12.0 mcg/ml) were considered therapeutic, and trough SGC (<2.0 mcg/ml) was considered nontoxic.[16] Study results indicated that all neonates at DSH, except one who weighed between 2000 and 2249 grams, had a peak SGC of >4 mcg/ml. Overall, 5 (10%) and 17 (29%) infants had a peak SGC level of $\geq$12 mcg/ml at CMC and DSH, respectively, and 10 (20%) and 4 (7%) cases at CMC and DSH, respectively, had a trough SGC level of $\geq$2 mcg/ml. However, no infant who weighed less than 2000 grams had a trough SGC level of $\geq$2 mcg/ml. We found no evidence of gentamicin nephrotoxicity or ototoxicity. These findings support the conclusion that safe, therapeutic gentamicin dosing regimens were identified for use in the Uniject device to treat neonatal sepsis in developing-country settings.[23,24] The dosing verification studies[24] led to the following plan for administration of gentamicin in Uniject to newborns:

Less than 2,000 grams:	10 mg every 48 hours
2,000–2,499 grams:	10 mg every 24 hours
Greater than 2,500 grams:	13.5 mg every 24 hours

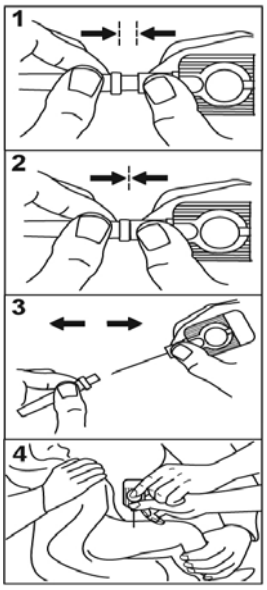
Thus, two different doses of gentamicin in Uniject were produced—a 10-mg dose and a 13.5-mg dose. As noted above, there were three different treatment approaches depending on weight of the neonate. This approach required weighing the newborn with a scale that could identify three different weight categories that correspond to the gentamicin in Uniject dosing regimens identified above.

2.6 Production of gentamicin in Uniject

The gentamicin in Uniject product was made by Instituto Biologico Argentino (BIOL) at its facility in Florencio Varela, outside Buenos Aires, Argentina. BIOL is a private Argentinean pharmaceutical manufacturer that has been in business for more than 100 years. It specializes in medicines for gynecology and obstetrics as well as vaccines, and exports to countries throughout Latin America.

BIOL is committed to international quality standards for all of its products and is certified by the International Organization for Standardization. To develop the gentamicin in Uniject product, the manufacturer conducted a 24-month stability evaluation per International Conference on Harmonisation guidelines, proving the compatibility of gentamicin for injection with the Uniject device. The national drug regulatory authority of Argentina, ANMAT, certified that production of the gentamicin in Uniject product for this study conformed to Good Manufacturing Practice (GMP) guidelines. The production lot supplied for this study was manufactured on June 26, 2007, and expired on June 25, 2009.

Figure 6. Low-literate instructions.



The manufacturer labeled the product with a green bar on the 13.5 mg-dose pouches and no color on the 10 mg-dose pouches. Product information was printed on the product in English. The manufacturer followed all appropriate GMP procedures for labeling and packaging operations, including control of the labels, complete separation of labeling processes for the two different product concentrations, and full post-labeling accounting for all unused labels. Pictorial low-literate instructions for use were printed on the outer package (see Figure 6).

Prior to initiation of the study, various options to differentiate the administration regimens were explored. FCHVs were consulted, and the following options were determined (Figure 7):

Figure 7. Color-coded gentamicin in Uniject devices.

1. Label 10-mg packages with a red color for very low weight infants.
2. Label 10-mg packages with a yellow color for low weight infants.
3. Label 13.5-mg packages with a green color for normal weight infants.

3. Study methods

3.1 Description of study area

Nepal's Morang district (Figures 8 and 9) was selected as the preferred site for this study for several reasons. As noted above, the National Neonatal Health Strategy was endorsed in 2004, and there is strong commitment from the MOHP and partners to decrease neonatal mortality.

Figure 8. Map of Nepal showing Morang district.

Figure 9. Five intervention VDCs in Morang.

The preliminary findings from the ongoing MINI program had been well-received by the DPHO and the MOHP, and this community-based approach for management of neonatal infections was already incorporated into a larger MOHP initiative, the Community-Based Newborn Care Package. However, the government voiced concerns about how distance, geography, lack of staffing, and other challenges in more remote districts might impact gentamicin completion rates if the same MINI model of care were replicated. Therefore, there was interest in testing the feasibility of using the gentamicin in Uniject device as an alternative care model.

Morang was the most suitable site for this design-stage feasibility study due to the existing MINI program and research infrastructure. The FCHVs were already familiar with the techniques for diagnosis and management of neonatal sepsis, so only the use of the device needed to be added as a new skill, along with correct disposal and recording of services. Further, the MINI office and infrastructure were already in place in the district headquarters, Biratnagar, to create a natural base for the study. The MINI database could be utilized to determine the VDCs with large numbers of births, and the existing data management systems ensured good-quality data. In addition, close monitoring and supervision of the study were possible due to the presence of the MINI field staff.

Five VDCs in Morang district with high birth rates and political stability were selected for inclusion in the study (Table 2). Selection of VDCs was purposive. Those with a high volume of PSBI episodes—as seen in the MINI database—were selected in order to maximize the likelihood of having adequate cases and also to vary the geographic settings. The five VDCs selected were Dainiya, Sorabhag, Govindapur, Madhumalla, and Hatimuda (Figure 9).

Table 2. VDC characteristics.

	Dainiya	Sorabhag	Govindapur	Madhumalla	Hatimuda
Estimated total population	14333	12168	17746	22799	9398
Estimated population younger than 1 year	331	281	410	527	217
Estimated population younger than 5 years	1744	1481	2159	2774	1143
Estimated MWRA population	2747	2332	3401	4369	1801
Estimated expected pregnancies	549	466	680	874	360

MWRA: married women of reproductive age.
Source: Morang DPHO, 2009.

3.2 Research questions and objectives

The primary research question of the study: 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?

Secondary research questions:

- Will the FCHVs be 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?
- Will the administration of gentamicin in Uniject by FCHVs as a treatment for neonatal sepsis be acceptable to community members?

The following research objectives were established:

1. Evaluate health worker comprehension of training materials on the use of the gentamicin in Uniject device in combination with an appropriate scale, including choosing the correct dose and dosing schedule and adhering to the correct dosing schedule.
2. Assess performance of gentamicin in Uniject characteristics, such as ease of use, dose accuracy, safety, and ease of disposal among health workers.
3. Assess acceptability of using gentamicin in Uniject by health workers and the community.

3.3 Study design

This was a post-test study only, a nonexperimental research design aimed toward assessing the feasibility of the gentamicin in Uniject device when used by FCHVs in a peripheral care setting.

Newborn infants up to 59 days of age who weighed less than 3500 grams and who were suspected of having PSBI as per the standardized diagnostic protocol/algorithm were treated with gentamicin and oral cotrimoxazole-p as per the MINI program standard of practice. In this study, the gentamicin was delivered via the Uniject device by FCHVs under supervision of a health worker (MCHW, VHW, or health facility in-charge).

The primary unit of analysis was the FCHVs. Additional study participants included newborn infants who were treated with gentamicin in Uniject, caretakers of infants who were treated with gentamicin in Uniject, and community leaders.

Eligibility inclusion criteria for the four groups of participants (health workers, sick young infants, caretakers of sick young infants, and local community leaders) were as follows:

1. Health providers, designated FCHVs, VHWs, MCHWs, or health facility workers who were trained on the use of gentamicin in Uniject and who were working in the MINI program area during the study period. The term “community health worker” (CHW) was used collectively to refer to FCHVs, VHWs, or MCHWs.
2. Newborn infants up to 59 days who weighed less than 3500 grams and were suspected of having PSBI per standardized diagnostic protocol.
3. Adult (age 18 or older) responsible for the care of the enrolled young infant.
4. Adult (age 18 or older) who was a member in a community group in the VDC where the intervention was taking place.

Feasibility of the use of gentamicin in Uniject by FCHVs to treat sick young infants at home was assessed by collecting data related to device performance, acceptability, indication accuracy, safety, and disposal. Both quantitative and qualitative data were collected using mixed methods.

3.4 Roles of FCHVs and health workers in treating PSBI at home

For the purposes of this study, PSBI was defined in the same way as it was in the regular MINI study. That is, PSBI was defined as presence of *any one* of the ten danger signs as shown in Figure 3.

If the FCHV identified one or more danger signs, she obtained consent from the family and initiated treatment for the sick young infant. The treatment regimen consisted of two drugs—oral cotrimoxazole-p and gentamicin. She provided cotrimoxazole-p tablets to the family for dosing at home after observing the administration of the first dose dissolved in breast milk. The family was provided with enough cotrimoxazole-p to treat the baby twice daily for 5 days, and the dose was based on the age of the baby. For those infants 0 to 1 month of age, the dose was one-half tablet twice daily for 5 days, and for babies 1 to 2 months of age, the dose was one tablet twice daily for 5 days. The FCHVs administered the gentamicin in Uniject to newborns at home at a dosage determined by weight (Table 3).

Table 3. Gentamicin in Uniject dosage according to weight of the infant.

Weight	Dose	Duration	Total doses
<2000 grams	10 mg every 48 hours (red)	9 days	5
2000–2499 grams	10 mg every 24 hours (yellow)	7 days	7
>2500 grams	13.5 mg every 24 hours (green)	7 days	7

The selection of the correct dosage of gentamicin was based on the weight of the baby, so the FCHVs weighed the babies using their color-coded Salter scale. Because some of the FCHVs were illiterate or semi-literate, and therefore, could have had difficulty reading weights, all of the gentamicin in Uniject packages were color-coded to match the readings on the scale. That is, for a young infant who weighed less than 2000 grams, with one or more danger signs, the scale would show a reading in the red zone and the FCHV would choose the gentamicin in Uniject device in the package marked with a red border. Likewise, a young infant who weighed between 2000 and 2499 grams would be dosed using gentamicin in Uniject packed in a package with a yellow border, and normal weight babies (2500 grams–3499 grams) would be dosed with the device in the package with a green border. Babies who weighed more than 3500 grams were referred to the health facility for treatment with gentamicin provided through a standard needle and syringe by health facility staff, a VHW, or an MCHW (the dose required for these larger babies was not available in the Uniject device).

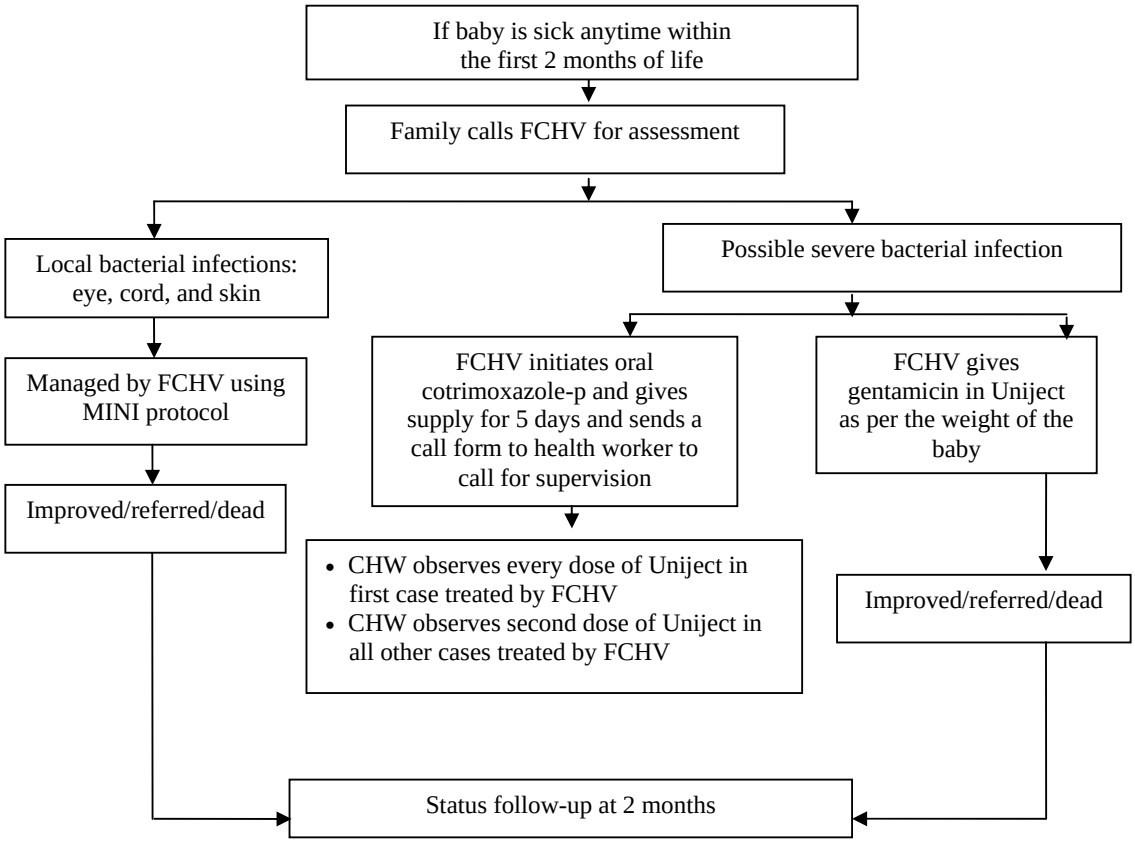
Before each subsequent treatment dose was administered by the FCHV, she would reassess the sick young infant—to determine the status—using the ten danger signs described above. If there was any worsening of the young infant's condition, then referral was advised. If referral was not required, the FCHV would continue to treat the baby daily in the home using gentamicin in Uniject, and she would follow up and ask about the home-based dosing with cotrimoxazole-p. The full treatment regimen for babies who weighed 2000 grams or more was seven doses, one dose per day for 7 days. For young infants who weighed less than 2000 grams, FCHVs referred them to the health facility, where they received a total of five doses, given on alternate days over a 9-day period. Sick young infants who weighed more than 3500 grams were treated by health facility workers who used a standard needle and syringe and gentamicin.

The VHWs and MCHWs, as supervisors of the FCHVs, and the health facility in-charge in the study area were all trained to use gentamicin in Uniject and also used it to treat cases presented directly to them at the health facilities.

In addition, they supported and supervised the FCHVs in the use of gentamicin in Uniject. FCHVs were certified competent to give gentamicin in Uniject at the end of their training and were observed by their supervisors for all treatment doses for their first case. The call form used in the MINI study was also used in this trial, to request a supervisor to come and

observe the FCHV using the device for the first case. The supervisors used a skills checklist that included all of the correct steps for giving the injections. If there were any errors, they were corrected and individual feedback was given on the spot.

Figure 10. Activities conducted by FCHVs to treat sick babies.



After successful completion of treatment of their first case, FCHVs were recertified as competent to use the device. For subsequent cases, they could give the first dose unsupervised to avoid any delays in initiating treatment, and called their supervisor to observe the second dose and verify that the technique and dosing choice were correct. If at any time, the family or the FCHV was not comfortable with continuing the treatment, supervisors were willing and able to complete the treatment using gentamicin in Uniject or gentamicin in a standard needle and syringe.

A special disposal box made of heavy, laminated cardboard (Figure 11) was prepared especially for this study. It had an external lid that could be opened and closed and an internal receptacle with a narrow mouth that could accommodate just the device. The FCHVs were trained to remove the cap of the device before injection and immediately place it in the mouth of the box. Then immediately after administration of the gentamicin to the young infant, they deposited the used device into the box without recapping and closed the external lid. The capacity of one box was adequate for receipt of all devices used for one round of PSBI treatment.

Figure 11. Disposal box for used Uniject devices.

After completion of treatment, FCHVs returned the disposal boxes to the health facility every month and they were burned. One disposal box was used for each sick baby.

The FCHVs maintained a treatment register in which they recorded all relevant data about the sick young infant, the presenting danger signs, and the daily record of treatment. These registers included a place for the supervisors to sign and verify that they had observed the doses given by the FCHVs. The other health workers also maintained treatment registers for cases that presented directly to them.

3.5 Training

Most of the training materials used in the MINI program were adapted by a team consisting of local technical experts from the Child Health Division of the MOHP, DPHO Morang, NFHP, MINI, USAID, and PATH. The materials were prepared in two phases, with the completion of the training materials first and the monitoring and evaluation tools second. The experts who were involved in the development of the training materials were primarily responsible for conducting the training at the district level. The experienced trainers of the DPHO, MINI, and the NFHP conducted the trainings up to the community level. The trainings were fully participatory and hands-on, with practical exposure whenever possible.

Figure 12. FCHV learning the weighing skill.

Due to the nature of the intervention, with FCHVs using an injectable for the first time, and the current sensitive political environment, it was decided that it was essential to conduct orientations about the study with local community leaders and community members at both the district and VDC levels. Therefore, orientations were conducted in late January and early February 2009, before any field-level trainings began. At the VDC level, verbal consent was obtained from the local community leaders in all five VDCs for the conduct of the study.

A day-long training for health workers was conducted in early February 2009 at the district headquarters in Biratnagar. This was followed by a 2-day training for the VHWs/MCHWs, in which they learned the necessary skills for assessing and treating sick young infants using the gentamicin in Uniject device and also began preparation for their role to supervise the FCHVs in this new intervention. The FCHV-level trainings were conducted at the local health facilities in their own VDCs, with the VHWs and MCHWs also attending to reinforce their role as supervisors of the FCHVs.

The FCHV training curriculum was covered in 4 days. The trainings utilized participatory methods and opportunities for all participants to do hands-on assessment and treatment. Dolls (with lead weights sewn into the lining) were used for practice with the Salter scale. This

Figure 13. District Public Health Administrator addressing the VDC orientation.

skill, though not new for the FCHVs, was reinforced, and the significance of the weight for dosing choices was emphasized.
For assessment of sick young infants, existing skills in assessment for danger signs were reviewed. Practice in using gentamicin in Uniject was conducted with water-filled units on fresh eggplants (long, thin vegetables that closely resemble the size and consistency of a young infant's thigh). The FCHVs also practiced using the disposal box correctly.

FCHVs were assessed on their practical abilities (weighing the baby, assessing for danger signs, administering gentamicin in Uniject), and skills were repeated until they were competent in all those necessary. They were also assessed on their ability to explain the illness and treatment options to the caretakers, for taking consent for treatment. Recordkeeping was learned using large flex charts on which the FCHVs could practice maintaining their treatment registers. At the end of the training, all FCHVs who were certified as competent were provided with color-coded gentamicin in Uniject devices (1 red, 7 yellow, and 14 green) to take home, along with some disposal boxes and treatment registers. Resupply was done by the health facilities as needed. At the end of the study period, research staff collected unused devices and disposed of them safely.

After training the FCHVs on the use of gentamicin in Uniject, a meeting was held at the village level (one per FCHV), where the FCHV was supported by health facility and DPHO/MINI program staff to inform her fellow villagers about her new training. She informed them that she could now treat sick newborns with cotrimoxazole-p and gentamicin in Uniject. VDC- and district-level orientations were also conducted before the introduction of the program, to inform village and local community leaders.

A post-training questionnaire was administered to all participants to evaluate the effectiveness of the training curriculum. For illiterate FCHVs, a trainer would read the questions aloud to the individual FCHV and then record her verbal responses on the questionnaire. A competency certification test was also performed for all health workers by one of the trainers. Only those FCHVs who passed this certification were provided with gentamicin in Uniject to take home.

3.6 Training materials

Most of the materials developed for the MINI program were adapted for this new intervention. All changes were minimized in order to reduce the recording and reporting burden for FCHVs. The following training materials were used specifically for this gentamicin in Uniject design-stage trial.

Training module. The training module used in the MINI intervention was revised to incorporate new technical content for the study. Two separate modules, "Community-based management of sick young infants with cotrimoxazole-p and gentamicin in Uniject for Health Workers" and "Community-based management of sick young infants with cotrimoxazole-p and gentamicin in Uniject for FCHVs" were developed.

Flex chart. Flex charts (flexible wall charts that can be written on and then cleaned for reuse) were developed to model treatment registers used in the study. The charts were used during training to practice recording and reporting.

Danglers. Danglers (job aids that can be suspended) that showed pictures of newborns with different danger signs were used to practice recognition of newborn danger signs and classification of illness by FCHVs.

Classification card. A pictorial classification card in a simple booklet form was developed for the FCHVs. The four-page classification card was used as a job aid to assess and classify illness in newborns and young infants (Appendix A). The first page of this colored card described the program by title and showed the scale and treatments being used. The second page contained the ten danger signs of PSBI, the signs of local bacterial infections, and ENC messages. The third page contained the color-coded weighing scale, which was linked with the dosing regimen for the gentamicin in Uniject as well as the dosing regimen for cotrimoxazole-p tablets. The last page contained information about the steps to be followed to give gentamicin in Uniject correctly, including advice on correct disposal. The FCHVs used this card as a job aid while they were assessing and treating the newborns and young infants.

Figure 14. Salter weighing scale.

Weighing scale. The color-coded Salter scale (Figure 14) was used for weighing newborns. The very low birth weight part of the scale was colored red, the low birth weight category was colored yellow, and the normal weight category was colored green. Also, a white mark on the Salter scale indicated a weight of 3500 grams. Any sick newborns that weighed more than 3500 grams were referred to the health facility, as they required a higher dose of gentamicin than those available in the Uniject devices.

Figure 15. Thermometer with cutoff points.

Thermometer. FCHVs were provided with a flat mercury thermometer with two separate marks to indicate the cutoffs for hypothermia and fever (Figure 15).

Colored laboratory coats. Three colored laboratory coats (red, yellow, and green) were used to practice assessment of danger signs. The danglers with different danger signs were provided to the FCHVs during training, and they had to decide how to classify the sign and then place the dangler on the person wearing the correct colored laboratory coat (Figure 16).

Safe-disposal box. A small disposal box was designed for the safe disposal of the used Uniject devices, as shown in Figure 11. One box was used to dispose of the used Uniject devices from the treatment of one sick child.

Eggplant. An eggplant was used during training to practice the skills for injection (Figure 17).

Figure 16. Practice of assessment of danger signs with colored laboratory coats.

Water-filled Uniject devices. Water-filled Uniject devices were used during training to master the skill of giving gentamicin in Uniject.

Dolls. Pieces of iron of three different weights (<2 kg, 2–2.5 kg, >2.5 kg) were inserted into the clothing of dolls. The dolls were used by FCHVs to practice the weighing skill during training.

Birth record form. A simple pictorial form (Appendix B) from the MINI program was used to record information at the time of birth. FCHVs used this form during the early postnatal visit. One part of the form was given to the family for official birth registration at the VDC, and the FCHV retained the other piece of the form for her records. The FCHVs recorded the status of newborns at the age of 2 months on the same form. Supervisors collected and collated this information from the FCHV records on a monthly basis.

Treatment register. A colored, pictorial register, with individual pages for individual babies (Appendix C), was used to record the history of treatment for a newborn in the event of illness. The consent was written on the front page of the register. The register included information about the classification of illness, consent given by the caretaker for treatment, and the treatment given to the sick newborn. Separate registers were used for FCHVs, VHWs, and facility-based health workers.

Figure 17. An FCHV practicing injection of gentamicin in Uniject in an eggplant.

Call form. The call form used in the MINI program to bring the VHW, MCHW, or AHW to the home to give the gentamicin injection was used to "call" the supervisor to come and observe the FCHV giving gentamicin in Uniject (Appendix D).

Data collection forms. Standard forms used in the MINI program were revised to collect information specific to this project. The information from the service registers was collected in these data collection forms by project staff.

3.7 Data collection and instruments

The NFHP hired a full-time consultant to serve as the field coordinator throughout the period of the study, and the existing MINI team provided additional support. Data were recorded by the health workers in their registers during the intervention. After completion of the intervention, focus group discussions (FGDs) with FCHVs and in-depth interviews with supervisors (MCHWs/VHWs and health facility staff) were conducted to assess perceptions, feasibility, and acceptability of use of gentamicin in Uniject, including interest in using the device long term. Both quantitative and qualitative data were collected as noted in Table 4 below.

Table 4. Data collection instruments. (Copies of forms are available upon request.)

Participant group	Data collection form	When/where form was used	Estimated amount of time required
FCHVs, MCHWs, VHWs	a. Post-training questionnaire	a. Immediately after training is completed, at training site	a. Up to 30 minutes
	b. Treatment register for recording sepsis cases and management	b. When health workers give gentamicin in Uniject	b. Up to 5 minutes
	c. Competency certificate checklist to assess correct use by FCHVs/HFs only	c. After training and when FCHVs give gentamicin in Uniject	c. Up to 20 minutes
	d. CHW interview form	d. Every 2 months during implementation, at work site	d. Up to 20 minutes
	e. Post-implementation questionnaire	e. At the end of the intervention period, at the work site	e. Up to 1 hour
	f. FGD/CHW interview	f. At the end of the intervention period, at the SHP in each VDC	f. Up to 2 hours
Health facility staff	a. Post-training questionnaire	a. Immediately after training is completed, at training site	a. Up to 30 minutes
	b. Treatment register for recording sepsis cases and management	b. When health workers give gentamicin in Uniject	b. Up to 5 minutes
	c. Supervisory checklist to assess correct use by FCHVs only	c. When FCHVs give gentamicin in Uniject	c. Up to 20 minutes
	d. Post-implementation questionnaire	d. At the end of the intervention period, at the work site	d. Up to 1 hour
	e. In-depth interview	e. At the end of the intervention period, at the SHP in each VDC	e. Up to 2 hours
Field supervisors	a. Post-training questionnaire	a. Immediately after training is completed, at training site	a. Up to 30 minutes
	b. Competency certification checklist	b. Immediately after training is completed, at training site	b. Up to 20 minutes
	c. Supervisory skills checklist	c. Immediately after training is completed, at training site	c. Up to 20 minutes
Caretakers	a. Structured questionnaire	a. Within 1 week of treatment of their infant with gentamicin in Uniject, at home	a. Up to 45 minutes
Community leaders	a. Key informant questionnaire	a. Within 4 weeks after completion of intervention, at home or office	a. Up to 1 hour

3.8 Statistical analysis

Data cleaning, coding, entry, and preliminary analysis were conducted in Nepal under the supervision of NFHP/MINI staff. For quantitative data, univariate and bivariate analyses of key variables were conducted. Because this study was exploratory in nature, our objective was to obtain feedback about device performance from the broadest range of FCHVs possible. Within the five VDCs, for the purposes of analysis, FCHVs were divided into two categories: (1) literate and (2) illiterate.

Notes were taken manually during all FGDs/in-depth interviews. For qualitative data, coding was done following the translation of the transcribed data set. A set of codes was developed, and data were sorted and analyzed thematically.

3.9 Ethical review and informed consent

The study protocol was reviewed and approved by the Nepal MOHP, the Nepal Health Research Council, and the PATH Research Ethics Committee. Oral consent by health workers was obtained by field supervisors immediately after training in use of gentamicin in Uniject was completed. Oral consent by health workers to participate in FGDs was obtained by field supervisors immediately before the discussion. Individual-level informed consent for treatment of neonatal sepsis using gentamicin in Uniject and oral cotrimoxazole was obtained from all caretakers of sick newborns in their homes prior to the use of gentamicin in Uniject. Oral consent by caretakers and community leaders to participate in key informant interviews was obtained by field supervisors immediately before the interview.

4. Results

Data were collected during the intervention period from January 1, 2009, to June 19, 2009. A total of 59 CHWs and health facility staff (45 FCHVs, 9 VHW/MCHWs, and 5 health facility in-charges) participated in this study. Among the 45 FCHVs who participated, only 33 had the opportunity to treat PSBI with gentamicin in Uniject. Therefore, data for some variables are available for only 33 FCHVs. The 33 FCHVs treated a total of 67 sick young infants during this period. In addition, data from 45 caretakers of infants who had been treated with gentamicin in Uniject at home and 10 community leaders were collected.

One FGD was conducted with FCHVs in each VDC (n=5). All nine FCHVs attended the FGD in her area, with the exception of one group that had only eight participants. Each FGD lasted about two hours. Two notetakers manually recorded each FGD. Results related to the following thematic areas: product use, acceptability, and training for use of gentamicin in Uniject.

4.1 Background of FCHVs

The mean age of the FCHVs was 40 years. There was only one FCHV who was less than 25 years of age. Most of the FCHVs were between 25 and 54 years. Ten FCHVs were between 25 and 34, 20 FCHVs were between 35 and 44, and 11 FCHVs were between the ages of 45 and 54. Three FCHVs were more than 54 years old. The literacy status of the FCHVs is shown in Table 5.

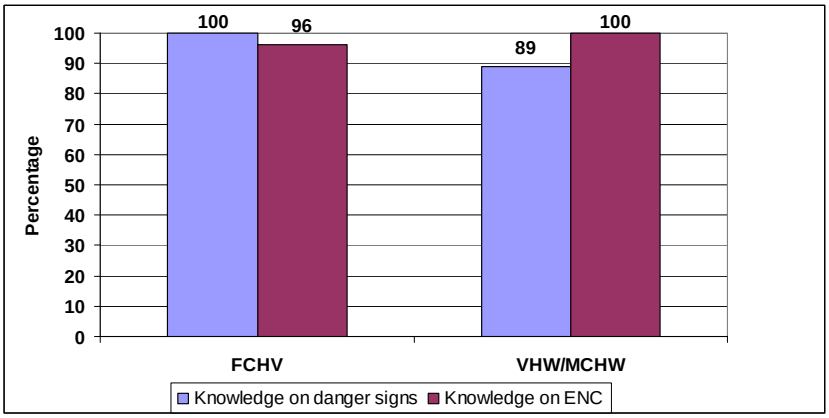
Table 5. Literacy status of FCHVs (n=45).

Literacy status	% (number)
No grade (illiterate, could not read and write)	11 (5)
Grades 1–4 (semi-literate, could read and write with difficulty)	27 (12)
Grade 5 or more (literate, could read and write)	62 (28)

4.2 Knowledge

Both FCHVs and VHWs/MCHWs were assessed for their knowledge on the ten danger signs (unable to feed, lethargic or unconscious, fast breathing, severe chest indrawing, grunting, fever, hypothermia, umbilical discharge with redness extending up to surrounding skin, ten or more skin pustules or one abscess, weak or absent cry) and ENC messages (drying baby, wrapping baby, delaying bathing for 24 hours, applying nothing to the cord, and breastfeeding within 1 hour of birth) (Figure 18).

Figure 18. Knowledge on danger signs and ENC among FCHVs and VHWs/MCHWs.



FCHVs and VHWs/MCHWs were interviewed twice during the intervention period regarding their knowledge of the correct dose selection of cotrimoxazole-p and gentamicin in Uniject. They were asked about the correct dose of cotrimoxazole-p for both age groups (less than 1 month and 1- to 2-month-old young infants). All health workers demonstrated knowledge of the correct dose of cotrimoxazole-p in both interviews (45 FCHVs and 9 VHWs/MCHWs). They were also asked about the correct dose selection of gentamicin in Uniject according to the weight of the young infant. Only 4% of FCHVs (n=2) in the first interview did not know the correct dose selection of gentamicin in Uniject for infants less than 2 kg, and this improved to 100% (n=45) in the second interview. All VHWs/MCHWs (n=9) knew the correct dose selection of gentamicin in Uniject for all age groups in both interviews.

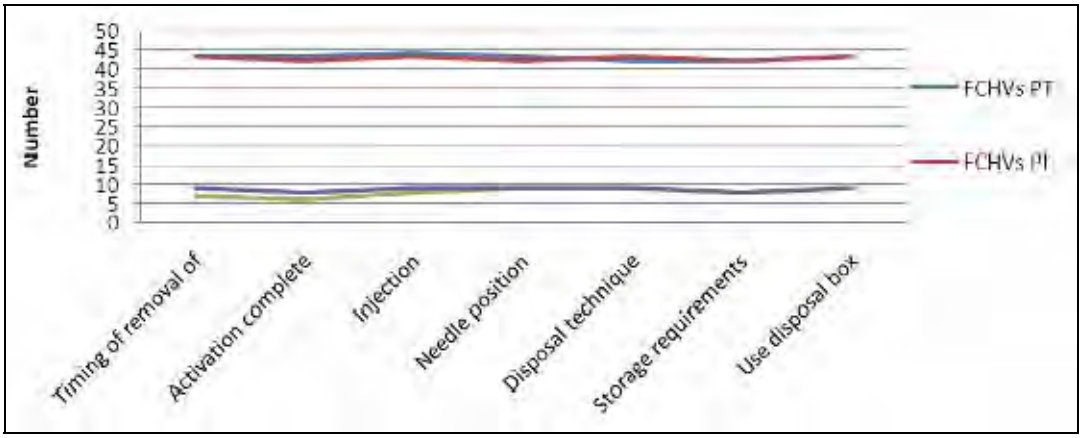
FCHVs, VHWs, and MCHWs were using the Uniject device for the first time. Two questionnaires, post-training (PT) and post-implementation (PI), were used to assess FCHV knowledge regarding the gentamicin in Uniject device. FCHVs were asked questions regarding overall knowledge about the performance of gentamicin in Uniject, correct timing of cap removal, correct timing of activation of injection, correct method of injection, correct angle of injection, correct disposal of the used gentamicin in Uniject devices, and disposal boxes. The results are shown in Table 6.

Table 6. Correct knowledge on device performance.

	FCHVs		VHWs/MCHWs	
Correct knowledge on device	PT (n=45)	PI (n=45)	PT (n=9)	PI (n=9)
Sterile in foil pouch	45	45	9	9
Single use	43	42	9	9
Volume = 1 dose	41	38	9	9
Unable to reuse	43	42	9	9
Cannot use without activation	40	42	9	8

They were also asked about the correct timing (before activation and after activation) of removal of the needle cap of gentamicin in Uniject, activation of the device, correct method and position of injection, disposal technique, and storage. The results are shown in Figure 19.

Figure 19. Knowledge on device performance.



As shown in Table 7, all FCHVs who treated PSBI demonstrated high levels of knowledge in all program areas. No association between literacy status and FCHVs' knowledge was present regarding key program activities.

Table 7. Knowledge of key program activities among FCHVs who treated PSBI, according to literacy status (n=33).

	Literate (n=21)	Semi-literate (n=10)	Illiterate (n=2)
Knowledge of all ten danger signs	100% (n=21)	100% (n=10)	100% (n=2)
Knowledge of all five ENC messages	95% (n=20)	90% (n=9)	100% (n=2)
Knowledge of correct dose of cotrimoxazole-p	100% (n=21)	100% (n=10)	100% (n=2)
Knowledge of correct dose of gentamicin in Uniject	90% (n=19)	100% (n=10)	100% (n=2)

The overall knowledge regarding program activities in all age categories was high, ranging from 86% to 100% (Table 8). There was no difference among ages of FCHVs who treated PSBI and knowledge regarding danger signs, ENC messages, correct dose of cotrimoxazole-p, and correct dose of gentamicin in Uniject.

Table 8. Knowledge of key program activities among FCHVs who treated PSBI, according to age group (n=33).

	25–34 years (n=6)	35–44 years (n=14)	45–54 years (n=10)	>54 years (n=3)
Knowledge of all ten danger signs	100% (n=6)	100% (n=14)	100% (n=10)	100% (n=10)
Knowledge of all five ENC messages	100% (n=6)	86% (n=12)	100% (n=10)	100% (n=10)
Knowledge of correct dose of cotrimoxazole-p	100% (n=6)	100% (n=14)	100% (n=10)	100% (n=10)
Knowledge of correct dose of gentamicin in Uniject	100% (n=6)	86% (n=12)	100% (n=10)	100% (n=10)

Figure 20. An FCHV with her treatment register.

Figure 21. FCHV giving gentamicin in Uniject.

Overall knowledge levels were high. No difference was observed regarding FCHV age and knowledge (Table 9). There was no association between literacy status and knowledge of gentamicin in Uniject in either group of FCHVs (those who treated PSBI and those who did not treat PSBI) (Tables 9 and 10). Similarly, knowledge levels increased slightly from post-training to post-implementation.

Table 9. Knowledge of the Uniject device among FCHVs who treated PSBI, according to literacy status, time point, and treatment experience (n=33).

Knowledge on Uniject device	Literate (n=22)		Semi-literate (n=9)		Illiterate (n=2)		Total	
	PT	PI	PT	PI	PT	PI	PT	PI
Overall knowledge of Uniject device performance	17	17	4	7	1	2	20	24
Correct timing of cap removal	22	21	8	9	1	1	29	29
Knowledge on activation of Uniject device	20	20	8	9	2	2	28	30
Knowledge on correct method of injection	22	22	9	9	2	2	31	30
Knowledge of correct angle of injection	22	22	9	7	2	2	31	28
Knowledge of correct disposal of used gentamicin in Uniject syringes	19	22	9	9	2	2	28	31
Knowledge of correct disposal of disposal boxes	22	22	9	8	2	2	31	30

Sources: post-training (PT) and post-implementation (PI) questionnaires.

Figure 22. Knowledge of the Uniject device among FCHVs who treated PSBI, according to literacy status, time point, and treatment experience (n=33).

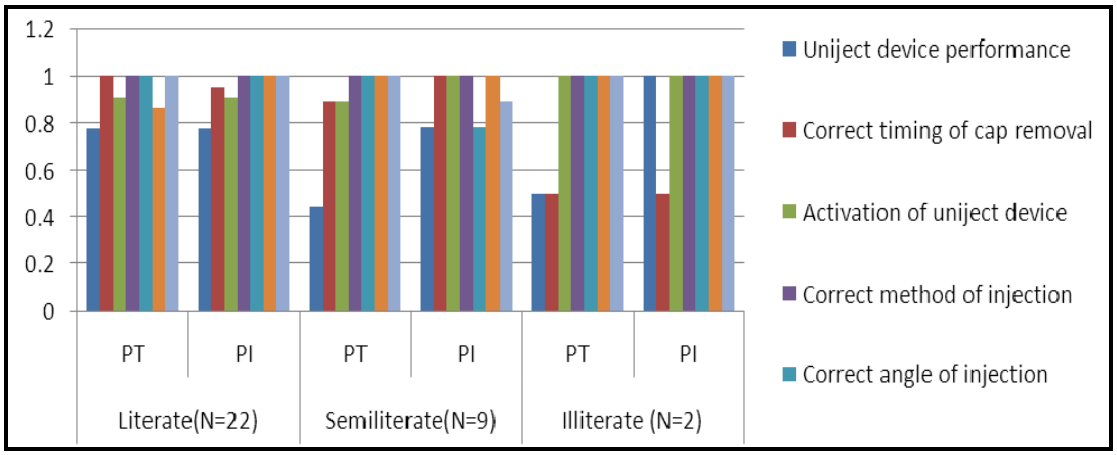


Table 10. Knowledge of the Uniject device among FCHVs who did not treat PSBI, according to literacy status (n=12).

Knowledge on Uniject device	Literate (n=6)		Semi-literate (n=3)		Illiterate (n=3)		Total	
	PT	PI	PT	PI	PT	PI	PT	PI
Overall knowledge of Uniject device performance	5	5	3	2	3	1	11	8
Correct timing of cap removal	6	6	3	3	3	3	12	12
Knowledge on activation of Uniject device	6	6	3	3	3	2	12	11
Knowledge on correct method of injection	6	5	2	3	3	2	11	10
Knowledge of correct angle of injection	6	6	3	3	3	2	12	11
Knowledge of correct disposal of used gentamicin in Uniject syringes	6	5	3	3	3	3	12	11
Knowledge of correct disposal of disposal boxes	6	6	3	3	3	3	12	12

Figure 23. FCHV counting the respiratory rate of a baby using an ARI timer.

Among the 45 FCHVs, 12 FCHVs did not get the opportunity to treat PSBI with gentamicin in Uniject. Therefore, separate analysis was done to determine the association between their age, literacy, knowledge of various program activities, and use of gentamicin in Uniject device (Tables 11 and 12). The age and literacy status of FCHVs who did not treat PSBI did not have any impact on their overall performance.

Table 11. FCHV knowledge of the Uniject device according to different age groups among those who treated PSBI (n=33).

Knowledge on Uniject device	25–34 years (n=6)		35–44 years (n=14)		45–54 years (n=10)		>54 years (n=3)		Total (n=33)	
	PT	PI	PT	PI	PT	PI	PT	PI	PT	PI
Overall knowledge of Uniject device performance	4	6	9	9	6	6	1	3	20	24
Correct timing of cap removal	6	6	12	13	9	7	2	3	29	29
Knowledge on activation of Uniject device	6	6	12	13	8	8	2	3	28	30
Knowledge on correct method of injection	6	6	13	13	10	8	2	3	31	30
Knowledge of correct angle of injection	6	6	13	11	10	8	2	3	31	28
Knowledge of correct disposal of used gentamicin in Uniject syringes	6	6	13	13	7	9	2	3	28	31
Knowledge of correct disposal of disposal boxes	6	6	13	12	10	9	2	3	31	30

Table 12. FCHV knowledge of the Uniject device according to different age groups among those who did not treat PSBI (n=12).

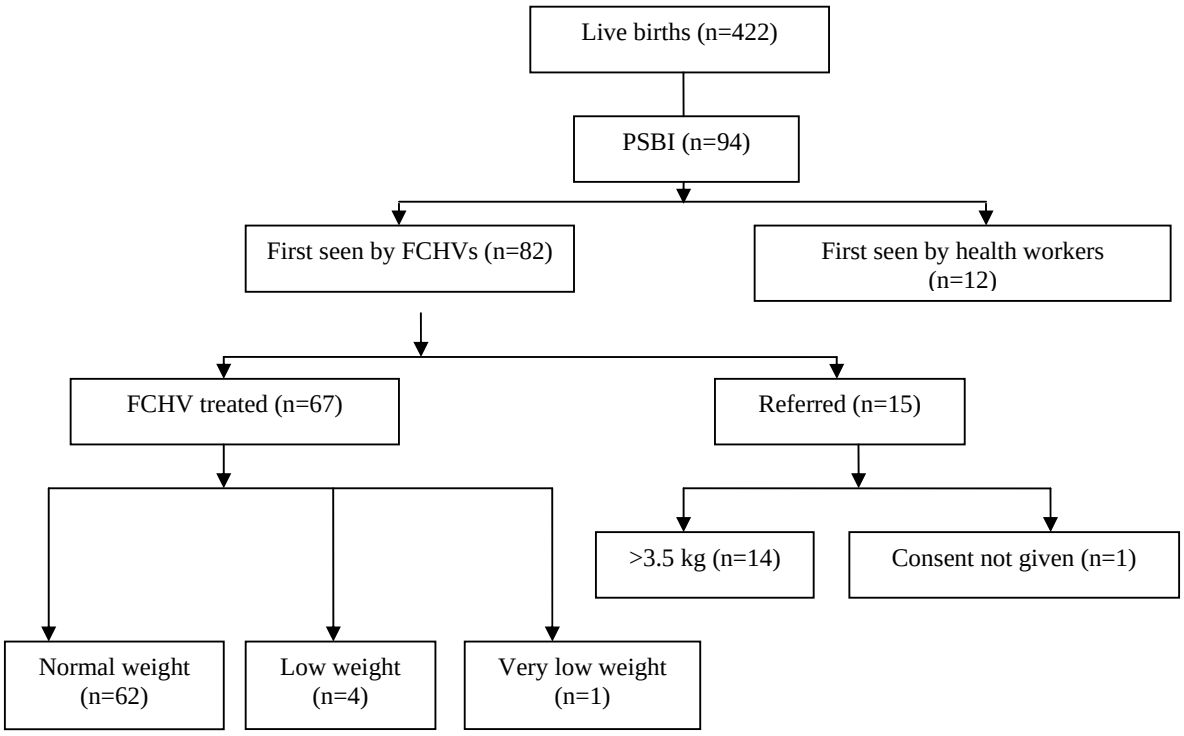
Knowledge on Uniject device	25–34 years (n=5)		35–44 years (n=6)		45–54 years (n=1)		Total (n=12)	
	PT	PI	PT	PI	PT	PI	PT	PI
Overall knowledge of Uniject device performance	4	4	6	3	0	0	10	7
Correct timing of cap removal	5	5	6	6	1	1	12	12
Knowledge on activation of Uniject device	5	5	6	5	1	1	12	11
Knowledge on correct method of injection	5	4	5	5	1	1	11	10
Knowledge of correct angle of injection	5	5	6	5	1	1	12	11
Knowledge of correct disposal of used gentamicin in Uniject syringes	5	4	6	6	1	1	12	11
Knowledge of correct disposal of disposal boxes	5	5	6	6	1	1	12	12

In summary, all the FCHVs—regardless of age and literacy—selected the correct dose of gentamicin in Uniject according to the weight of the sick young infant. All FCHVs sent a call form to their immediate supervisors for supervision, and all FCHVs achieved a 100% completion rate for administering gentamicin in Uniject. All the FCHVs stored the device appropriately and correctly disposed of the used gentamicin in Uniject devices. According to interviews with supervisors and caretakers of infants who were treated by the FCHVs, both supervisors and caretakers were 100% satisfied with the services provided by the FCHVs, regardless of their literacy status and age.

4.3 Treatment findings

During the study period, a total of 422 live births were recorded by the FCHVs. Of these, 94 were identified as PSBI: 87% (n=82) were seen by FCHVs, and 13% (n=12) went directly to HFs/VHWs/MCHWs. Among them were 3 very low weight, 5 low weight, and 68 normal weight infants, and 18 weighed more than 3.5 kg. Among the 82 PSBI episodes first seen by FCHVs, 67 were treated by them with gentamicin in Uniject. The remaining 15 episodes were referred to HFs/VHWs/MCHWs. FCHVs were instructed to refer PSBI cases that were more than 3.5 kg to receive gentamicin from a standard needle and syringe (the dose required for these larger babies was not available in the Uniject device). Among those 15 cases, 14 were more than 3.5 kg, and 1 refused to give consent for treatment by the FCHV and therefore was referred to a health facility. Among the 67 cases treated by the FCHVs, 62 were normal weight, 4 were low weight, and 1was very low weight. The very low weight baby was recommended for referral, but the family did not comply, so the baby was treated by the FCHV (Figure 24). Among the 12 PSBI cases first seen by health workers, 5 were normal weight, 1 was low weight, 2 were very low weight, and 4 weighed more than 3.5 kg.

Figure 24. Treatment findings of PSBI treated by FCHVs.



Outcome of PSBI treated by FCHVs

Among the 67 cases treated by FCHVs, the completion rate was 100% for both cotrimoxazole-p and gentamicin in Uniject. There was no local reaction observed apart from mild redness at the injection site in two cases. In both of these cases, the mild redness subsided on its own. All 67 cases improved by the last day of treatment with gentamicin in Uniject (on day 9 for very low weight babies receiving alternate-day gentamicin in Uniject and on day 7 for low weight and normal weight babies). FCHVs provided the call form to caretakers for all 82 cases first seen by them. For the 67 cases that FCHVs treated, call forms were given to their supervisors to request their observation of the FCHVs giving gentamicin in Uniject. Additionally, 14 call forms were given for regular gentamicin injections for babies who weighed more than 3.5 kg, and 1 was referred after not giving consent for treatment by the FCHV. All 33 first cases treated by FCHVs were supervised everyday for 7 days by their immediate supervisors, and the remaining 34 cases were all supervised for the second dose. In all 67 cases, the FCHVs followed the correct disposal of used gentamicin in Uniject devices by placing them in the disposal box without recapping and by returning the full disposal boxes to their respective supervisors.

Timing of care for PBSI

Around 82% of sick young infants received their first dose of gentamicin in Uniject on the same day as their first contact with the FCHV/VHW/MCHW/HF. The median time for the first visit provided by the FCHVs for sick young infants and the gap between the onset of illness and the first dose of gentamicin in Uniject was 2 days (Table 13). This suggests that FCHVs were able to initiate treatment for PSBI immediately upon their first visit. According to the caretaker interviews, the median time lag between the first dose of cotrimoxazole-p and the first dose of gentamicin in Uniject was 6.5 hours, due to the study requirement that supervisors be present at the time of injection of the first case.

Table 13. Timing of care for PSBI by FCHVs.

Median days of FCHV first visit for all young infants*	2 days (minimum 0, maximum 59 days)
Median days of onset of illness to FCHV first visit for sick babies*	2 days (minimum 0, maximum 9 days)
Median days of illness to first dose of gentamicin in Uniject*	2 days (minimum 0, maximum 9 days)
Median time lag between cotrimoxazole-p and first dose of gentamicin in Uniject**	6.5 hours (minimum 1, max 24 hours)

Sources: *treatment record, **caretaker interview.

4.4 Ease of use of the gentamicin in Uniject device by FCHVs

Among the 45 FCHVs, 40 FCHVs (89%) reported that activation of the gentamicin in Uniject device was easy and the remaining 5 FCHVs (11%) found it acceptable. None of the FCHVs reported activation of gentamicin in Uniject was difficult. Similarly, 35 FCHVs (78%) found it easy to give gentamicin in Uniject, 9 (20%) felt it was acceptable, and 1 FCHV reported difficulties while giving gentamicin in Uniject. Eighty percent (n=36) of the FCHVs liked the gentamicin in Uniject device very much, while 16% (n=7) liked it but had some problems, and 4% (n=2) did not like the device.

Among the 45 FCHVs, 43 reported that they did not face any difficulties while giving gentamicin in Uniject in the eggplant during training. However, among the 33 FCHVs who used gentamicin in Uniject for treating young infants, 2 FCHVs reported that they had

difficulty squeezing the bulb to inject the entire dose of medicine; they also faced problems while trying to hold the baby in the correct position.

FCHVs in all five FGDs expressed confidence in their selection of the correct dose of gentamicin in Uniject. Selecting the correct dose required the FCHVs to weigh the baby, identify the newborn's color-coded weight category, and then match the newborn's weight category with the appropriate gentamicin in Uniject dosing regimen. They attributed their confidence to their previous training in weighing babies through the MINI program and to the color-coded gentamicin in Uniject packages that corresponded to their dose administration chart.

The majority of FCHVs (87%) reported storing the gentamicin in Uniject devices in a tin box, 9% stored them in their carry bag, 2% stored them in their cupboard, and the remaining 2% stored them in a polythene bag. FGD participants expressed satisfaction with storage and supply of gentamicin in Uniject. Most participants stated that they stored the product in tin boxes supplied by the MINI program. They felt these boxes ensured safe storage, since neither children nor vermin such as rats could access the gentamicin in Uniject. Participants mentioned several instances of FCHVs running out of product. In these instances, the FCHVs said that they borrowed product from an FCHV in a neighboring ward.

Likewise, disposal of gentamicin in Uniject was not considered a problem by the FCHVs. Participants in all FGDs stated that they used their disposal boxes to dispose of the product. FCHVs thought the disposal boxes were safe to use. One group said that they uncapped the Uniject, put the cap in the disposal box, gave the injection, and then put the injection in the disposal box. In this way, they avoided the possibility of recapping the needle and thus prevented needle stick injuries.

None of the FCHVs made mistakes while using gentamicin in Uniject, as reported by their immediate supervisors. No needle stick injuries occurred during the study, and all the used gentamicin in Uniject devices were correctly disposed in a disposal box without having been recapped by the FCHVs. Caretakers whose babies were treated with gentamicin in Uniject confirmed that FCHVs correctly discarded the used devices in the disposal boxes. Immediate supervisors correctly disposed of all used devices after receiving the disposal boxes with used gentamicin in Uniject devices. Among the 12 supervisors, 8 reported using an incinerator and 4 used the traditional ditch/burial method for destroying used disposal boxes and gentamicin in Uniject devices. Only 2 out of 12 supervisors reported having difficulties while disposing of the disposal box, due to lack of kerosene oil for igniting the fire.

The largest challenge participants faced in using gentamicin in Uniject related to their level of confidence in using the device, especially for the first time. One FGD participant expressed her fear:

> *"Could not sleep whole night after giving the first dose, but after second dose, baby was well and I felt relieved…since then I am confident."* Madhumalla VDC

Participants described the following scenarios as provoking fear for them:

- Afraid injection would result in a wound or local infection at the injection site.
- Afraid health status of the baby would not improve after the first injection.

- Afraid the family of the sick newborn would be unhappy or dissatisfied if the health of the newborn did not improve.
- Afraid that the injection would be given in the wrong location or hit the bone.
- Afraid that giving seven injections would harm the newborn.
- Afraid that the full treatment could not be given to the newborn because the FCHV or the newborn was not at home.

During FGDs, participants in all groups were asked about the advantages and disadvantages of the features of gentamicin in Uniject. Responses are included in Table 14.

Table 14. Advantages and disadvantages of gentamicin in Uniject as identified by FCHVs.

Advantage	Number of groups that mentioned feature	Disadvantage	Number of groups that mentioned feature
Easy to differentiate by color/select the dose	(5)	Difficult to squeeze bulb	(2)
No need to mix drug or draw syringe	(5)	Not able to leave house during injection period	(1)
Easy to carry	(3)		
Safe for person injecting	(3)		
Easy to dispose	(2)		
Does not break	(2)		
Easy to use/inject	(2)		
Can be kept in bag	(1)		
Easy to store	(1)		

4.5 Supervision

Supervision was an important component of this study. All supervisors were requested to provide supervision and support to their FCHVs while giving gentamicin in Uniject. In particular, the immediate supervisor certified the competency of the FCHV after observing the completion of treatment of their first case.

Supervisors provided regular supervision for the first case as well as the second dose of all subsequent cases. All 33 FCHVs who treated 67 PSBI cases with gentamicin in Uniject received guidance from their supervisors. On average, one supervisor had to supervise six PSBI cases over the course of the study. The range of cases that supervisors had to monitor was from 1 to 15 over the study period.

While analyzing the difficulties faced, one-half (n=6) of supervisors (n=12) reported facing difficulties in supervising FCHVs giving gentamicin in Uniject, and the remaining six did not have any problems. Supervisors reported the most common problems as being managing time, transportation cost, communication cost (using their personal cell phones), and lack of simple commodities such as soap for handwashing in caretakers' homes.

During their supervision, none of the supervisors found FCHVs making any mistakes while assessing the babies. However, 6% of FCHVs were found making mistakes while giving gentamicin in Uniject. Among them, one had a problem squeezing the bulb to inject the medicine and another faced a problem holding the baby in the right position, as well as holding the Uniject device. This resulted in slight bleeding from the injection site. When

asked about the need for external supervision of FCHVs to continue providing services with gentamicin in Uniject, four supervisors reported that additional supervision was not necessary. For the remaining five supervisors, improvement of skills, filling the gap of human resources, sharing experiences, and regular logistic supply were some of the reasons for the need for external supervision.

Figure 25. Field coordinator conducting competency certification during training.

For the most part, supervisors observed the FCHVs giving the gentamicin in Uniject injections at least once during the 7-day course of treatment. The FCHVs in the FGDs noted that supervisors were amenable to conducting observation visits in the home of the newborn even on holidays such as Saturday or when they did not have a vehicle. Some FGD participants reported that supervisors were not able to make the visits due to political strikes, equipment failure such as flat tires on their motorcycles, or very long distance to the home. Other participants noted that if the supervisor was not able to reach the FCHV on time to observe the injection, he observed her treatment records and asked questions about the treatment process.

Although FCHVs unanimously agreed that using gentamicin in Uniject was easy, they also appreciated the support given to them by their supervisors—especially during their initial use of the device. Many FGD participants stated that the presence of the supervisor helped them overcome their initial fear and anxiety related to the use of gentamicin in Uniject, as noted by the following participant:

> *"Initially, I was worried that something might go wrong. But the presence of the supervisor helped me overcome that worry."* Dainiya VDC

FGD participants reported that supervisors often came for all seven doses even though the study protocol required them to visit only once during treatment, within 48 hours of the first dose. This level of supervision reduced in some VDCs over time:

> *"In the first case that I treated, the supervisor came for seven days. In the second case, he came for two times. If the supervisor is in front, then he/she will correct your mistake immediately. But without the presence of supervisors, we can also give injections."* Sorabhag VDC

FGD participants also noted that the presence of supervisors during administration of gentamicin in Uniject appeared to enhance the level of trust among community members. Only one participant stated that these supervisory visits were stressful:

> *"The presence of the supervisor gave me confidence to give injection. But at the same time, I was afraid that I might do something wrong in front of the supervisor."* Govindapur VDC

Participants in four of the five FGDs agreed that, in the future, supervisors should come at least once during the course of treatment, preferably on the first or second day. Participants in one FGD had an alternative viewpoint, stating that day 3 of treatment would be the best time for a supervisory visit. Participants in this FGD explained that:

> *"If the supervisors can go on the third day in which we do the follow-up and reassessment of the sick newborn, then this will be good. They can advise us after reassessing the sick newborn."* Madhumalla VDC

4.6 Service provision

Perception of burden by FCHVs

On average, FCHVs spent 8 hours per week on Uniject activities. Among the 33 FCHVs who treated PSBI cases with gentamicin in Uniject, 31 did not perceive giving gentamicin in Uniject as an extra burden, while 2 FCHVs reported this activity as an extra burden to them. In the FGDs, the FCHVs identified several challenges in their work to treat sick newborns (Table 15).

Table 15. Challenges faced by FCHVs.

Traveling to the home of the infant to treat for 7 consecutive days is a burden both in terms of time and distance.	*"It takes 2-3 hours to go for treatment. So we have to adjust the time from family work."* Sorabhag VDC
Concern about their liability if the baby they are treating dies.	*"I was worried because if something goes wrong, then what the community will say?"* Hatimuda VDC
Concern that community members think they are receiving payment for their services.	*"Volunteerism is a challenge; people do not trust that we work for free."* Madhumalla VDC

Health-seeking behavior by caretakers of sick infants

Among the 45 caretakers interviewed, 37 (82%) knew about provision of treatment with gentamicin in Uniject by the FCHVs in their communities. All caretakers knew at least one of the ten danger signs of PSBI, yet only two caretakers (4%) knew at least five signs.

Twenty-four percent of caretakers knew that the baby should be dried thoroughly after delivery, and 24% of them had practiced it after their last delivery. Similarly, 89% knew to dry and keep the baby warm and 91% of them had done so. Forty-two percent of caretakers had the knowledge and practiced delaying bathing for 24 hours. A total of 69% of caretakers understood that nothing should be applied to the umbilical cord, but more caretakers (89%) had actually practiced this. Fifty-one percent of caretakers knew the baby should be breastfed within one hour of birth, yet 56% of them were able to breastfeed the newborn within one hour. Despite their weak knowledge regarding danger signs, the practice of ENC and care-seeking was good. The median days of care-seeking from onset of illness to first contact with a health worker was only 2 days. Therefore, knowledge of danger signs did not have any negative impact on actual practice and early care-seeking.

Participants in the FGDs with FCHVs reported that all types of people came to them for treatment services, including socially disadvantaged groups (e.g., lower caste, poor, Muslim). Generally, participants agreed that poorer families were more likely to come to them for treatment than wealthier families.

During the study, gentamicin in Uniject was provided at no cost. FGD participants identified the availability of free product to treat sick newborns as being an advantage of the product. The provision of free treatment was also satisfying to the FCHVs and the families of the sick infants. Participants in all FGDs mentioned that not having to spend money for treatment of sick newborns was a notable aspect of the program.

4.7 Acceptability of gentamicin in Uniject

Acceptability by heath workers and caretakers of sick infants

The gentamicin in Uniject device was acceptable to the FCHVs, health workers, caretakers, and communities. Of the 45 FCHVs, 44 liked the device and only 1 stated that she did not like the device. Reasons that health workers liked the gentamicin in Uniject device are reported in Table 16.

Table 16. Reasons for liking the gentamicin in Uniject device.

	FCHVs (n=44)	HFs/VHWs/MCHWs (n=12)
Easy to give injection	51% (n=23)	100% (n=12)
No need to draw drug	22% (n=10)	100% (n=12)
Easy to carry	24% (n=11)	100% (n=12)
Easy to dispose	4% (n=2)	100% (n=12)
Small needle	2% (n=1)	16% (n=2)
Not frightening	4% (n=2)	58% (n=7)
Effective	27% (n=12)	92% (n=11)
Happy caretakers	87% (n=39)	100% (n=12)
Others	31% (n=14)	0% (n=0)

Ninety-two percent of supervisors (HF/VHW/MCHW) (n=11) were satisfied with FCHVs giving gentamicin in Uniject. The health workers thought that this would decrease their own work load, and the communities would receive prompt treatment with the services brought closer to home. They stated that the FCHVs were well-trained and that this also built trust in the communities. Similarly, caretakers expressed their satisfaction with the treatment model. Ninety-five percent of caretakers of sick infants were satisfied with the services provided by the FCHVs. Caretakers said that they could receive services at home that were free of cost. They also stated that since the FCHVs reside in the communities, the services could be brought closer to home and they could receive prompt treatment from a familiar person. Overall, caretakers reported a good impression about FCHVs giving the gentamicin in Uniject injection.

These themes were repeated in the FGDs with FCHVs. FGD participants reported that families of infants who received treatment were satisfied with their services. For the most part, families accepted the FCHVs as skilled and knowledgeable to treat their sick newborns. Of all the cases treated by the FCHVs, only one family refused treatment. The father of the infant was working abroad, and the family was afraid that he might be unhappy if the infant were treated at home. Instead, the family took the infant to the hospital for treatment.

FGD participants gave various reasons when asked why families prefer home treatment to treatment in the facility, noted in Table 17.

Table 17. Preference for home treatment over facility treatment.

Distance to the health facility	*"The drug is the same, so why go farther away."* Hatimuda VDC
Availability of treatment at any time	*"They prefer FCHV because of the time, they provide treatment at home and they work on holidays, day and night, ready to help at any time."* Madhumalla VDC
Availability of treatment in the home	*"Community people believe that the newborn should not be taken out of the home."* Sorabhag VDC
Community trust in the knowledge and skills of FCHVs to treat sick newborns	*"The family of the sick child trusts us because they know we have been trained for Uniject."* Dainiya VDC
Babies appear to get fat after treatment with gentamicin in Uniject	*"Babies are gaining weight, so why won't they be happy?"* Sorabhag VDC

Many (47%) of the caretakers of sick infants stated that they preferred an FCHV as their service provider and said that an FCHV would be their first choice for treatment if their baby were sick. Seven other caretakers preferred to go to a clinic. A majority of caretakers (80%) preferred to use FCHVs for gentamicin in Uniject in the future.

All 12 supervisors (VHWs/MCHWs/HFs) stated that FCHVs could manage sick young infants by using gentamicin in Uniject. Of these 12 CHWs, 8 thought FCHVs could independently manage sick young infants with gentamicin in Uniject after successfully completing two competency tests, while 4 of them did not believe that FCHVs could do it without supervision. Nine CHWs thought that FCHVs' gentamicin in Uniject skills would be retained even after a gap of 6 months, while three of them thought that FCHVs would not be able to treat sick young infants after discontinuation of the program for 6 months.

Of the 12 supervisors interviewed, 3 believed that the FCHVs should start treating sick infants after receiving competency certificates, while the majority of VHWs/MCHWs/HFs (75%) stated that this responsibility should not be given to them irrespective of their competency status unless supervision were provided. Overall, according to the supervisors, there was 100% acceptance of gentamicin in Uniject by the community. They thought that the communities chose to obtain treatment for sick young infants by FCHVs at home because the FCHVs are the first point of contact, they reside in the communities, are always available, and can provide prompt treatment without any cost.

Acceptability by community leaders

We assessed community acceptability of the use of gentamicin in Uniject by FCHVs to treat sick young infants in the home through key informant interviews at the VDC level. In each VDC, we conducted interviews with two local community leaders. Interviews consisted of ten open-ended questions with community leaders at the end of the 4-month intervention period. The respondents were chosen on the basis of their leadership abilities in various sectors. Respondents were members of a health facility management committee or nongovernmental organization, teachers, and local political leaders. The respondents were 32 to 49 years old. A total of ten key informant interviews (two in each VDC) were conducted.

All respondents were aware that FCHVs, VHWs, and MCHWs in their VDCs were using gentamicin in Uniject to treat sick young infants who had PBSIs. All respondents said that FCHVs could correctly administer gentamicin in Uniject to sick babies after being trained on this new task. The community leaders had confidence that FCHVs could administer gentamicin in Uniject correctly because FCHVs were experienced in skills needed to deliver

community-based neonatal health programs and were getting direct support and supervision from health facilities.

Overall, community leaders were positive about the use of gentamicin in Uniject in the communities. They did not hear any negative reports about the use of gentamicin in Uniject from community members. Community leaders reported that FCHVs were treating the babies at home and that poor families benefited by saving time and money associated with traveling to a city for treatment at a facility. One respondent said:

> *"At first, I was curious about what would happen after FCHVs were using injection to treat the sick babies. But when I saw baby was getting better, I did not have any negative thinking about gentamicin in Uniject."* [01]

All community leaders reported that their overall impression of having FCHVs treat sick young infants in their community with gentamicin in Uniject was very good. They said that this way of treating newborns in the community allowed for early detection and prompt treatment. One respondent said:

> *"Mobilizing FCHVs for newborn care helps to reduce cost and increase service accessibility."* [09]

Nine of ten community leaders thought that the best treatment option for sick young infants was to be treated by FCHVs using oral antibiotics and gentamicin in Uniject at home. Five of the community leaders felt this to be the best treatment option because it could save "time, money, and life." Two of the community leaders felt home treatment by FCHVs to be the best option because it could provide the most prompt treatment, thereby reducing the number of infant deaths. Another two community leaders said that the health facilities were far away and provided services only during fixed hours, and that many people were poor and could not afford the transportation costs to take their babies to a facility for treatment.

One community leader felt that the best treatment option for sick young infants was to be treated by FCHVs in the home using oral antibiotics only and then having health workers at the health post give the gentamicin injection. The community leader explained that only a trained health worker such as those at the health facility would be able to diagnose the infant further and treat accordingly, if needed.

Community leaders thought that gentamicin in Uniject would be most needed in remote and rural areas, such as hill and mountain regions, and among poor communities. Two community leaders explained that the priority areas for use of gentamicin in Uniject would be places where transportation facilities were hardly available.

Eight of ten community leaders said that people living in their community would be willing to pay for delivery of antibiotics in a Uniject device containing gentamicin for sick young infants. Three of the eight community leaders who said their community would be willing to pay for the injection also said that it would be better if the gentamicin in Uniject were provided free of charge. The two community leaders who reported that people in their community would not be willing to pay for the injection felt that the government should pay for it. Community leaders explained their economic reality:

> *"If it is coming at free of cost to the government, it should be given at free of cost. If government is buying, people have to pay."* [07]

> *"Twenty-five percent of my community people can pay Rs 500 to 1000 for all doses of injection. Among remaining 75%, 40% could pay minimum amount, whereas 35% could not pay any amount. For these 35%, it should be at free of cost."* [06]

The amount of money community leaders were willing to pay for use of gentamicin in Uniject to treat their neonate varied. The majority of responses ranged from Rs 25 to Rs 100 for the full course of treatment, primarily because they felt this price would be affordable in their communities (one-half day of labor is equal to Rs 50). One community leader stated a price of Rs 500-1000 would be acceptable. In contrast, another community leader reported that people in communities currently pay Rs 1200-1500 for treatment outside of their community, in the private sector.

All community leaders stated they would be willing to receive an injection using gentamicin in Uniject if their infant were sick in the future. According to their statements, they would be comfortable with this treatment option because they trust the skills and knowledge of the FCHVs and the quality of health services they have been providing in the community for a long time. Overall, community leaders appeared to find the use of gentamicin in Uniject by FCHVs to treat sick young infants in the home to be an acceptable care option for themselves and the people in their communities.

5. Discussion

The gentamicin in Uniject design-stage trial was conducted in Morang district with the base of currently existing community-based management of neonatal infections: MINI. Therefore, FCHVs and the supervisors involved in this study were already experienced in managing neonatal infections in the community. The FCHVs were already trained to measure weight, temperature, and respiratory rate, and to classify neonatal infection using an algorithm containing ten danger signs. The gentamicin in Uniject injection was the only new skill added for the purpose of this study.

Figure 26. FCHV giving gentamicin in Uniject.

Overall, gentamicin in Uniject functioned well in terms of device performance, including ease of use, dose accuracy, safety, and ease of disposal among health workers. Gentamicin in Uniject was acceptable to both health workers and community members. Given this, it appears that gentamicin in Uniject, in combination with oral cotrimoxazole and an appropriate scale, is a feasible option for the treatment of neonatal sepsis when administered at home by FCHVs. Further, the FCHVs were motivated to use gentamicin in Uniject and demonstrated their ability to use this treatment modality in a program setting. Health workers demonstrated their ability to use the gentamicin in Uniject device in combination with an appropriate scale, including choosing the correct dose and dosing schedule and adhering to that schedule. Finally, administration of gentamicin in Uniject by FCHVs as a treatment for neonatal sepsis was highly acceptable to both community leaders and caretakers of sick young infants who had been treated with the device.

5.1 Ease of new skills' acquisition

Individuals who had never delivered an injection were able to successfully do so with the Uniject device after minimal training. The FCHVs involved in the gentamicin in Uniject study were of various ages and literacy status. FCHVs as young as 24 years up to 56 years participated in the study. Similarly, the majority of FCHVs were literate (having achieved grade 5 or higher), while the remainder of FCHVs could read and write with difficulty or not at all. Importantly, irrespective of their age and literacy status, FCHVs displayed high levels of knowledge regarding sepsis identification and treatment with gentamicin in Uniject. The compliance of cotrimoxazole-p and gentamicin in Uniject was high, as evidenced by the 100% completion rate of both. No severe local reactions were observed, and all babies treated with gentamicin in Uniject had improved by the last day of treatment.

We believe that these positive results stem, at least in part, from the FCHVs' previous experience in the community-based neonatal care program, which provided a solid base from which they could acquire new knowledge and skills relatively easily.

In this study, FCHVs were trained for 4 days to acquire the skill of injecting gentamicin in Uniject. Because this new skill built on other already existing skills of community-based management of neonatal infections, 4 days of training was adequate to introduce and perfect the use of gentamicin in Uniject. However, many FCHVs reported that 4 days of training was not enough. Programs interested in replicating this type of community-based sepsis treatment model must take into account whether or not health workers already have a solid experience base of managing newborn infections. If no previous experience is evident, an additional one or 2 days of training should be considered.

Similarly, the FCHVs trained for this study were familiar with existing MINI training tools and materials. Their quick learning and easy skills' development may have been due to the use of existing MINI training tools and materials that were adapted for the purpose of this study. Similarly, using trainers who were already experienced in community-based management of neonatal infections facilitated the transfer of skills and knowledge.

5.2 Training for use of gentamicin in Uniject

All FGDs with FCHVs recorded general satisfaction with the training. Participants in all FGDs suggested that the number of training days be increased from 4 days to 7–10 days, because of the substantial amount of material that must be covered. The relatively large number of forms that needed to be completed for the study was considered to be particularly burdensome. Participants also stated that the name of the product "gentamicin in Uniject" was difficult to understand and to say initially and that their ability to say the product name improved as they became more familiar with it. As one participant noted:

> "*Doctor banna parne, teti chhoto samayama garho nai bhayo ni.*"
> *[It was difficult to become a doctor in such a short period.]* Madhumalla VDC

Figure 27. District supervisor providing training to FCHVs.

In addition to lengthening the training time, FCHVs suggested that future program efforts should consider three additional points. First, orient mothers in addition to community leaders, since mothers are the main point of contact between the FCHV and the sick baby. This would raise awareness among mothers and their families and alleviate any hesitation on the part of the family to allow the FCHV to treat the sick newborn. Second, give FCHVs cell phones to contact their supervisors immediately when a sick baby is identified, rather than using the traditional "call card" system, which takes longer to transmit such an urgent message. Third, optimize the location of treatment of sick newborns. Treatment could take place in the home of the FCHV rather than in the home of the newborn for all or part of the treatment course. This would reduce the burden on the FCHV to find adequate time to travel to the home of the newborn once a day for 7 days.

5.3 Impact on the health system

The use of gentamicin in Uniject during the study appeared to have a favorable impact on neonatal morbidity and mortality due to sepsis. During the study period, the prevalence of PSBI was 22% and all of these cases were treated successfully in the communities by the FCHVs. Most of the treatments were provided at the home of the young infant or close to home (outreach clinic, expanded program on immunization clinic). The median days of illness to first treatment with gentamicin in Uniject was 2 days, and the time lag between treatment with cotrimoxazole-p and gentamicin in Uniject was 6.5 hours. This suggests that a treatment model that uses gentamicin in Uniject provides services closer to home and in a timely manner. Issues related to how/if FCHVs expect to be compensated or incentivized for this additional work and how that would affect the overall health system will need to be addressed in any program scale-up effort. In this study, FCHVs asked for commodities to assist them in their work, such as bicycles and cell phones.

The use of this community-based treatment model appeared to have a positive impact on the government health system. The most peripheral government health workers were responsible for supervising FCHVs while giving gentamicin in Uniject. They were also responsible for providing competency certification after successful treatment of the first case of PSBI. All the cases treated by FCHVs were supervised by the supervisors. None of the supervisors reported facing any difficulties while supervising. Some of the supervisors also reported that having FCHVs as injectors in the communities helped to divide the work load as well as provide prompt treatment to sick neonates, which was critical, as neonatal infections progress rapidly. However, some supervisors asserted the need for health system improvements in areas such as transportation and communication services. Morang, where the gentamicin in Uniject study was implemented, is in the flatland, with relatively easy access as compared to the hill and mountain regions of the country. Supervising each dose for the first case and the second dose of subsequent cases was not incredibly difficult in this setting. Based on our experience, we believe that hill and mountainous areas should be the target regions for implementing a scale-up of gentamicin in Uniject. Supervisory models that have VHWs/MCHWs supervise all doses of the first case treated by FCHVs may not be feasible in hill and mountain regions. This suggests that the use of a peer support network for FCHVs, possibly through using cell phones, may be appropriate.

The cost of the device will be a determining factor in potential scale-up. Gentamicin in Uniject is a prefilled injection system that simplifies dosing and integrates reuse prevention. The device will always be more expensive than gentamicin in an ampoule delivered with a standard needle and syringe. Currently, best guess price estimates from the manufacturer range from $0.80 to $1.00 per dose. This price does not include the additional cost of making it available within the country, such as transportation, local taxes, and distributor margin. This added cost should be considered within the context that the simplicity of the intervention allows for minimally trained and supervised community health volunteers to provide this lifesaving treatment to newborns in communities that would otherwise not be reached.

5.4 Acceptability

Gentamicin in Uniject was well-accepted by caretakers, community leaders, and health workers, and well-received by communities and caretakers, all of whom expressed that they were ready to take services from the FCHVs in the future. They were satisfied that their sick young infants were receiving correct treatment in their homes by the FCHVs who were familiar to them. They also liked gentamicin in Uniject because it was available free of cost,

was administered in a timely manner, and reduced the extra burden of going to a health facility. Some caretakers also perceived this service as beneficial, as it did not interrupt wage-earning because they did not have to take their sick infants to a health facility. Communities were happy to see sick young infants improve with the use of gentamicin in Uniject.

Community leaders perceived the service provided by the FCHVs as innovative. They were happy to see FCHVs as injectors and recommended that programs like this be continued in their communities. According to community leaders, their communities would be ready to share a minimum cost if the service could not be provided free of charge. They were happy that the sick young infants in their communities did not have to travel long distances for treatment. They also thought that this program reached the disadvantaged communities that would not have been able to afford these services otherwise. Overall, community leaders were satisfied with this treatment model and would recommend it for future use.

Community leaders thought that use of gentamicin in Uniject would be most needed in remote and rural areas, such as hill and mountain regions, and in poor communities. Two community leaders explained that the priority areas for use of gentamicin in Uniject would be places where transportation facilities are hardly available.

Peripheral government health workers (VHWs/MCHWs/AHWs) who were immediate supervisors of FCHVs were also satisfied with FCHVs as injectors. They accepted this program well and recommended that FCHVs be able to continue providing this service. According to their observations, FCHVs were able to follow all the steps and protocols of the study and none of the FCHVs had any difficulty providing the services. Therefore, they think that the FCHVs are able to inject gentamicin in Uniject, and that FCHVs are well-accepted by the communities. The peripheral government health workers involved in this study recommended that this treatment model be continued and replicated in other districts of the country.

6. Limitations of the study

All studies have certain limitations. This study was limited because it was not comparative in design and had no control group to demonstrate the effect of the intervention. An exploratory pre-test/post-test design such as this was appropriate, however, given that this study explored initial feasibility of device performance. Further, this study was limited to one district in Nepal, which had experience in community-based sepsis management. It is possible that results of this study cannot be generalized to other areas that are not experienced in community-based sepsis management strategies.

7. Recommendations

The use of injectable gentamicin coupled with injectable procaine penicillin-G is the first line of treatment for sepsis in developing countries. However, the use of gentamicin is currently limited to facilities where trained health care workers can determine the appropriate dose based on infant weight, administer the drug with a standard needle and syringe, and monitor for side effects. Gentamicin in the Uniject device combined with an oral antibiotic (cotrimoxazole or amoxicillin) is one of several second-line treatment options. The drug and delivery system combination would simplify the dosing regimen by providing a simple, prefilled device with dosing based on newborn weight. Gentamicin in Uniject, in combination with an oral antibiotic, offers the potential benefit of expanding the coverage of this lifesaving treatment by allowing minimally trained health workers and/or traditional birth attendants the option of administering the antibiotic in rural communities or peripheral care settings where most neonatal deaths occur. Ultimately, gentamicin in Uniject could be implemented in regions that are geographically difficult to access, where cultural barriers do not allow newborns to move out of the home, and/or possibly in places where health referral systems are weak or nonexistent. This would allow for early identification and correct management of neonatal infection at the community level.

Specific recommendations related to the results of this design-stage study are as follows:

1. Gentamicin in Uniject should be implemented within the existing government health system and should use existing cadres of health workers and volunteers where possible.
2. Available training tools and materials should be utilized to maximize cost-effectiveness to maximize time and cost-efficiency.
3. In settings where community-based management of neonatal infection is new, the duration of training should be adequate to acquire the necessary knowledge and skills.
4. In Nepal, gentamicin in Uniject should be piloted in a hill or mountain district, with extensive monitoring to determine the overall impact of the program (coverage and cost-effectiveness) before scaling up to the national level.

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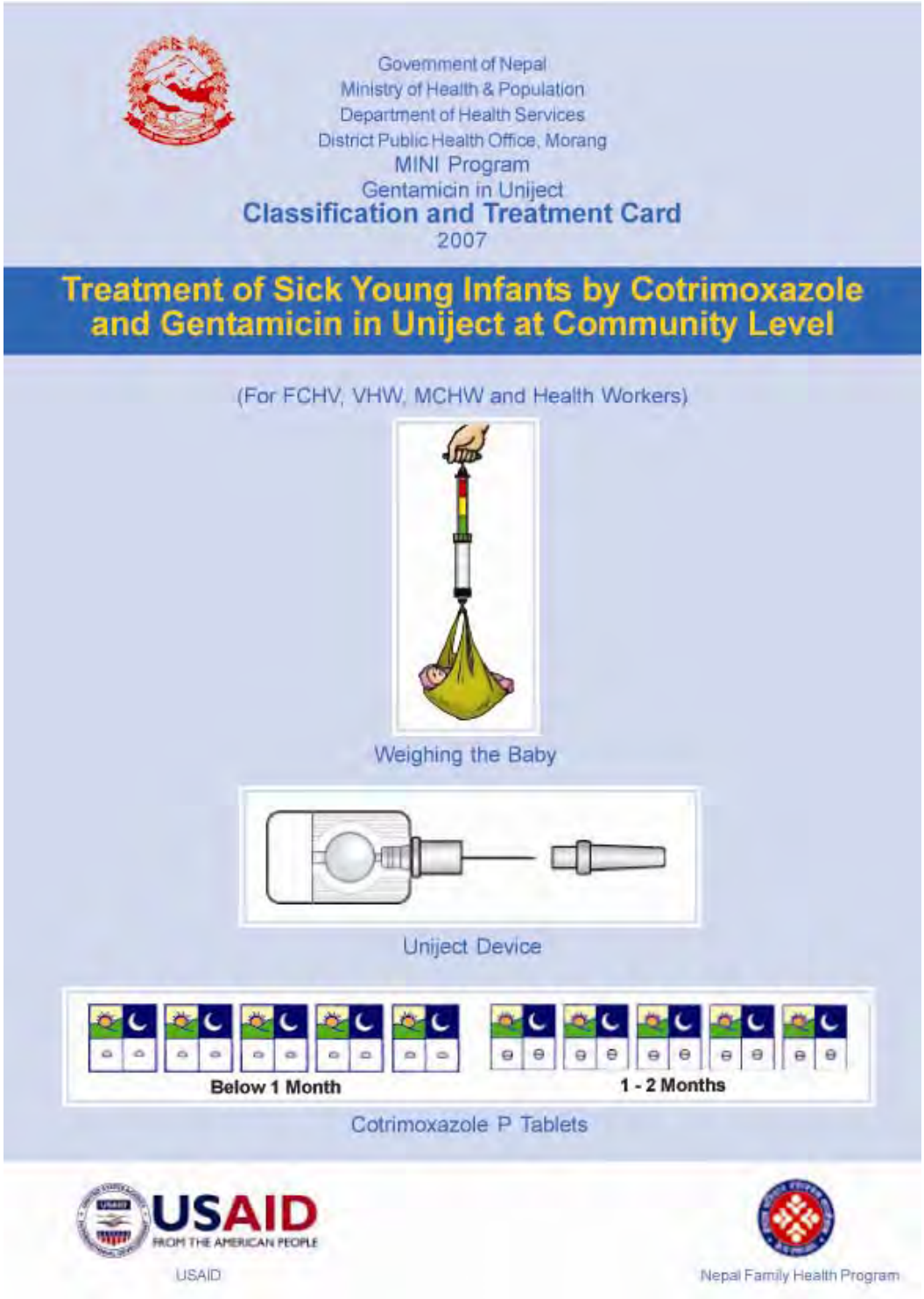
Appendix A



Government of Nepal
Ministry of Health & Population
Department of Health Services
District Public Health Office, Morang
MINI Program
Gentamicin in Uniject

Classification and Treatment Card

2007

Treatment of Sick Young Infants by Cotrimoxazole and Gentamicin in Uniject at Community Level

(For FCHV, VHW, MCHW and Health Workers)

Weighing the Baby

Uniject Device

Below 1 Month **1 - 2 Months**

Cotrimoxazole P Tablets

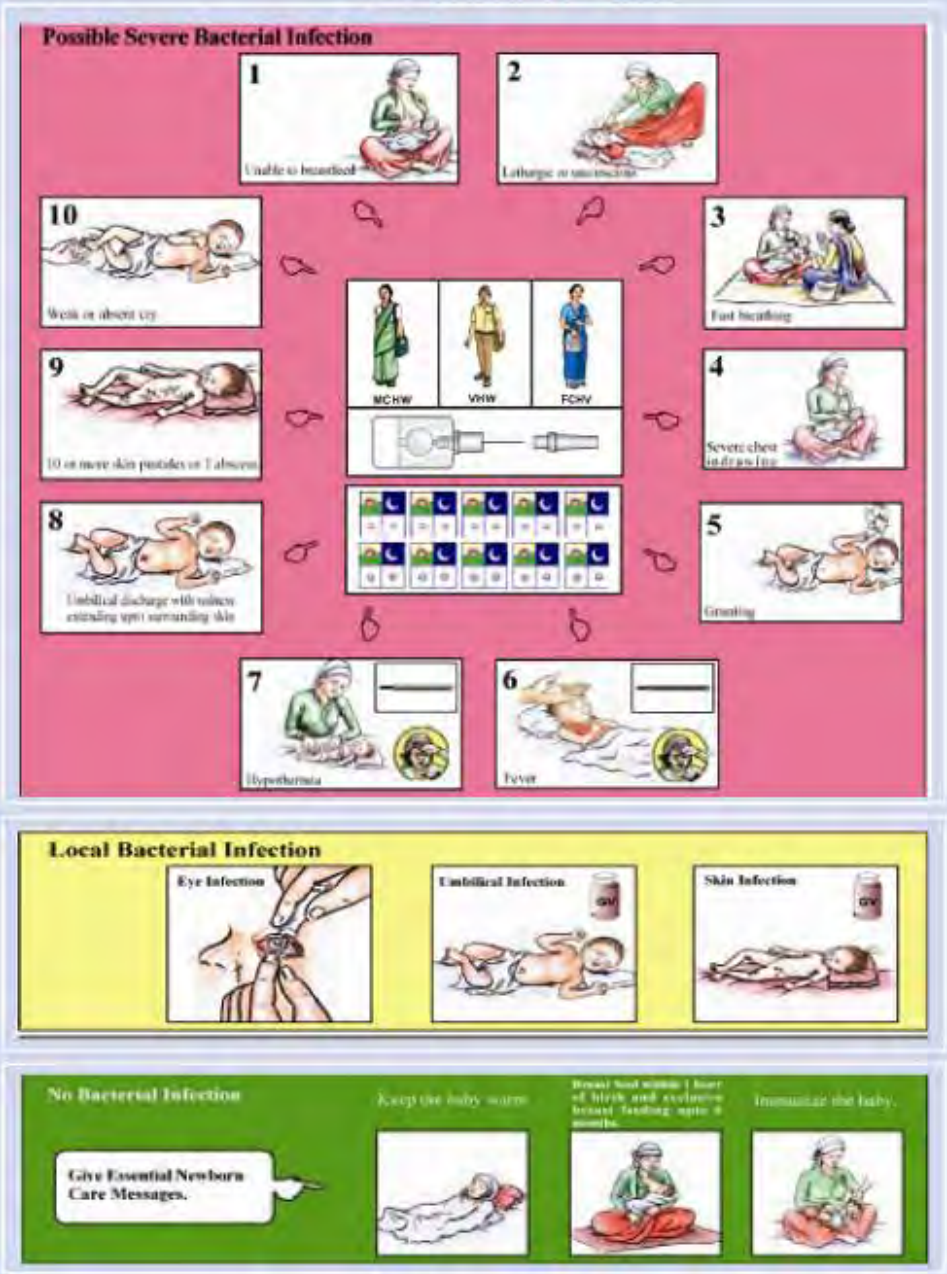
USAID

Nepal Family Health Program

Government of Nepal
Ministry of Health and Population
Department of Health Services
District Public Health Office, Morang
MINI Program

2007

Classification Card



Give Gentamicin in Uniject by weight and start Gentamicin Uniject treatment according to treatment card.

Give Cotrimoxazole table for 5 days according to age of young infant.

Dose of Cotrimoxazole

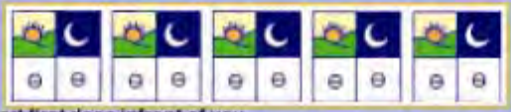
Dose of Cotrim for under 1 month

Age	Dose	Times per day	Total days
Under 1 month	Half tablet	twice	5 days

Give 5 tablets of Cotrimoxazole to mother and start first dose infront of you.

Dose of Cotrim for between 1-2 months

Age	Dose	Times per day	Total days
1 - 2 month	One tablet	twice	5 days



Give 10 tablets of Cotrimoxazole to mother and start first dose infront of you.

Ask on 3rd Day Follow-up

	Improved	Same	Worse	Refer	Don't Know	Death
Status	☺	😐	☹		?	

Steps for Injection:

Wash your hands properly.

Hold cap and part with medicine just like in the picture.

To prepare the medicine, please join the two parts without leaving a gap.

Open the cap.

Injection into the anterior thigh of the baby and squeeze the bulb with medicine.

Dispose of the used needle safely (without recapping) in the safe disposal box.

Instructions

1. All the doses of gentamicin in uniject in first case treated should be given under the supervision of health worker

2. For rest of the cases, second dose of gentamicin in uniject should be given under the supervision of health workers

Appendix B

Government of Nepal
Ministry of Health and Population
Department of Health Services
District Public Health Office, Morang

FCHV/Baby ID. ....

Birth Recording Form

Name of baby: _____

Mother's Name : _____

Father's Name : _____

VDC : _____ Ward No. _____ Tole : _____

Date of Birth

Day	Month	Year

Date of Visit

Day	Month	Year

Birth Place: Home → Skilled Birth Attendant; Health facility

Condition at Birth: Live; Still

Sex of Baby: Female; Male

Weight of Newborn

Normal Weight (2500 grams or above); Low Weight (2000 - <2500 grams); Refer — First time in day 3 and there after follow up every week. 1 2 3 4; Very Low Weight (Below 2000 grams)

First place of treament when baby was sick

Home; Clinic; Health Facility; Traditional Healer; FCHV

Status at the age of 2 months

Alive; Unknown; Death

Day	Month	Year

Government of Nepal
Ministry of Health and Population
Department of Health Services
District Public Health Office, Morang

FCHV/Baby ID. ....

Birth Recording Form

Name of baby: _____

Mother's Name : _____

Father's Name : _____

VDC : _____ Ward No. _____ Tole : _____

Birth Place

Home; Health facility

Weight of Newborn

Normal Weight (2500 grams or above); Low Weight (2000 - less than 2500 grams); Very Low Weight (Below 2000 grams)

Female; Male

Date of Birth

Day	Month	Year

Recording FCHV's

Name : _____

Signature : _____

Date : _____

Register birth of your baby within 35 days of birth in your own VDC.

Appendix C

Government of Nepal
Ministry of Health and Population
Department of Health Services
District Public Health Office, Morang
Morang Uniject Genta Program
2065

FCHV Treatment Register

USAID
FROM THE AMERICAN PEOPLE

Instructions

1. Introduction

The records of sick young infant will keep in this register

2. Need:

To keep records of sick young infant and their treatment management in our VDC.

3. Method:

1. Use only one form for one baby
2. Give same baby id from birth register to sick baby
3. Circle the appropriate sign and symptoms of sick young infant and also circle in treatment by using classification card.
4. If a baby become sick second time, give the baby id as previos but use new register to keep record of that baby

FCHV ID/Baby ID. .....

Government of Nepal
Ministry of Health and Population
Department of Health Services
District Public Health Office, Morang
Morang Uniject Jenta Program

VHW/MCHW Register

2065

Female | Male

Name of sick baby :- _____

Baby's Mother's Name :- _____

Baby's Father's Name :- _____

Address: VDC _____ Ward No _____ Tole _____

If Having Local Bacterial Infection **Consent from Guardian** Yes | No

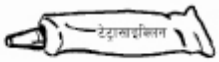
Date of birth

Day	Month	Year

Date of first visit for LBI

Day	Month	Year

Eye Infection



Follow up

Improve	Same	Worse
☺	😐	☹

Umbilical Infection

Follow up

Improve	Same	Worse
☺	😐	☹

Skin Pustules

Follow up

Improve	Same	Worse
☺	😐	☹

If Possible Severe Bactarial Infection **Consent from Guardian** Yes No

Date of Birth

Date	Month	Year

Date of onset of illness

Date	Month	Year

Date of visit for severe infection

Date	Month	Year

Possible Severe Bacterial Infection

& Call MCHW and VHW

Treatment of PSBI using uniject gentamycin

Consent from guardian: Yes | No

Weight the baby: Normal | Low weight | Very Low wt | More than 3500 gm

Date of first dose of gentamicin: Day | Month | Year

Refer

Local infection of uniject genta: Yes | No

If yes: Absccess | Redness

Refer

Ask on third day follow up

Receiving Cotrim

Receiving uniject genta

Giving message on ENC

Improve	Same	worse	Refer	Donot know	Death
☺	😐	☹		?	

Last dose of gentamicin

Date of last genta: Day | Month | Year

Total dose:

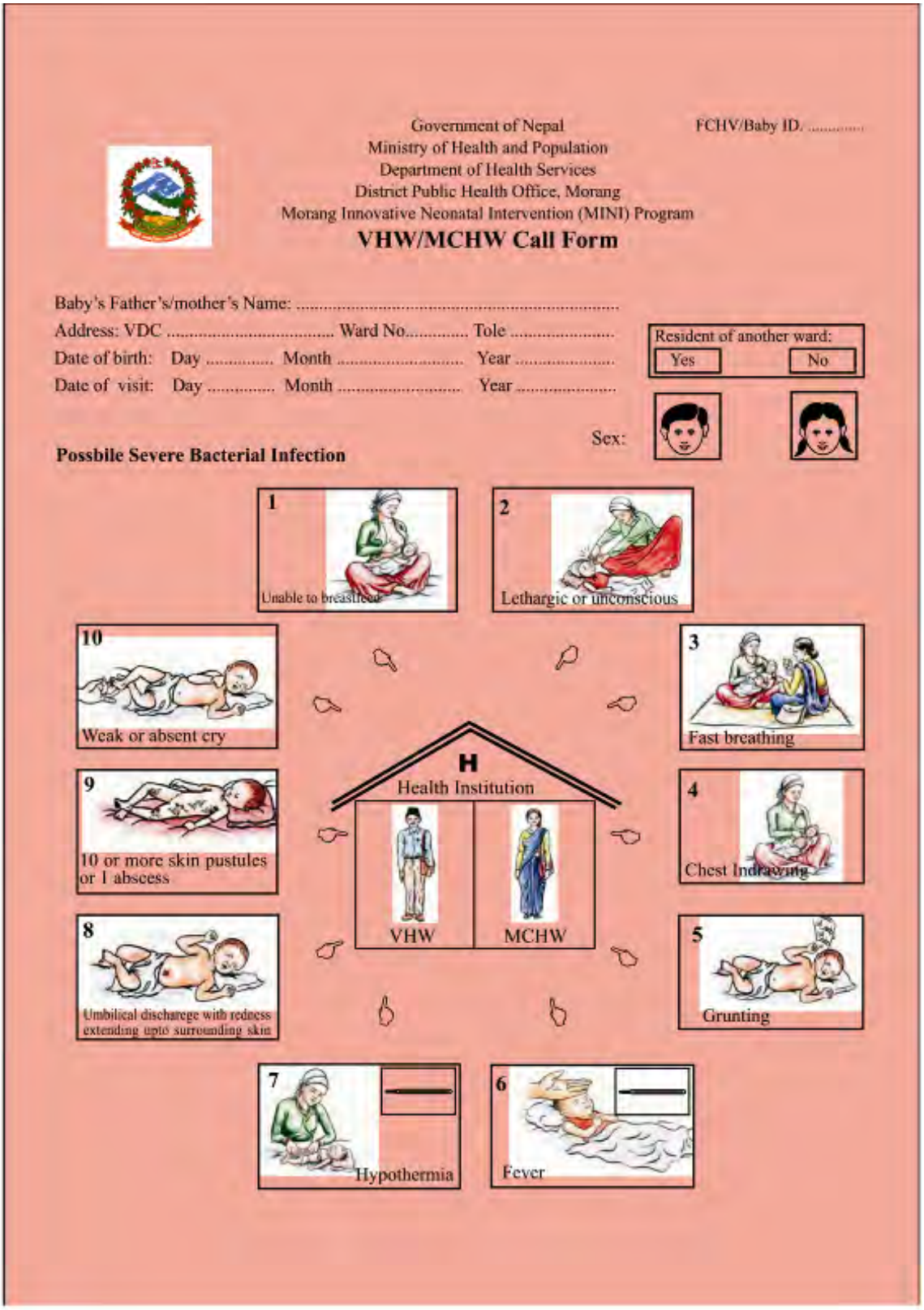
Cotrim completion: Yes | No | Donot know

Supervised date, dose and signature of health worker

Dose	1	2	3	4	5	6	7
Name and Post							
Signature							
Date							

Feedback: .....

Appendix D



Government of Nepal
Ministry of Health and Population
Department of Health Services
District Public Health Office, Morang
Morang Innovative Neonatal Intervention (MINI) Program

FCHV/Baby ID. .....

VHW/MCHW Call Form

Baby's Father's/mother's Name: .....
Address: VDC ..... Ward No..... Tole .....
Date of birth: Day ..... Month ..... Year .....
Date of visit: Day ..... Month ..... Year .....

Resident of another ward: Yes No

Sex:

Possbile Severe Bacterial Infection

1 Unable to breastfeed
2 Lethargic or unconscious
3 Fast breathing
4 Chest Indrawing
5 Grunting
6 Fever
7 Hypothermia
8 Umbilical discharege with redness extending upto surrounding skin
9 10 or more skin pustules or 1 abscess
10 Weak or absent cry

H
Health Institution
VHW
MCHW

Appendix E

Preparing for training.

DPHO addressing the district orientation.

Observation visit by senior pediatricians.

FCHV practicing use of the Salter scale.

FCHV reading a thermometer.