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# Management of Possible Serious Bacterial Infection in the Private Sector of Nepal's Health System Pilot study report

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The Maternal and Child Survival Program (MCSP) is a global, \$560 million, 5-year cooperative agreement funded by the United States Agency for International Development (USAID) to introduce and support scale-up of high-impact health interventions among USAID's 25 maternal and child health priority countries, as well as other countries. MCSP is focused on ensuring that all women, newborns and children most in need have equitable access to quality health care services to save lives. MCSP supports programming in maternal, newborn and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment.

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# Acknowledgments

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# Abbreviations

CHD	Child Health Division
CRS	Contraceptive Retail Sales
DDA	Department of Drug Administration
D/PHO	District Public Health Office
DoHS	Department of Health Services
ENAP	Every Newborn Action Plan
ENC	Essential newborn care
FHD	Family Health Division
FWD	Family Welfare Division
IMNCI	Integrated Management of Newborn and Childhood Illness
MCSP	Maternal and Child Survival Program
MCH	Maternal and child health
MOHP	Ministry of Health and Population
NDHS	Nepal Demographic and Health Survey
PSBI	Possible serious bacterial infection
SNL	Saving Newborn Lives
USAID	US Agency for International Development
WHO	World Health Organization

# Executive Summary

The 2016 Nepal Demographic Health Survey (NDHS) estimates neonatal mortality contributes to 54% of under-5 deaths in the country. Among these deaths, neonatal infection (sepsis) – which is preventable and treatable – is one of the leading causes. For Nepal to reach its important and ambitious target of 10.9 newborn deaths by 2035,<sup>1</sup> improving the quality of infection management is critical. Moreover, given the private sector accounts for the largest proportion of possible serious bacterial infection (PSBI) cases treated in Nepal, there is need to understand and to improve quality of care among these providers.

From 2016 to 2019, USAID’s Maternal and Children Survival Program (MCSP) in Nepal collaborated with the Ministry of Health and Population (MoHP) to gain a better understanding of the current provision of outpatient PSBI<sup>2</sup> care for newborns in the private sector. A nationally representative survey was undertaken in 25 districts in June/July 2017. Following this, and under the leadership of the MoHP’s Family Welfare Division and the District Public Health Office (D/PHO) in Kavrepalanchok (Kavre) district, MCSP Nepal implemented a PSBI pilot in partnership with Nepal Contraceptive Retail Sales (CRS) Company. This included training of providers, promoting access to and use of clinical protocols, and establishing functional mechanisms to facilitate timely and reliable referral for more critically ill cases.

The findings and lessons learned from the implementation of this pilot were intended to help the Government of Nepal to develop strategies for short and long-term interventions for improving the management of sick young infants in the private sector. Key recommendations related to policy, design and implementation were identified to enable the government and other partners, including UN organizations and INGOs, to further take up the next steps. These include:

- Consider appropriate policies for registration and/or regulation of private providers to encourage pharmacies and clinics to be more transparent and to improve quality of care.
- Review the current PSBI management protocol in light of recent evidence.
- Involve key stakeholders, private sector representatives and providers, and government counterparts in the early planning and design stages for future interventions, to ensure buy-in and ownership.
- Interventions to improve quality of care among private providers should be comprehensive, encompassing training, resource utilization, service delivery, reporting, strengthening referral pathways, and creating an enabling environment through policies and regulations. Initiatives should also include capacity building for providers, as these were effective incentives in the pilot program.

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<sup>1</sup> <http://www.healthynewbornnetwork.org/hnn-content/uploads/NENAP-final-low-resolution.pdf>

<sup>2</sup> WHO defines the clinical signs of PSBI as: fast breathing (respiratory rate  $\geq 60$  breaths/minute); severe chest in-drawing; fever (temperature  $\geq 38$  °C); hypothermia (temperature  $< 35.5$  °C); no movement at all or movement only on stimulation; feeding poorly or not feeding at all; convulsions.

# Background

Nepal has made significant progress in reducing child mortality to 39 per 1,000 live births in 2016 but, despite this progress, the 2016 Nepal Demographic and Health Survey (NDHS) estimated that neonatal mortality contributed to 54% of under-5 mortality. One of the leading causes of newborn deaths in Nepal is neonatal infection (sepsis), which is preventable and treatable. Nepal's Every Newborn Action Plan aspires to reduce newborn deaths to 18.9 per 1,000 live births by 2020 and to 10.9 by 2035. To do so, improving quality of infection management requires more attention, given the burden of newborn deaths resulting from Possible Serious Bacterial Infection (PSBI).

The private sector accounts for the largest proportion of PSBI cases treated in Nepal. According to the 2016 NDHS, 74% of caretakers who sought care for children under 5 years old with acute respiratory infection or diarrhea went to the private sector, mostly to private pharmacies or private clinics. However, nationally representative data on the quality and appropriateness of care for sick young infants provided in the private sector have been limited. In 2016, Save the Children's Saving Newborn Lives (SNL) program supported the Child Health Division (CHD) of the Department of Health Services (DoHS) to carry out a situation analysis of the management of PSBI cases in drug shops in six districts of Nepal. The study identified several concerns related to quality of care, such as inaccurate and potentially dangerous weighing/dosing, and use of steroids for treatment of sick young infants, but it also revealed promising opportunities for improvements.

USAID Nepal then requested that MCSP build on the SNL situation analysis and coordinate a large, nationally representative survey to provide a more definitive picture of the current provision of outpatient PSBI care for newborns in the private sector. The survey was conducted in a representative sample of 25 districts between June and July 2017. Criteria for appropriate assessment, treatment, referral, and follow-up were defined in line with national guidelines to characterize management of sick young infants ages 0–2 months with PSBI. Ultimately, 400 shops that managed and treated sick young infants with antibiotics were interviewed, and 82 interviews were completed at physician-run private clinics. Key stakeholders then identified implications and recommendations for the country.

From these findings, MCSP Nepal developed an intervention for improving the quality of care for treatment of sick young infants and tested the intervention in a proof-of-concept approach within private medicine shops and clinics. Under leadership of the CHD and the district public health office in Kavre district, MCSP implemented a pilot that included training, provision of necessary equipment, and a strengthened referral system that links a provider with a practicing physician at the referral hospital and allows for mobile consultations to facilitate the referral (since the gold standard of care is referral). Providers should provide treatment only if referral is not possible or refused. During implementation from June 2018 through February 2019, 222 sick young infants were reported, of which 43% were identified with PSBI. Importantly, none of the medicine shops or clinics adhered to the complete protocol for treatment of the PSBI cases. However, several promising learnings emerged from the study related to how to better motivate, train, and support private providers to manage PSBI per national protocol. These results will enable the Ministry of Health and Population (MOHP) and the private sector to work together to provide lifesaving treatment for sick young infants at the points of care.

## Pilot Design

The clinical protocol for the pilot was adapted from the WHO IMNCI Guideline to reflect the national CB-IMNCI clinical protocol for management of PSBI in newborns and young infants (0-59 days old). The adapted clinical protocol for the pilot included counseling plus immediate referral with the first dose of pre-referral injectable antibiotics (gentamicin and ampicillin). However, if referral was refused or not possible, the protocol mandated that the child diagnosed with PSBI be treated with injectable gentamicin and ampicillin; if injectable ampicillin could not be administered, a combination of injectable gentamicin and oral amoxicillin for seven days were to be prescribed. The guidance encouraged mothers to continue breastfeeding and provide skin-to-skin care during illness. If there were no signs of recovery in the child, urgent referral to a

tertiary center was recommended. A facilitator’s guide, participants’ manual, and several tools were developed for the pilot, including a service register and referral slip for the private providers to record cases of sick young infants, and job-aids in the forms of a flip chart, monitoring tools, and client interview checklists.

The overall goal of the pilot was to improve the quality of management care practices for sick young infants by medicine shop service providers<sup>3</sup> and clinics. The specific objectives were:

- To orient the private providers on how to manage PSBI cases;
- To improve the referral of PSBI cases to appropriate hospitals;
- To improve private providers’ adherence to PSBI management as per the national IMNCI protocol; and,
- To establish a sick young infant recording system in the private sector.

In Kavre district, the following key strategies and interventions were implemented as part of the MCSP-supported pilot:

- Training on assessment and identification of danger signs, appropriate treatment regimens, and protocol for referral and follow up of cases;
- Provision of necessary equipment<sup>4</sup>; and,
- Strengthening the referral system to link private providers with a practicing physician at the referral hospital (including phone consultations).

A Technical Advisory Group (TAG) was established, consisting of representatives of CHD/FWD, D/PHO Kavre, USAID, and Dhulikhel Hospital, to provide guidance and feedback to the implementation team on the operation and monitoring plan. The TAG also monitored the progress of the pilot, and participated in monitoring visits to sites, providing feedback for improvement based on observations during the visits.

Kavre district was selected for the pilot in discussion with the CHD, and was endorsed by the Integrated Management of Neonatal and Childhood Illness (IMNCI) Technical Committee. Kavre was selected for three main reasons: the district has an established tertiary level referral center for newborn and young infant care, it represents a mix of accessible and some very difficult geographical terrain, and it is close to Kathmandu, which allows for more intensive monitoring.

Activity sites<sup>5</sup> within Kavre were identified through three main sources: the national PSBI private sector survey, CRS’s network including the *Sangini* Network,<sup>6</sup> and consultations with local stakeholders and the Kavre D/PHO. The eligibility criteria for inclusion in the pilot were as follows:

1. Service providers must have a formal credential or qualification to assess and treat children, and
2. Providers must be currently engaged in providing care to sick young infants.

The national survey identified 46 medicine shops, some of which were *Sangini* Network outlets. An additional 24 medicine shops and clinics for the pilot were identified by the network and the D/PHO.<sup>7</sup> As shown in Figure 1, these sources were combined and mapped to form a list of 70 sites, which were later verified by district coordinators in the field, to confirm their eligibility. This served as a crosscheck to ensure that the pilot did not miss any functional outlets within its inclusion criteria. Of the 70 sites identified, 62 met the pilot’s eligibility as mentioned above, with eight not included due to the non-health background of the providers, remoteness, and/or closure. Of these 62, five sites were dropped during the implementation phase:

<sup>3</sup> “Service Provider” in whole of the report is defined as individual who works in an outlet, either medicine shop or clinic, and provides clinical services to children or general public

<sup>4</sup> A Pan Scale, a Digital Thermometer, and a Respiratory Rate Timer

<sup>5</sup> Activity sites are defined as the outlets (medicine shops and small clinics in Kavre) whose individuals were trained and engaged during the period of pilot implementation (June 2018 – Feb 2019)

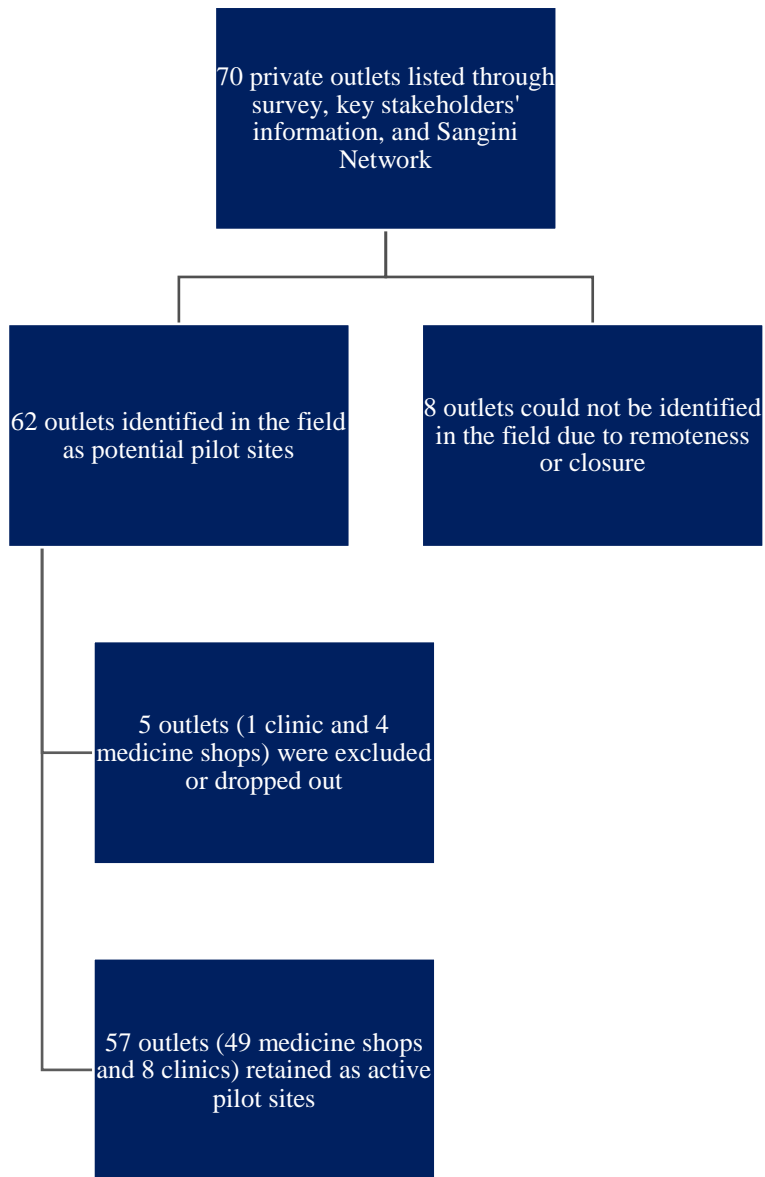
<sup>6</sup> The Sangini Network is a social franchising model managed by Nepal Contraceptive Retail Sales (CRS). It operates through existing medical outlets (pharmacies), which receive training and certification from CRS to provide injectable progesterone for family planning. Sangini is the Nepali brand name for injectable progesterone.

<sup>7</sup> For the purposes of this pilot, “clinic” refers to an entity that is registered as a clinic with the DPHO. “Medicine shop” refers to an entity that sells medications, and may or may not be registered with the DDA.



one was shut down by Department of Drug Administration (DDA) as it was not registered, three refused to provide data for the pilot (for unstated reasons), and one closed its business and shut its outlet service point.

**Figure 1. Site identification and selection**

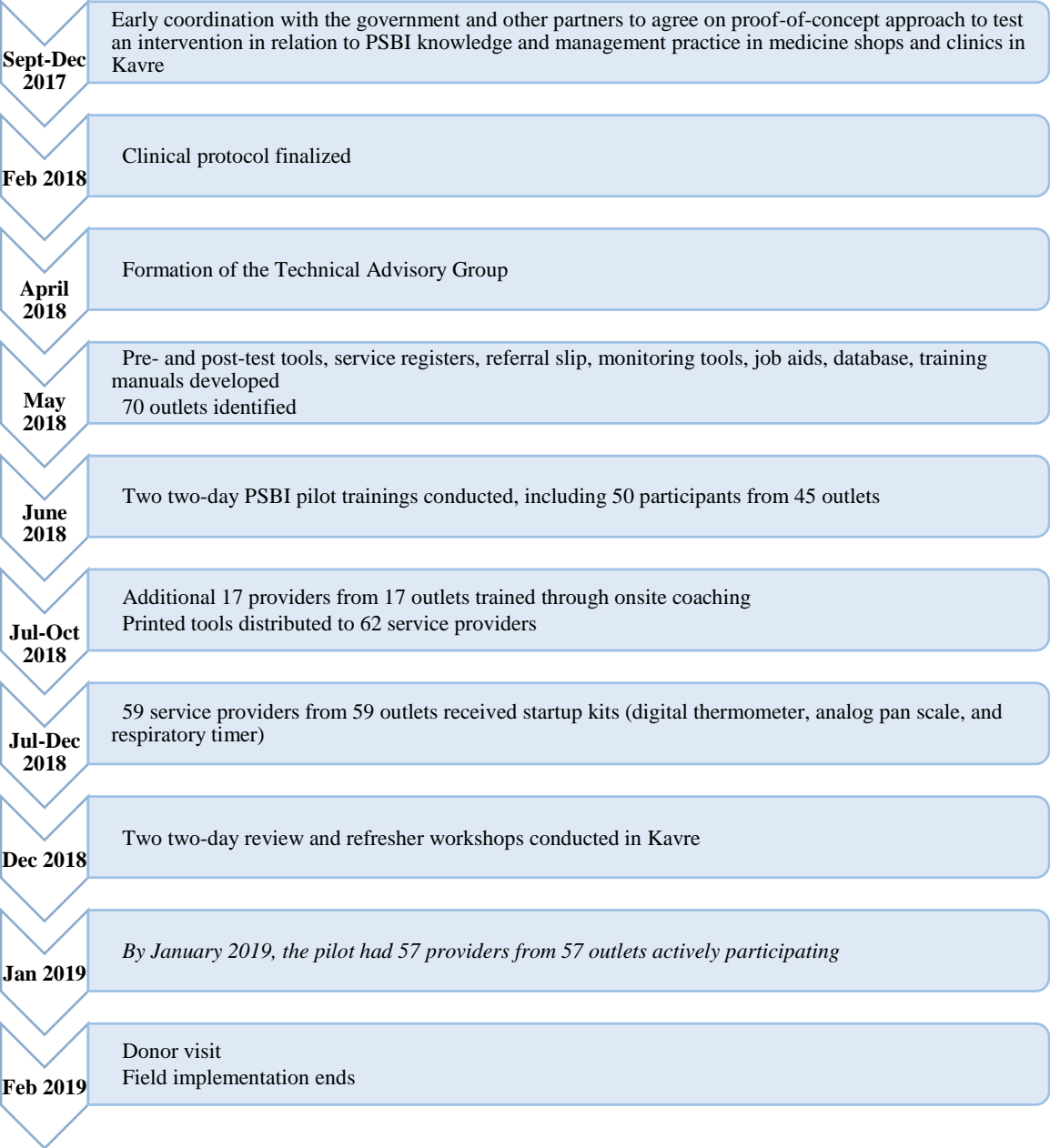




# Implementation

Implementation took place over nine months, from June 2018 through February 2019. Figure 2 lays out the timeline of activities undertaken by the pilot.

**Figure 2. Timeline of activities for the pilot\***



\*Monitoring visits were conducted throughout the project period, from June 2018 through February 2019. Details are described below in the section on monitoring visits.

## Training and Outreach

In May 2018, 50 sites were informed by the Kavre D/PHO about the PSBI training. Sites were requested to identify and release the provider that is primarily responsible for taking care of newborns and young infants for the PSBI training. D/PHO chose not to include service providers from 12 recently trained medicine shops through the on-going IMNCI program roll out in the district. There were more outlets in the initial list than the ones participated in the training (Table 1).

**Table I. Training type and number of trainees**

Type of training	Participating trainees with formal credentials (Total = 62)
Formal Offsite Training	45
Onsite Coaching	4
Onsite Coaching	4
Onsite Coaching	5
Onsite Coaching	4

A total of 50 service providers (15F, 35M) from 45 private outlets (nine clinics and 36 medicine shops) participated in the formal offsite training in June 2018. Of these, it was later determined that five of the 50 participants did not meet the pilot’s eligibility criteria (based on their credentials), so were not counted as part of the final number of formal trainees. An additional 17 service providers from 17 outlets received onsite coaching on the protocol between July-October 2018. Of the 62 trainees who received either offsite training or onsite coaching, five dropped

out over the course of the pilot.

Both formal offsite training and onsite coaching used the *Private Service Provider on Management of PSBI Cases* training manual, which was adapted from the national CB-IMNCI protocol. The training focused on the four components of clinical practice of PSBI reflected in the survey: assessment and classification, treatment, referral, and follow-up. Onsite coaching was then focused only on the PSBI identification, classification, treatment, referral and follow-up, whereas, the offsite formal coaching covered other aspects of illness, for example diarrhea, nutrition, and breastfeeding. Flip-chart job aids and start-up training kits (consisting of a digital thermometer, pan scale, and respiratory timer) were subsequently provided to both groups.

The training focused on four components of PSBI management: assessment, treatment (including pre-referral injectable antibiotics), referral (including calling the referral sites and arranging transportation), and appropriate follow-up of PSBI cases. In addition, the training provided guidance on how to complete service registers and referral slips, the use of job aids, and the appropriate use of related equipment. Participants provided recommendations on how to improve the design of the tools to make them more user-friendly and less time-consuming, including color-coding danger signs to distinguish them as PSBI and non-PSBI. Job aids were also revised in the form of small flip charts instead of hanging charts. While the training emphasized the importance of providing appropriate counseling to beneficiaries on care-seeking, it did not go into detail on counseling techniques or specific content of counseling messages. The training did not include any clinical skills sessions on providing injections.

Pre- and post-training evaluations showed an increase in the average knowledge of participants (n=50): out of a total possible score of 12, the average score increased from 5.6 to 10.

The prior survey conducted in 25 districts found that many outlets lacked proper kits to manage PSBI cases. These items are essential to diagnose PSBI and to identify an appropriate treatment regimen. To address this, the pilot procured start-up kits for enrolled outlets: each kit included a scale, respiratory timer, and digital thermometer. While these relatively inexpensive items are generally available in Nepal, the project team chose to procure them directly and distribute to providers to encourage skills practice on quality equipment. The goal was to distribute the kits during the training itself but procurement delays of up to six weeks for certain remote outlets. Throughout the course of pilot implementation, the project team replaced or recalibrated equipment, as needed.

## Review Meetings

In December 2018, two workshops were organized to review the implementation progress and challenges, to discuss possible solutions, and to provide refresher training. The workshops were chaired by the Chief Public Health Officer of the District Health Office and the IMNCI focal person from the Family Welfare Division. Fifty-two of 58 participating providers attended (39M, 13F) and worked through a series of interactive sessions and group work. Skill refresher sessions on data collection and reporting were provided, and

learnings and concerns were documented. Pre- and post-tests showed an increase in average score from 8.3 to 10.5 (out of a total score of 12).

## Monitoring, Evaluation, and Learning

A monitoring, evaluation, and learning plan was developed for the pilot with the purpose of generating evidence to be used for program improvements. Table 2 summarizes the MEL activities that took place over the course of the pilot.

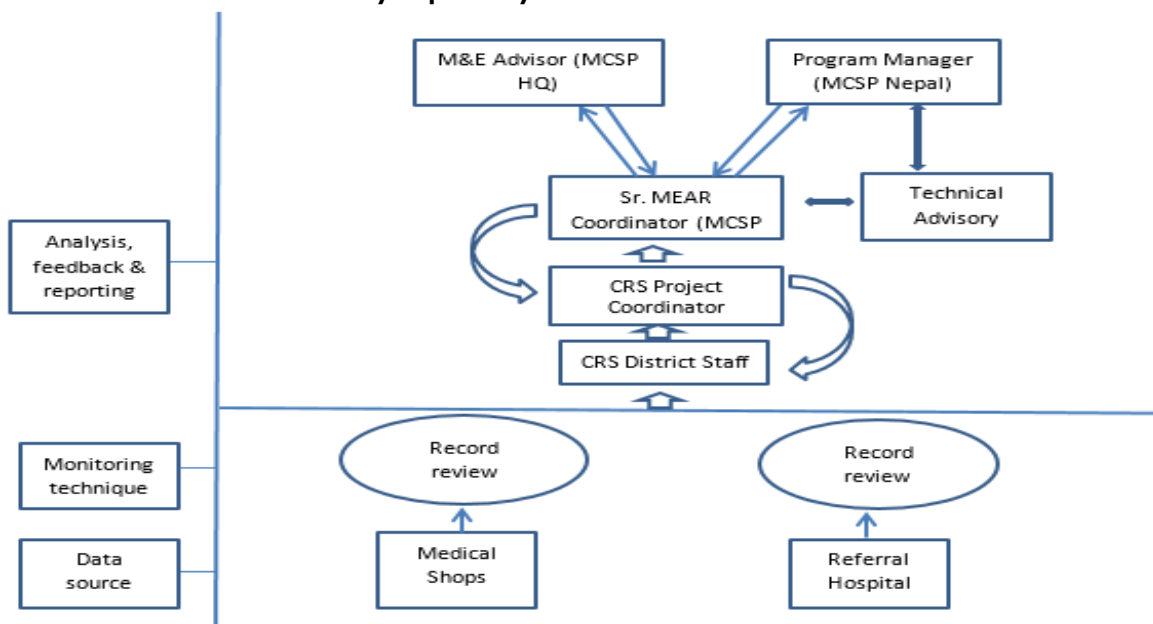
**Table 2: Details of the MEL activities during the pilot implementation**

Activities	Timeline
Detailed MEL plan developed	Finalized July 2018
Baseline and mid-line knowledge assessment of service providers	During training first week of June 2018 During review meetings mid-December 2018
Monthly monitoring visits undertaken by District Coordinator to collect quantitative and qualitative information.	Conducted monthly from June 2018 - Feb 2019 in selected outlets
Joint M&E visit by TAG representatives, including DHO and FWD, to gather qualitative information including case studies.	Seven joint visits from June 2018 - Feb 2019
Review meeting to identify enablers and barriers to pilot implementation.	Mid-December, 2018
Data Analysis to assess progress against MEL indicators, performance gaps and to highlight learning.	Monthly
Measure to ensure Data Protection for CRS and MCSP	All through pilot period
Reporting to share key findings and learning with USAID	Monthly meetings with the Nepal USAID Mission Quarterly and annual reports

### Routine Monitoring Data Sources and Management Procedures

Two district coordinators were hired by the local partner, CRS. These staff were based in Kavre district and were responsible for district-level data collection. The pilot utilized a mixed methods design, and two approaches were used for data collection: *event-based* and *periodic*. Event-based data included training records, pre- and post-test results, details of individuals who participated in the training, and qualitative data gathered through discussions with service providers and clients during the joint monitoring visits, and information gathered through review meetings. Periodic data included service register data maintained by the service providers, interviews with service providers, supervision records from monitoring visits. District coordinators collected and compiled records at the district level and shared them with the CRS central office. An MCSP team member backstopped this process at each level. Figure 3 illustrates the data collection and analysis pathway.

**Figure 3. Data collection and analysis pathway**



### Quantitative Data

Quantitative data mainly aimed to assess the number of sick young infant cases identified, treated, followed-up, and referred by private providers. The main sources of quantitative data included:

- **Training records:** Participants knowledge regarding care of sick young infants were collected during the formal training and review meeting through pre- and post-tests. The tests were conducted using a self-administered tool consisting of 12 questions, each correct question was given score 1. Average score was obtained by dividing the total score by number of the participants.
- **Service statistics:** Routine data from private service providers participating in the pilot were collected on a monthly basis. Individual trainees in the outlets were given service registers to document the assessment, classification, treatment, referral and follow-up of sick young infants. They were also provided with referral slips to facilitate the referral process. During the monitoring visits, district coordinators reviewed the registers and copies of referral slips, and entered data into an Excel database.<sup>8</sup> The data were later exported to SPSS (v20) for further cleaning and analysis.

### Observational Data

Observations, while limited in scope and nature, were taken to provide further understanding of the context in which the pilot was implemented. Observations were conducted during the monitoring visits, which allowed for a small number of semi-structured interviews with clients (n=3) and providers (n=7), and the data review meeting with providers. Per the MEL plan, the intended timeframe for collecting such qualitative information (as per the MEL plan) was during the first three months and the last three months of the study. However, due to other programmatic priorities during the initial phase of the pilot, only the latter phase occurred.

### Monitoring Visits

Throughout the nine months of implementation, a series of monitoring visits were conducted to mentor service providers to ensure adherence to the clinical protocol. Monitoring visits were operationally classified in two categories: joint visits and periodic visits. Joint visits were conducted by members of the

<sup>8</sup> Confidentiality of the photos of forms, as well as any other materials containing personally identifiable data, were maintained in a protected file at the MCSP Nepal office. Information from the registers and forms was only used to triangulate other data, and was not shared with any other entities outside of the data analysis team.

implementation team from CRS and MCSP, and/or government counterparts, and/or Dhulikhel Hospital representatives. The team aimed for one joint visit every month, with the following objectives:

- monitor adherence to IMNCI treatment protocol
- monitor record keeping
- understand service provider’s perspective on PSBI pilot project
- understand perception of patient/client towards private sector for PSBI case management
- provide on-site feedback to service providers on gaps seen

Outlets were selected based on a review of monitoring data and reported performance; for instance, the volume of PSBI cases, compliance/non-compliance in following treatment protocols, referral cases, and follow-up. Ultimately, seven joint monitoring visits were conducted to 23 outlets (18 medical shops and 5 clinics) and two referral centers. These visits included service register reviews and face-to-face interviews with some providers and clients using a prepared questionnaire. Questions commonly asked during joint visits included:

- What was your experience being in the pilot?
- What are the challenges you faced and benefits you received?
- What barriers are faced in filing out the services registers?
- What has been your overall experience and how can we make this beneficial for you?

Periodic visits were conducted routinely by CRS staff, primarily the district coordinators hired in Kavre, to provide on-site coaching and mentoring to service providers, particularly with data collection and register completion, as well as data verification through service register reviews, and to ensure equipment is functioning properly. Periodic visits focused on the information recorded in the service registers and any referred cases, and frequently asked questions included: How many cases have been seen? What signs did you see when conducting assessments? Have you recorded all of the case data? Did you facilitate any referrals? Are you using your job aids? Did the patient come for follow up, and why or why not?

All outlets received visits, though some more than others as outlets that requested a visit or required extra monitoring received more frequent visits. Table 3 provides a summary of observations and feedback provided to service providers during periodic visits.

**Table 3. Observations and feedback from periodic monitoring visits**

Observations	Feedback Provided
Service registers were not filled appropriately, or service providers failed to register 0-2 months non-PSBI cases.	On-site mentoring to service providers to appropriately complete registers.
Service providers admitted failing to register some non-PSBI cases, either due to time restraints or to misunderstanding regarding needing to register these cases	On-site mentoring to service providers to register all appropriate cases.
Some of the cases had issue of not taking referral slips to referred center, which resulted in not receiving timely services from the referred facility	Encouraged service providers to regularly counsel clients on the importance of referral slips
Follow up schedules are not complied by the clients once the child shows signs of recovery.	Encouraged service providers to counsel clients on the importance of follow up visits
Equipment malfunction (primarily the pan scale).	Team members demonstrated how to manually adjust and maintain pan scales during on-site mentoring. Faulty equipment were replaced

### Data Quality Assurance

MCSP employed the following strategies for data collection and cleaning, in an effort to ensure quality of the data:

- Development of standard operating procedures/protocol for the pilot
- Training private service providers on data recording procedures
- Regular data verification/correction through periodic and joint monitoring visits
- Data entered were validated through source checking (service register, client, referral hospital)

### ***Data Processing, Use, and Reporting***

Data from training and supervision activities were collected using a paper-based tool, and were subsequently entered into Excel; this process was managed by the CRS District Coordinators (DCs) in the field, under the close supervision from the CRS Project Coordinator and MCSP team. Observational data and information, collected during visits and the review meeting, were noted, and included in monitoring reports.

Routine project data were analyzed on a monthly basis, focusing key performance indicators and project management needs. To facilitate use of data for real-time programmatic adjustments, MCSP engaged the Technical Advisory Group (TAG) at the central and district level to review data, discuss implications, and agree on corrective actions. In addition, quarterly and annual reports were submitted to USAID Nepal in order share updates on the pilot progress, and USAID provided constructive feedback and support to further improve implementation.

### ***Ethical Review***

Upon submission of the pilot design to the JHPIEGO ethics review board in Washington, the board agreed that the proposal was not designated as human subjects research and instead as a pilot implementation program. Therefore, all the data collected during implementation was considered program monitoring data.

### ***Data Backup, Confidentiality, and Data Sharing***

Program data, including electronic database data and photos of registers, were stored and maintained at the MCSP Nepal office. All data stored electronically were de-identified. Any sensitive or potentially-identifiable data (such as copies of service records) were stored separately in a locked cabinet; photos of registers were stored in a password protected computer. These materials will be destroyed once final project deliverables are accepted and approved by USAID. The electronic database was maintained in a password-protected computer with access only by MCSP key personnel. Hard copies of data were stored securely in a locked cabinet with access granted only to essential project staff. Relevant data will be shared in accordance with USAID's Data Sharing Policy.

## **Results**

This section details the findings from the monitoring data collected during the pilot's nine months of implementation, between June 2018 and February 2019. Of the 57 private providers, data are presented from the 30 private service providers' registers that recorded case information for 222 sick young infants aged 0-59 months.

### ***Background Characteristics of Private Providers***

Fifty-seven private service providers participated in the pilot for nine months of implementation, 49 of whom were from medicine shops and eight were from clinics (Table 4). Providers were relatively evenly split in terms of their location: 37% proximal (within 30 minutes from the referral hospital), 33% semi-proximal (30-60 minutes from the referral hospital), and 30% remote (more than an hour from the referral hospital). The majority of providers received the formal PSBI management training that was delivered in June 2018 (77%), and the rest received onsite coaching delivered by district coordinators hired by the pilot.



**Table 4. Background characteristics of private providers**

Characteristic	% of providers (n)
<b>Location</b>	
Proximal	36.8% (21)
Semi proximal	33.3% (19)
Remote	29.8% (17)
<b>Type of outlet</b>	
Medicine Shops	86% (49)
Clinic	14% (8)
<b>Training participation*</b>	
Onsite coaching	22.8% (13)
Formal Training	77.2% (44**)
<b>Total</b>	<b>100% (57)</b>
*Formal training defined as participation in a two-day offsite training provided at the beginning of the pilot.	
**45 providers received formal training in the beginning of the pilot, however one dropped out in Dec 2018.	

### Background Characteristics of Sick Young Infants/PSBI Cases

During the study period, 222 sick young infants were reported by 30 private providers. Most (132) of the cases were reported only later in the implementation period (August to September 2018), possibly reflecting the slow initiation of implementation, which was due in part to delays in the distribution of kits and job aids to providers (described above in further detail). Most (84%) cases were reported by providers who had received the formal training, compared to providers who received only the onsite training (16% of all sick young infant cases). Of the total sick infants seen, 95 (43%) were PSBI cases. PSBI cases were observed in only 22 of the 57 outlets (data not shown). The remaining outlet providers did not report or record in the provided registers any sick young infant cases during the pilot implementation period. Key background characteristics for all sick young infant cases and PSBI-specific cases are presented in Table 5. The majority of PSBI cases were observed in infants 29-59 days (59%), medicine shops (86%), and in outlets that were located in remote and semi-proximal areas (46% and 42%, respectively).

**Table 5. Background characteristics of all sick young infants and infants with PSBI reported during pilot period**

	All sick young infants		Infants with PSBI	
	%	N	%	n
<b>Age *</b>				
<28 days	46	102	41	39
29-59 days	54	119	59	56
<b>Sex</b>				
Female	40	89	51	48
Male	60	133	49	47
<b>Distance</b>				
Remote	41	91	46	44
Semi-proximal	44	98	42	40
Proximal	15	33	12	11
<b>Type of outlet</b>				
Medicine shop	84	186	86	82
Clinic	16	36	14	13
<b>Total</b>		<b>222</b>	<b>43%</b>	<b>95</b>

\*Missing age data from one infant

## Reported Clinical Signs among PSBI Cases

Among the PSBI cases, the most commonly reported sign was fever (54%), followed by grunting (42%) and fast breathing (39%) (Table 6). A few of the cases also reported critical danger signs, including being unable to breastfeed (six cases), convulsions (four cases), and lethargy/unconsciousness (one case). A total of 56 cases reported two or more clinical signs.

**Table 6. Reported clinical signs among PSBI cases (N = 95)**

Clinical sign	Percent (%)	n
Fever	53.7	51
Grunting	42.1	40
Fast breathing	38.9	37
Nasal flaring	21.1	20
Severe chest in-drawing	16.8	16
Skin rash	9.5	9
Umbilicus infection	6.3	6
Unable to breastfeed	6.3	6
Hypothermia	4.2	4
Convulsions	4.2	4
Bulging fontanelle	2.1	2
Lethargic or unconscious	1.1	1
Two or more reported signs	58.9	56
Only fast breathing		
0-6 days	0	0
7-59 days	4.2	4

## Treatment, Follow-Up, and Referral Practices for PSBI Cases

The pilot followed the national protocol on treatment of PSBI cases, which recommends that when referral is not possible, identified PSBI cases should receive a five-day regimen of oral amoxicillin and seven days of injectable gentamycin. Of the 95 reported PSBI cases, 81 cases were classified as non-referred (received treatment from the private provider), either because a provider did not refer them for further treatment at a referral hospital, or because the caregiver refused referral. All of the 81 cases treated by private providers received at least some treatment from the provider, but only one case out of the 81 received the complete treatment regimen of oral amoxicillin and injectable gentamycin as per the protocol (Table 7). Notably, about 68% (55 of the 81 cases) of PSBI cases were treated with only oral amoxicillin.

Among cases treated with only oral amoxicillin, only 11 (20%) of the 55 cases were treated with the appropriate dose, duration, and frequency of the drug per the pilot's clinical protocol. We acknowledge that the revised WHO IMNCI protocol, based on the WHO guidance<sup>9</sup> published in 2015, recommends only oral amoxicillin for fast breathing cases between 7-59 days old. However, the pilot used the then-existing IMNCI protocol, which, noting that only fast breathing was still classified as PSBI in IMNCI, recommended injectable gentamicin and oral amoxicillin for all non-referred cases. Nevertheless, of the four cases that presented with only fast breathing, one received only oral amoxicillin with appropriate dose and duration, which is classified as non-adherence as per the pilot protocol. Of the other three cases, two were advised for home remedy and one was sent home after being counseled that the fast breathing would eventually go away.

In terms of follow-up practices after the provision of treatment, private service providers were strongly encouraged to ensure face-to-face follow-up visits with PSBI cases that refused referral or were not otherwise referred, with a recommendation for the follow-up to be on the third and fifth days of the standard treatment regimen (per the pilot's protocol). Of the total 81 non-referred PSBI cases, only 5% received a follow-up with the provider on the third and fifth day, while one-third received at least one follow-up visit.

<sup>9</sup> Guideline: Managing Possible Serious Bacterial Infection in young infants when referral is not feasible. World Health Organization. 2015.

**Table 7. Treatment and follow-up practices of private providers for non-referred PSBI cases**

Non-referred PSBI cases	Medicine shops		Clinics		All outlets	
	%	N	%	N	%	N
Treated with gentamycin and amoxicillin	5.6	4	0.0	0	4.9	4
Received complete dose of gentamycin and amoxicillin	1.4	1	0.0	0	1.2	1
Treated with gentamycin alone	0.0	0	0.0	0	0.0	0
Treated with amoxicillin alone	72.2	52	33.3	3	67.9	55
Other treatment	22.2	16	66.7	6	32.1	22
<b>Total cases</b>		<b>72</b>		<b>9</b>		<b>81</b>
PSBI cases treated with amoxicillin alone	Medicine shops		Clinics		All outlets	
	%	N	%	N	%	N
Treated accordingly to protocol	17.3	10	33.3	1	20.0	11
<b>Total cases</b>		<b>52</b>		<b>3</b>		<b>55</b>
Follow-up of non-referred PSBI cases	Medicine shops		Clinics		All outlets	
	%	N	%	N	%	N
Received at least one follow-up	<b>33.3</b>	<b>24</b>	<b>33.3</b>	<b>3</b>	<b>33</b>	<b>27</b>
Received follow-up at least on 3 <sup>rd</sup> and 5 <sup>th</sup> day	<b>5.6</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>5</b>	<b>4</b>

The remaining 14 cases (out of total 95 cases) were referred to referral hospitals (Table 8). Most referrals were made to the Dhulikhel Hospital, with which the pilot program maintained a close partnership. In 10 of the 14 cases, the referral was facilitated by the provider, meaning that the provider called ahead to the hospital, ensured the physician was available, and counseled the caregiver on danger signs and transportation to the referral site. The provider registers confirmed that referral was completed (i.e., beneficiaries sought care from the referral hospital) in five of the 14 cases. The project team was unable to confirm referral completion in the remaining nine cases as contact information for the care seekers had not been appropriately recorded in the service registers. In cases of referral, receipt of pre-referral antibiotics was very low: only two of the 14 cases received pre-referral injectable gentamicin. Further, the pilot protocol indicates that referral cases should receive injectable gentamycin and ampicillin as pre-referral antibiotics, but gentamycin and amoxicillin were provided.

**Table 8: Referral practices of private providers for PSBI cases**

All PSBI cases	Medicine shops		Clinics		All outlets	
	%	N	%	N	%	N
PSBI cases referred (by type of site)	12.2	10	30.8	4	14.7	14
<b>Total PSBI cases</b>		<b>82</b>		<b>13</b>		<b>95</b>
Referred PSBI cases only						
% of referrals with facilitation	80	8	50	2	71.4	10
% of referrals with pre-referral antibiotics	25	2	0	0	14.3	2
% of referrals that were completed	40	4	25	1	35.7	5
Hospitals receiving referred cases						
Dhulikhel Hospital	70	7	100	4	78.6	11
Scheer Memorial Hospital	20	2	0	0	14.3	2
Siddhi Smriti Pratisthan	10	1	0	0	7.1	1
<b>Total PSBI referred cases</b>		<b>10</b>		<b>4</b>		<b>14</b>

## Discussion, Implications, and Recommendations

Parents and caregivers of 222 sick young infants sought treatment at pilot sites from June 2018 through February 2019, of which 43% were identified with PSBI. Of the 57 providers engaged in the pilot, 27 did not report or register treating a sick young infant case, most commonly due to a lack of cases, but also due to a lack of sufficient time to complete service registers when a family did seek care.

The pilot also found that only 5 of the 20 (25%) service providers whose outlets were not registered under DDA reported cases, while 25 of 37 (67%) registered service providers reported cases. Conversely, the national survey that preceded the pilot found that both registered and non-registered service providers reported seeing such cases on a regular basis. While the survey and pilot used different methodologies for recording cases, this finding nevertheless calls for further research to understand why case reporting is low for unregistered private providers.

In general, reporting of PSBI cases from public facilities is inconsistent across the country. The last annual report<sup>10</sup> published by Department of Health Services showed that Kavre district reported 41 PSBI cases in FY 2016/17 while Bardiya district reported 686 PSBI cases, the highest among districts in the fiscal year. The district of Kathmandu reported only 17 PSBI cases even though its annual projected population under-2 months of age was 1359 for that period. While as stated above, methodologies for public and private sector providers are different, these inconsistencies suggest that a review is needed to examine case reporting from all providers, both within public and private sectors, particularly given many private providers also work in the public sector.

In this MCSP-supported pilot, among those providers that did report cases, none of the medicine shops or clinics adhered to the complete protocol for treatment of the PSBI cases. In addition to challenges with treating PSBI with injectable antibiotics, the data highlighted that treatment completion and appropriate follow-up is a challenge. The prominent reasons cited by service providers for not completing the full seven days of treatment was a lack of compliance from the parents or guardians, and the perceived sense of recovery after few days of treatment. This common perception of being “fully cured” when the child starts to show signs of recovery may be why many guardians halted treatment partway through. Even when only oral drugs were provided and the family was advised to bring the child back after treatment completion on the third and fifth days for follow-up, parents seldom returned: only 5% completed at least one follow-up visit on at least the third or fifth day.

It is important to note the limitations of the data captured by the pilot. First, case numbers were fairly small and the implementation period was brief. In addition, delays were faced with mapping providers and distributing start-up kits, which may have negatively affected the length of time for which providers were implementing. That said, several promising learnings emerged. The following section discusses quantitative findings captured from service registers and monitoring records, and informal qualitative information captured through provider discussions during monitoring visits and the data review meeting. This information is presented through the four components of the PSBI management protocol: assessment, treatment, referral, and follow up.

## Assessment

The pilot did not include direct observation of clinical assessment, but the data captured in the service registers indicated that assessment and classification was done in a relatively correct manner. Providers noted this was because the pilot engaged service providers in the development of service registers and job aids, which possibly led to ownership and understanding of the tools. Other factors that contributed included the initial classroom training, regular onsite coaching, and mentoring, which helped ensure providers were well versed with the protocol and confident in assessment techniques.

Providers cited availability and training on use of the equipment provided in the start-up kits as another important factor that boosted their skills to assess cases properly. In addition, staff trained providers on how to troubleshoot basic mechanical failures of equipment, ensuring continuity of maintenance practices.

## Treatment

Overall treatment adherence, or lack thereof, in the pilot raised many questions and highlighted the complexities of the national protocol. According to the national protocol, all referred PSBI cases were to receive pre-referral injectable antibiotics (gentamycin and ampicillin). Of the 14 referred cases, none received

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<sup>10</sup> Ministry of Health and Population. *Annual Report*. Kathmandu, Nepal (2017)

ampicillin, and only two received injectable gentamycin with oral amoxicillin. Many cited their lack of experience with injectable ampicillin as the main factor for not providing it, whereas they were more comfortable with gentamycin because they had either given the doses to other clients or had seen it given. A few providers indicated that they had provided injectable antibiotics for PSBI-like illnesses before the pilot started, but that they did so based on their clinical judgement of “severity” rather than on danger signs identified in the protocol. Given this reluctance, the project team anticipated that referral rates would be higher, reflecting provider lack of confidence in giving injections, but the referral numbers were quite low.

For non-referred cases (including those for which referral was refused), the national protocol dictates that the patient should receive seven days of injectable gentamycin and five days of oral amoxicillin. Only four cases received gentamycin with amoxicillin, of which only one received the complete and proper dose and frequency of both drugs as per protocol. Two cases received the complete dose of gentamycin only, and 55 (72%) received only amoxicillin.

From the interactions during monitoring visits and review meetings, the project team learned that some providers felt uncomfortable delivering injections to neonates and young infants even when they are quite comfortable giving injections to adults. Other reasons that emerged for lack of adherence to appropriate treatment protocol with injectables included: parents of the child reportedly refused the injection, providers feared negative backlash or violence by family or community members if the child’s condition worsened after administering injections, and a widespread perception among some communities and health service providers in Kavre that it is harmful to inject medicine into very young children regardless of their condition. The pilot was able to identify this latter perception through various interactions in the district, but many anecdotal reports from other sources have also shown the perception is prevalent across the country. A study<sup>11</sup> done in Baglung district of Nepal showed that many prefer oral medicines to injectables because of convenience, fear of pain, and perceived side effects, and that some perceive that injections should only be used for “serious” illness, and that they are addictive and should not be used “often.”

The pilot did not examine or capture service provider skillsets in delivering injections to children younger than 59 days, nor did it provide any clinical training or skill refresher on such. When questioned, some of the providers that provided oral medications for non-referred cases defended their treatment modality by highlighting their many positive years of personal experience with these drugs. It was evident that many providers put their faith in their previous experience with oral medications citing “perceived full recovery,” and that they did not seem intent on changing practice to adhere to the protocol. One provider said, “I have been treating these sick newborns and young infants in my pharmacy for the last 10 to 12 years with oral drugs alone. No one has died or had any complications yet. Then why should I take risk and administer injectable now?” Ironically, providers consistently indicated their understanding of (and belief in) the value of counseling to parents on adherence to treatment protocols, but the pilot did not directly observe or capture data regarding counseling on treatment.

## **Referral**

The pilot captured valuable learnings on the referral system for PSBI cases. During the design phase, the pilot team established a strong linkage with Dhulikhel Hospital and its pediatricians. This was one of the most appreciated aspects of the pilot. The hospital’s hotline numbers and the mobile phone number of the pediatrician were provided to the private service providers, which enhanced access of the providers to seek treatment advice from the pediatricians, not only for PSBI but for other cases as well. The response from the hospital was generally positive, with few exceptions; service providers reported that the response from a tertiary referral hospital would be a factor for them in determining whether to encourage future referrals.

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<sup>11</sup> Gyawali S, Rathore DS, Bhuvan KC, Shankar PR. Study of status of safe injection practice and knowledge regarding injection safety among primary health care workers in Baglung district, western Nepal. BMC international health and human rights. 2013. Dec; 13(1):3. <https://bmcpubhealth.biomedcentral.com/articles/10.1186/s12889-015-1775-5>

That said, despite referral being emphasized in the formal training and onsite mentoring and the strong partnership with Dhulikhel Hospital, results indicate that referral was not done as consistently as the project team had anticipated, confirming some of the findings from the national survey. The survey had found that nationally, 72% of medicine shops and 98% of clinic service providers, and 76% of medicine shop providers in Kavre, could correctly identify indications for referral. However, during the pilot, service providers failed to refer 81 out of 95 PSBI cases, though it is important to note that this included at least 13 cases who refused to seek care from a higher facility against the provider's advice. Incomplete service registers meant the project team could not follow up with the remaining 68 cases. Nevertheless, it was evident from discussions that one reason for not referring cases was the aforementioned personal positive treatment experience with oral antibiotics.

"I express my gratitude towards PSBI Pilot to facilitate the system of linkage with referral hospital as it has been extremely valuable. With this program, I can directly communicate with focal person for the management of PSBI cases adhering to IMNCI protocol."  
Service provider, Kavre

It was challenging to gather information on referral completion during the pilot. The project team was only able to confirm that five out of 14 referred cases did complete referral; contact information and/or data were missing for the remaining cases. The referral slips sent with the referred clients were used only for accessing services from the referral center, and were not intended to be returned to the outlet.

The pilot's findings also suggest that distance from the referral center may not be the most important factor in referral. Of 11 PSBI cases classified by service providers within the proximal strata (i.e., within 30 minutes of the referral hospital), only three cases were referred. Through mentoring discussions, many providers stated that parents and guardians do not want to go to the hospital, but the pilot has limited quantitative data to support this. Furthermore, the pilot neither observed nor collected data on counseling to parents about danger signs, care during illness, or the importance of follow-up care, and therefore is unable to verify if the service providers provided quality counseling or had sufficient knowledge and capacity to do so.

### **Follow-up**

In addition to challenges in treating PSBI with injectable antibiotics, the data highlight that treatment completion and appropriate follow-up are challenging. The two prominent reasons cited by service providers for not completing the full seven days of treatment included a lack of compliance from the parents or guardians, and the perceived sense of recovery after few days of treatment, as referenced above. In cases where only oral medication was provided and the child was advised to return after treatment completion on the third and fifth days for follow-up, the follow-up seldom happened: only 5% completed at least one follow-up visit on at least the third or fifth day. Importantly, the pilot training emphasized counseling but did not provide any skill-based coaching, so it is not known whether providers were counseling appropriately; data suggest that quality counseling could have been a very important component to behavior change in these instances.

Anecdotally, the project team observed and heard from providers at all three types of facilities (medicine shops, clinics, and the referral hospital) that reasons for lack of adherence to appropriate follow-up protocol included a cultural practice prevalent across the country, including Kavre, that newly delivered mothers generally do not want to leave their homes during the first two weeks after birth, meaning that newborns are not taken for follow-up.

### **Challenges**

The intention of the MCSP-supported pilot was to implement a standardized protocol across all medicine shops and clinics that met the criteria and agreed to participate in the project. Importantly, DDA registration was not a criterion as survey findings demonstrated that families seek care for sick young infants from private providers irrespective of outlets' registration status. MCSP therefore purposefully targeted registered and unregistered providers; however, working with unregistered outlets posed some challenges with implementation. For example, during monitoring, one outlet was shut down by a DDA investigation team, which highlights the risk of engaging unregistered outlets in the project. In addition, discussions around if and

how to regulate private sector providers are occurring in many countries, and recommendations for future implementation may be dependent upon whether or not providers are willing to register with the government.

Changing clinical practice behaviors for providers during the pilot was a significant challenge. As one example, gentamycin use is reported to be quite low as many providers are uncomfortable with administering injectables, and some clients are uncomfortable with their young children receiving injectables. Since the pilot neither assessed provider competencies nor trained providers on clinical skills for injecting antibiotics, it cannot associate competencies around lack of pre-referral injections as evidence. However, the issue was discussed with providers during a review meeting and the proposed solution was to probe clients regarding their discomfort and then counsel them on the appropriate treatment accordingly. Investment in social and behavior change communication interventions is needed in order to change family and community beliefs and behaviors regarding injectable antibiotics and referrals, as many providers noted that client refusal was a main barrier to adhering to protocol.

Misconceptions among providers and clients regarding current health service related policy was a challenge. Some providers reported that clients would not follow through with a referral due to assumptions about cost of care, despite the national protocol allowing for free health care for newborns in public hospitals and institutions. FWD officials were particularly helpful when this information needed to be better communicated to providers, doing so during the review meeting in December 2018. However, Dhulikhel Hospital, which is a private medical institution, was not part of the government-run Free Newborn Care program, although it does have a social welfare scheme that waives many costs for patients lacking the financial resources to pay for services. Hospital staff consistently stressed to program staff that they would do all they could to alleviate the costs for families, but reinforcing this message to the beneficiaries themselves was challenging. In order to minimize this challenge, additional work is needed to establish more well-functioning government- or public-run hospitals where the cost of care for neonates is free. However, even should that happen, financial burdens will remain for infants 29 to 59 days old, who are not covered under the Free Newborn Care Program.

## *Lessons Learned*

Strong collaboration was a major facilitator in this pilot project. From the early stages of planning, a consortium of national-level partners from across the non-profit, government, and private sectors were involved, allowing for critical buy-in throughout the pilot. At the central level, the MCSP team engaged representatives from the CHD/FWD, the Kavre D/PHO, and USAID throughout the project, including: conceptualizing the pilot, developing protocols, engaging the IMNCI technical committee for feedback and endorsement, receiving critical government and donor approvals, providing briefings to government and committee members, conducting joint monitoring visits to the pilot sites, reviewing and presenting findings, and formulating recommendations.

In addition, the project coordinated with referral hospitals from the beginning of the pilot. MCSP Nepal conducted a formal orientation of the program in Dhulikhel Hospital and found that ensuring the service providers at all levels of the hospital were informed and engaged resulted in stronger support for participating providers and a more comprehensive understanding of the referral system. In addition to sitting on the Technical Advisory Group, partner pediatricians from these hospitals helped to oversee trainings, participated in review meetings, and provided mentoring support. Dhulikhel Hospital also provided their Paediatrics Unit's hotline numbers to providers so that it would be easier to call the hospital before a referral. Finally, it is worth noting that a similar partnership was sought with Scheer Memorial Hospital, but challenges were faced in the administrative approvals required to establish the formal partnership. Therefore, the partnership was not as formal as Dhulikhel Hospital, but Scheer Memorial did receive referrals and was visited by a joint CRS-SC-Government monitoring team to monitor the care sought by the one case referred there. Additional key learning from the pilot included:

- Many assume that private service providers are motivated by monetary profit, but the providers in this pilot were immensely motivated by their reach, the ability to provide life-saving care to newborns, and by the professional linkages to partner pediatricians at the referral hospital.

- “Certificates” after training were in high demand. The pilot could not provide certificates to providers as this needed to have a wider consent from all levels of MoH and USAID. However, it was evident that certificates would have further motivated many service providers.
- Flip-chart job aids and color-coded service registers improved providers’ abilities to identify danger signs and assess for PSBI.
- A responsive referral center can greatly encourage service providers for more referrals with facilitations. Dhulikhel Hospital, one of the pilot’s key referral hospital, was very responsive to calls from private service providers. This encouraged the service providers to call and refer cases.
- Perhaps the most important conclusion from the pilot is that all participating private providers reported a positive intention in continuing to manage PSBI per the protocol.

## Recommendations

Based on its experience and learning gleaned from this PSBI pilot implementation, MCSP respectfully offers the following recommendations for future efforts to strengthen PSBI management for sick newborns and young infants in Nepal:







- As current policies and practices in Nepal do not prevent care-seeking from the private sector for young infant illnesses, and thus do not prevent the possible provision of inadequate or inappropriate care from private outlets, the best possible solution is to engage private outlets and train them to provide recommended care to children 0-59 days old.
- Social and behavioral campaigns conducted at provincial or national level to encourage beneficiaries to adhere to the guidance and counseling offered by service providers should be considered to improve patient compliance.
- Engage private sector providers with referral hospital experts to improve relationships and better coordination. This has been an effective mechanisms to strengthen the referral pathway.
- Findings suggested that the user-friendly, color-coded job-aids increased the use of reference materials and ultimately contributed to improved service delivery overall. Engaging providers in the development of these job aids was instrumental to learning what they preferred and why. Future guidelines and programs should do the same.
- Interventions to improve quality of care among private providers should be comprehensive, encompassing training, resource utilization, service delivery, reporting, strengthening referral pathways, and creating an enabling environment through policies and regulations. Initiatives should also include capacity building for providers, as these were effective incentives in the pilot program.
- Consider reviewing current policies and practices for registration and/or regulation of private providers to encourage private sector outlets to be more transparent and to improve their quality of care.
- Nepal’s current PSBI management protocol, which includes injectables, should be reviewed in light of new evidence including WHO recommendations for management of cases where referral is not possible.<sup>12</sup> Revising the protocol per WHO’s guideline would allow for treatment of non-referred cases, both with only fast breathing or with other danger signs/symptoms, with a simpler regimen. Nepal’s current protocol of providing injectable drugs for seven days in an outpatient setting presents challenges to appropriate PSBI management in both private and public sectors, as the pilot experienced numerous provider compliance issues. Simplifying the protocol may improve compliance and acceptance.

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<sup>12</sup> Guideline: Managing possible serious bacterial infection in young infants when referral is not feasible. World Health Organization. 2015.



# Appendix A. List of PSBI materials and tools developed or adapted by MCSP

#	Material / Tool	Technical Area
1.	Service Register	 Tool 1_Service Register.pptx
2.	Referral Slip	 Tool 2 Referral Slip.xlsx
3.	Monitoring Checklist	 Tool 4_Monitoring checklist.docx
4.	Client Interview Tool	 Tool 3_Client Interview_English.docx
5.	Training Manual – Facilitators’ Guide (Adapted from Integrated Management of Newborn and Childhood Illness [IMNCI] Training Manual)	 Private sector_Facilitator's C
6.	Training Manual – Participants’ Manual (Adapted from IMNCI Training Manual)	 Private sector_Participant m