Management of YOUNG INFANTS with PSBI using SIMPLIFIED ANTIBIOTIC Regimen at the PRIMARY CARE LEVEL: Experience from Rural SAHARSA, BIHAR, INDIA



BACKGROUND

Possible Serious Bacterial Infection (PSBI) is one of the major causes of mortality among young infants in India with nearly one-third of the 760,000 newborns dying annually in India, succumbing to infections and sepsis (including pneumonia and diarrhea). The Government of India (Gol) has put in policies to ensure PSBI management at the Primary Health Care level covering both the health facility and the community. At the health facility, in-patient treatment with injectable antibiotics for Seven days for young infants with PSBI is recommended, while at the community level the Auxiliary Nurse Midwife (ANM) and Accredited Social Health Activist (ASHA) have been trained to identify the danger signs in young infants and administer single dose of oral antibiotic before referring the young infant to health facility. To further enhance treatment access for the population living in resource constrained settings, the GoI in 2014 authorized use of injectable antibiotic by the ANMs for





Source: Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. Liu et al. Lancet 2012; 379 (9832): 2151-2161.

management of sepsis in young infants under specific situations. The policy emphasizes screening for PSBI signs by the ANMs, giving pre-referral antibiotic dose, and referral to the higher facility for completion of treatment. However in case referral is not feasible or is refused by the family, the ANMs are authorized to complete the seven days course of treatment at the community level with the simplified antibiotic regime (injection Gentamicin once-a-day and oral Amoxicillin twice-daily).

Despite availability of policy guidelines at the primary care level, implementation across the country has been slow and inconsistent. This is particularly true for the 2014 policy of ANMs being authorized to complete antibiotic treatment where referral is refused or not feasible. An operational research study was undertaken to identify various challenges affecting PSBI management at primary care level, and explore ways of improving it. This study was conducted under the BMGF supported Integrated Family Health Initiative (IFHI) program in Bihar, in collaboration with the State Government of Bihar. CARE-India was the lead implementing partner in the project while Saving Newborn Lives (SNL), Save the Children was the technical partner for newborn health.

METHODOLOGY PRIMARY OBJECTIVE:

To learn what it takes to translate a policy on PSBI management at primary (health care level into implementation in a rural district of Bihar, India.



SECONDARY OBJECTIVES:

- To assess the changes from baseline in the proportions of families with sick young infants seeking care from the public health system subsequent to the implementation of our package of interventions
- To evaluate families' acceptability of the treatment offered at public health facilities in rural Bihar subsequent to the implementation of our package of interventions



STUDY AREA: The study was conducted in Saharsa district of Bihar, a designated High Priority District (HPD) under the Government of India's RMNCH+A Strategy.The district's Neonatal Mortality Rate (NMR) is 37 per 1000 live births, a figure which is substantially higher compared to the state average of 28 per 1000 live births. Similarly the Crude Birth Rate (CBR) is 32.1 per 1000 population compared to the state average of 21 per 1000 population. The population is largely agrarian with 86% of them being Hindus and the remaining 14% being Muslims.

For the study, 5 blocks (out of 10) were purposively selected based on geographical accessibility (the other 5 blocks become inaccessible for few months due to seasonal flooding every year). The combined population of these blocks is about one million; the literacy rate ranges from 38.5% to 46.5%, while the population of under-privileged sections (SC/ST) ranged from 11% to 21% (Census 2011).

STUDY DESIGN: A Study with pre-posttest assessments (hybrid design).

Neonatal

Mortality

Rate (NMR) is

Per 1000





STUDY DURATION: April 2015 to March 2017.

BASELINE ASSESSMENT

Baseline assessment consisted of mixed methods assessments viz. (house-to-house survey (quantitative), exploratory study (qualitative), and health facility assessments using structured checklists. The key findings were:

- Nearly half of the respondents (women who had delivered recently) were 20-24 years of age; 58% were illiterate and an additional 19% had up to primary education. Other backward classes comprised 55% of the respondents.
- There was high degree of contact with the public health sector during antenatal care, labor and delivery; however postnatal contacts were much infrequent.
- There was lack of knowledge of maternal and newborn care, and a poor record of following healthy practices. There were misconceptions about signs of severe illness while overall awareness was poor.





State Average Live Births Per 1000

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HEALTH SYSTEM PREPAREDNESS AT LEVEL OF PRIMARY CARE

Public Health Facility level (Primary Health Centers/PHCs & Additional PHCs):

- Functional out-patient (OPD) services for newborn care were minimal at the PHCs; on an average, only five newborns were seen per month at these centers. All sick newborns were referred either to District Hospital or private providers with few receiving pre-referral advice.
- None of the 19 APHCs had functional newborn OPD services.
- More than half (53%) of Medical Officers were in position and most of them had been formally trained in IMNCI/ F-IMNCI; however, over a period of time, their knowledge and case management skills had decreased.

Outreach/Community level:

- More than 80% ANMs were in position and IMNCI trained; however their confidence to identify and manage sick newborns was low
- Majority of the ANMs were not staying at the Sub-Health Centers (SHCs); none of the 101 SHCs had functional OPD services.
- The supply of Injection Gentamicin & Oral amoxicillin was erratic.
- Village Health, Sanitation and Nutrition Day (VHSND), the only functional platform of contact between ANM and newborns/mothers in the community, was primarily used for Routine Immunization and Antenatal Care only.

Home level

- Nearly 90% ASHAs were in place and formally trained for identifying danger signs in young infants; some of them even had the knowledge/skills of identifying danger signs for PSBI. They referred every young infant that appeared 'unwell' in any way (universal referral). However, in the absence of a referral health facility that assured of quality treatment for PSBI cases, the referral advice was imprecise, inconsistent and frequently failed to mobilize these babies to the public health system.
- ASHAs were provided with IEC material but messaging around PSBI & referral was missing



In addition, there were issues related to logistics, reporting/recording and data use, and supervisory mechanism at all the levels.

- Up to 44% of respondents reported at least one known symptom or sign of newborn sickness in the last three months prior to the survey. Of these, close to 60% reported at least two known danger signs while 30% reported at least three danger signs.
- Fever (29%), difficult/fast breathing (22%) and baby feeling cold to touch (23%) were the common danger signs reported by mothers during the newborn's most serious illness episode for which health care was sought. These episodes occurred within the first week after birth in nearly 25% of cases, and after the first week in 65% of cases.
- More than 90% sick newborns sought care, but almost exclusively outside the public health sector. Over half (55%) sought care from the private sector, 28% from the village doctor; only 4% sought care from public sector (Figure 3).
- Medications were provided in nearly all the cases (99% of cases), but the primary drugs for treatment (ampicillin, amoxicillin, gentamicin) were far less prescribed than the other drugs. Nearly 10% cases received second or third-generation antibiotics,

while vitamins (10%) and other non-antibiotics (23%) were also frequently prescribed.

STUDY APPROACH: Continuum of Newborn Care through Health System Strengthening

The Baseline Assessment had found gaps in the knowledge and skills of trained staff, logistics, record keeping, monitoring, and supervision. Two other notable gaps were the lack of availability of inpatient care for sick young infants at public health facilities, and lack of effective linkage between home, outreach (eg, community sub-centers staffed by ANMs) and health facility care. There was also an identified need to undertake social behavior change communication for the providers in the system so that they are confident to manage sick young infants with PSBI.

The Continuum-of-Newborn care (Home-Community-Facility continuum) approach was adopted to improve the management of PSBI by strengthening the existing health system platforms at the Primary Health Care level. External inputs were primarily focused on ensuring sustainability of efforts beyond the project life, and these included capacity building, logistics management, improving monitoring, supportive supervision, and data recording and reporting.

Figure 4 and Table 1depict the approaches used in the study to strengthen PSBI management at three

platforms within the primary level of care i.e. facility care at PHCs, community management through ANMs at sub-centers (wherever possible), and homebased care through ASHAs. All the interventions were delivered by the existing public health staff without any additional project personnel support.

Figure 4: Continuum-of-Care Approach of the Study to Health System Strengthening at the Primary Care Level

Platform Facility Primary Health Centre	Providers Medical Officer & Staff Nurse	 Service Provision Diagnosis Treatment with Simplified antibiotic (Inj. Gentamicin & oral amoxicillin) 	 Capacity building
Community Sub Health Centre & Outreach	Auxiliary Nurse Midwife (ANM)	 Referral to higher level facilities Identification & referral (inj. Gentamicin & oral amoxicillin) Treat PSBI when referral not possible (Inj. Gentamicin & oral amoxicillin) Follow-up & Full-course Treatment (Rx) completion Community Mobilization: Village Health, Sanitation and Nutrition Day (VHSND) 	 Logistics & supplies Monitoring and data use Supportive supervision
Home Home Based Newborn Care	Accredited Social Health Activist (ASHA)	 Home Visits & Counselling Indentification & referral of sick Newborn 	 Social Behavior Change Communication (SBCC)

 Table 1: Package of Interventions implemented to Strengthen PSBI management at the Primary Care level while

 leveraging existing program resources through adaptation and customization

PLATFORM	SERVICE PROVIDERS	KEY INPUTS TO STRENGTHENING THE SERVICE PROVISION	ADAPTATION/ADJUSTMENT
Health Facility: Primary Health Center/Sub- District Hospital	Medical Officer, Nurses/ANMs	 Training of MOs and Staff nurses on F-IMNCI Post-training on-site mentoring Hand holding support in management of OPD services, with priority for sick young infants Identification of nodal person at each PHC to improve access & ensure record keeping IEC material in OPDs Pre-discharge distribution of community calendar with signs of sepsis to recently delivered women in PHC 	 Five days Gol F-IMNCI module adapted to 3 days as per PHC need Out patient management of PSBI with simplified antibiotic initiated at PHC Empowerment of Nurse/ANM as the nodal person for PSBI management Timely forecasting of relevant supplies every month
Community: Sub Health Center & Outreach	ANMs (Outreach)	 Refresher training to ANMs at block level monthly meeting Supportive supervision by sector MOs. Facilitated adequate supply of antibiotics and syringes 	 Existing videos adapted into a refresher package Additional training on communication skills

PLATFORM	SERVICE PROVIDERS	KEY INPUTS TO STRENGTHENING THE SERVICE PROVISION	ADAPTATION/ADJUSTMENT
		 Support in follow-up for completion of treatment Job-aid on post-natal care (PNC) and sepsis management Regular follow-up and case discussion at SHC meetings 	 Utilization of VHSND session for screening of sick newborn and follow-up Job aids for ANM on PNC & sepsis management introduced. Improved communication between ANM & ASHA
Home	ASHAs and mothers/ families with young infants	 Refresher training on HBNC at regular block & sector level monthly meeting Strengthened Supportive supervision through Block Community Mobilizers (BCMs) Job-aid cum counselling card on postnatal care and identification of sepsis & referral Regular feedback and review by using ASHA monthly report Storytelling and audio messaging for self- motivation and pride at work Follow-up to all the young infants with PSBI who received treatment at public health system 	 Existing videos converted into a refresher package ASHAs required refresher on HBNC, which was otherwise "forgotten" or "never learned" Innovation mechanism introduced for young infants with PSBI who received treatment from public health facilities

THE MONITORING, EVALUATION AND LEARNING FRAMEWORK

Three data sources were used for monitoring and evaluation. The Government's existing reporting system was used for monitoring various activities, with 10% data validated by the research team. The project team also collected additional information on trainings of personnel and on tracking of sick young infants with PSBI who were initiated on antibiotic treatment at PHCs or from other providers in the public health system. This additional information from tracking was collected retrospectively

TRENDS FROM MONITORING DATA



During the 15 months of implementation, there was an overall improvement in the performance of the ASHAs and ANMs under the HBNC and IMNCI programs. For the HBNC program, a consistent increase was observed in the number of home visitation, number of ASHAs carrying HBNC kits during home visitation, and number of supervisory visits received by ASHAs. Reporting by ANMs on PSBI increased significantly from 34% to 94%. Improvement was also observed in availability of antibiotics and related supplies (Injection Gentamicin, Syrup Amoxicillin, 1 ml syringe) at both the PHCs and SHCs/ANMs. after 1-2 months of treatment initiation, and included type and severity of symptoms/signs of PSBI cases, their referral pattern, and details of antibiotic treatment (place, regime, duration, outcomes). Data trends were critically examined by the SNL team, learning's highlighted and document, and feedback provided to the district and block health program managers in review and quality assurance meetings every month.

TRENDS FROM THE TRACKING DATA

Figure 7: Number of Young Infants with PSBI who initiated treatment with Public Health system per 100 live births (n=1036)



Figure 8: % Young Infants with PSBI completing full course of treatment in Public Health system (n=1036)



During the 15 months of study intervention, there was a consistent increase in the number of young infants with PSBI who were initiated on treatment at the PHCs – from 1.7 per 100 live births (n=83/4891) in Dec'15-Feb'16 quarter to 5.5 per 100 live births (n=266/4846) in Dec'16-Feb'17 quarter. Of these, the proportion of young infants completing the full (7 day) course of antibiotic treatment (Injection Gentamicin + Syp Amoxicillin) ranged between 63% and 77%, with the average treatment completion rate of 70%.

Figure 9: Place of completing full course of Treatment



Of the 70% Infants with PSBI completing full course of antibiotic treatment within the Public Health system, majority of cases (93%) received all seven doses at the PHCs. In the remaining 7% cases, ANMs were involved in providing treatment usually in combination with the PHC and private providers.

Of the PSBI cases who received treatment in the Public Health system (partial or complete), more than 95% cases had survived and were thriving well. A total of 9 deaths were reported (case fatality less than 1%) and all these took place during the course of treatment between the 1st and 3rd day of treatment. More than 2% cases were lost to follow-up.

Another important observation was the increased proportion of clinically severe cases of PSBI (with at least one of the severe features – lethargy, hypothermia/ hyperthermia, poor feeding, unconsciousness or convulsions) being treated in the Public Health system. Figure 10: Outcome of Young Infants with PSBI who initiated treatment at PHC (n=1036)



ENDLINE ASSESSMENTS

The endline assessments were conducted in the first quarter of 2017. These included (i) a qualitative exploration with stakeholders (program managers, providers, beneficiaries and community representatives) of how and why things had progressed/ changed the way they did through the course of implementation of the project package, and (ii) a quantitative house-to-house survey (n= 1726). The participants for both qualitative and quantitative assessments were sampled from all the five study blocks with due consideration to representativeness and dispersion.

Qualitative Assessment

 There was a perceivable increase in the pregnancy and postnatal contact between frontline workers and beneficiaries.

- The ASHAs and ANMs felt confident in identifying the clinical features of PSBI and in making a timely and efficient referral to the PHC. Their self-esteem had increased.
- Though the skill set of ANMs had improved considerably, hey were still in the process of owning up the responsibility of managing sick young infants with PSBI.
- The PHC had evolved as a lead player in confirmation and management of young infants with PSBI.
- The trust of communities in the facilities and in the primary health providers was stronger than before not just for PSBI, but also for general illness.
- Lack of adequate infrastructure and inconsistent logistic supplies continued to pose challenges to care in the public health system, especially with an improved mobilization of young infants with PSBI for seven day antibiotic course in the system.

QUANTITATIVE HOUSE-TO-HOUSE SURVEY



Figure 11: Symptoms reported by mother of sick newborns with PSBI





While only 4.6% of the sick newborns had ever received any treatment from the public health facility at baseline, the statistic changed to 19.4% at end line (p<0.0001) with an Adjusted Odds Ratio (AOR) of 4.27 (p<0.0001).

On the other hand, care seeking from the private sector for sick newborns slumped from 24.8% at baseline to 11.0% at endline (p<0.0001) with AOR=0.67 (p=0.0202).

For sick newborns with PSBI, there was five-fold rise in care seeking from the providers in the public health system while the private sector (organized) registered a 14 percentage point reduction. There was no remarkable change in care seeking from the local practitioners but the project team learnt that even these practitioners had started using the simplified antibiotic regimen instead of haphazard use of higher antibiotics (vide informal interactions with local practitioners).

KEY LESSONS: GUIDANCE FOR IMPROVING IMPLEMENTATION

The key lessons learnt from our work can be summed up in following categories:

- Effective implementation of the policy on **PSBI** management at **Primary** Care level requires strong linkages between the three levels of service delivery and their service providers. ASHAs are responsible for early identification and referral of PSBI cases for treatment; the ANMs are either not available or hesitant to start the treatment. Medical officers and Staff nurses of PHCs need to take lead in initiating the treatment which can then be completed by ANMs (or at PHC if she is unavailable) with proper follow-up by ASHAs. Hence, the overall management is an integrated team effort. This is relevant not only for PSBI management in young infants, but also for other maternal and childhood illnesses, and beyond it to other domains covered under RMNCH+A strategy.
- Strengthening the existing health system delivery platforms while simultaneously introducing 'newer policies' requires innovative approaches for effective implementation. Block as the unit of planning with PHC as the 'activity hub' helped in a more realistic planning and coordinated implementation.

Adaptation of existing training curriculum (5-day F-IMNCI module to 3-day module for PHC) and introduction of rapid refresher training packages (for ANMs, ASHAs) catalyzed capacity building efforts within the system. Regular meetings and discussion (on reports, records, case follow-up) facilitated by the system supervisors ensured improved communication and ownership of the process.

A functional Primary Health Centre plays a vital role in improving primary care for the community. Improving availability and quality of services at the PHC helped in not only building the trust of the communities, but also facilitated confidence building among ASHAs and ANMs. There was a significant shift of cases from the private to the public sector with PHCs acting as the primary site for management of PSBI in young infants. This holds promise for standardized management practices at the primary care level by the multitude of care providers while simultaneously reducing potential abuse of antibiotics and out-of-pocket expenses for the care seeker. Moreover the centers acted as 'Activity Hubs' for refresher trainings and monthly meetings, leading to improved coordination and ownership of the process at the primary care level.

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