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A High-Impact Intervention: Institutionalizing Newborn Vaccination

EXPERIENCE FROM INDIA

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The Maternal and Child Health Integrated Program (MCHIP) is the USAID Bureau for Global Health's flagship maternal, neonatal and child health (MNCH) program. MCHIP supports programming in maternal, newborn and child health, immunization, family planning, malaria, nutrition, and HIV/AIDS, and strongly encourages opportunities for integration. Cross-cutting technical areas include water, sanitation, hygiene, urban health and health systems strengthening.

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Abbreviations

BCG	Bacillus Calmette-Guerin
CES	Coverage Evaluation Survey
EPI	Expanded Program on Immunization
JSY	<i>Janani Suraksha Yojna</i>
MCHIP	Maternal and Child Health Integrated Program
MCTS	Maternal and Child Tracking System
NFHS	National Family Health Survey
OPV	Oral Polio Vaccine
UIP	Universal Immunization Program
VPD	Vaccine-Preventable Diseases
WHO	World Health Organization

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Background

The efficacy of vaccines in preventing certain serious illnesses and diseases, known as “vaccine-preventable diseases” (VPD), has been well-proven. Children inherit some degree of transient passive immunity from their mothers, but this dissipates rapidly in the case of some VPDs for longer periods. Hence it is essential that all newborns be provided vaccination against certain VPDs as early as possible after birth. This practice is helpful in boosting newborns’ immunity, preventing early infections, priming the antigenic response to subsequent doses of the same vaccines, as well as linking newborns to the immunization program.

World Health Organization (WHO) position papers recommend administration of three vaccines— Oral Polio Vaccine (OPV), Bacillus Calmette-Guerin (BCG), and Hepatitis B vaccine—as early as possible after birth, preferably within 24 hours. Early administration of these vaccines has evidence-based benefits as described below:

Oral Polio Vaccine	Ensuring the earliest possible immunity shield for newborns assumes great significance for polio eradication. This necessitates administration of a birth dose of OPV (known as the zero dose) in all polio-endemic countries and in countries at high risk for importation and subsequent spread. Administered as soon as possible after birth, OPV significantly improves the sero-conversion rates of subsequent doses, and induces mucosal protection before enteric pathogens can interfere with the immune response.
BCG	One dose of BCG vaccine as early as possible after birth is recommended in countries with a high burden of tuberculosis (like India) in order to provide protection against TB meningitis and disseminated TB disease during childhood.
Hepatitis B	One dose of Hepatitis B vaccine given within 24 hours of birth (the birth dose) helps to prevent perinatal transmission of infection, which accounts for more than one-third of chronic infections in areas of low endemicity. A Hepatitis-B birth dose is advocated by WHO as a critical indicator for measuring performance of all immunization programs.

Rationale

The Universal Immunization Program (UIP), launched by the Government of India 1985, follows a specific immunization schedule for vaccines, doses, and appropriate ages for vaccination.¹ This schedule is revised periodically based on scientific evidence and when new vaccines are introduced. The national immunization schedule in India aligns very well with WHO guidelines.

India's immunization program is one of the leading public health programs in the country, and it provides a platform for delivery of other mother and child health interventions. The program has achieved gradual improvements in immunization coverage since its inception in 1978 as the Expanded Program on Immunization (EPI). The National Family Health Survey (NFHS)² series revealed increased proportions of fully immunized children in the country from 35.4% (1992–93) to 43.5% (2005–06), with concomitant increases in coverage of all the antigens. The District Level Household Survey (2007–08)³ and more recent Coverage Evaluation Survey (CES 2009)⁴ showed full immunization coverage at 53.5% and 61% respectively.

Table 1 shows coverage data for BCG, OPV, and Hep-B at birth along with full immunization coverage for children as per different coverage evaluation surveys. It can be seen that the coverage with BCG is high, but no data are available on the birth dose of BCG. Coverage for the OPV birth dose is minimal, and coverage for the birth dose of Hep-B vaccine has been available since 2011 when the vaccine was universalized in India.

Table 1: Status of Coverage of Newborn Vaccines as per Different Evaluations

EVALUATION SURVEY	BCG COVERAGE	OPV ZERO DOSE COVERAGE	HEP B BIRTH DOSE COVERAGE*
NFHS 1 (1992–93)	62.2% (Range: 93.5% Goa–19.4% Nagaland)	4.6% (Range: 19.4% Tamil Nadu–0.8% Tripura)	
NFHS 3 (2005–06)	78.1% (Range: 99.5% Tamil Nadu–46.3% Nagaland)	48.4% (Range: 94.5% Tamil Nadu–13.2% Nagaland)	
DLHS 3 (2007–08)	86.7% (Range: 100% Lakshadweep–73.3% Uttar Pradesh)	20.1% (Range: 100% Puducherry–33.1% Rajasthan)	
CES (2009)	86.9% (Range: 100% Sikkim–66.1% Nagaland)	66% (Range: 92.3% Maharashtra–19.5% Nagaland)	29.2%

* Hepatitis B vaccination was phased into the National Immunization Schedule from 2007–08 across different states of the country.

The country has witnessed a rising trend of institutional deliveries, thanks to the JSY⁵ (*Janani Suraksha Yojna*) scheme launched by the Government of India. This rising trend enables vaccination of newborns in health care facilities immediately after the birth to contribute to

¹ Ministry of Health and Family Welfare, Government of India. *Immunization Handbook for Medical Officers*, 2009.

² International Institute for Population Sciences (IIPS), *National Family Health Surveys*.

³ International Institute for Population Sciences (IIPS), 2010. *District Level Household and Facility Survey (DLHS-3), 2007–08: India: Key Indicators: States and Districts*, Mumbai: IIPS.

⁴ UNICEF Coverage Evaluation Survey, 2009 National Fact Sheet.

⁵ Janani Suraksha Yojana (JSY) is a safe motherhood intervention under the National Rural Health Mission (NHM). <http://nrhm.gov.in/nrhm-components/rmnch-a/maternal-health/janani-suraksha-yojana/background.html>.

early immunization and coverage. Apart from this, more facility births should also facilitate early registration of beneficiaries in the Maternal and Child Tracking System (MCTS).

To understand the underlying constraints and conceptualize a practical roadmap to ensure timely vaccination of newborns/infants across all health facilities where deliveries are conducted, the Maternal and Child Health Integrated Program (MCHIP)⁶ undertook an assessment of childhood vaccination in delivery facilities, followed by interventions in five focus districts in the states of Jharkhand and Uttar Pradesh.

Findings from MCHIP's Preliminary Assessment

MCHIP carried out an initial assessment from January to June 2011 in two districts of Jharkhand (Deoghar and Jamtara) and three districts of Uttar Pradesh (Banda, Gonda, and Varanasi) with the aim of understanding the status of newborn vaccination and the knowledge and practices of health staff. Forty-six district and sub-district health facilities were short-listed in these five focus districts on the basis of availability of a functional cold chain point (vaccine storage) and a labor room.

The assessment involved evaluation of practices followed by health staff for newborn vaccination and level of awareness of relevant government policies and guidelines. Besides this, availability of records (e.g., delivery register and immunization clinic register) and reports (monthly facility reports) were reviewed and retrospective data were collected on the newborns vaccinated.

KEY OBSERVATIONS

- Lack of awareness among health care staff about the importance of early immunization
During the assessment, it was observed that at the majority of the facilities, deliveries were conducted by staff nurses or Auxiliary Nurse Midwives. At most facilities, delivery room staff were not aware of the additional benefits of early vaccination. The staff acknowledged that BCG and OPV vaccines need to be administered to newborns before the mother is discharged from the facility.
- Concern for vaccine wastage
Because the “Open Vial Policy” was not implemented before October 2011, an important barrier to vaccinating every newborn was health workers’ reluctance to waste vaccines by opening a multi-dose vial for one or two beneficiaries. This is particularly pertinent to BCG vaccine, which is a freeze-dried, 10-dose vaccine and, as per the operational guidelines, all remaining reconstituted vaccine doses should be discarded within four hours after reconstitution.⁷ Even the facility in-charges and district-level program managers were found to be reluctant to open a new vial to vaccinate a single newborn (although guidelines do favor opening a vial in this case), owing to increased wastage.
- Absence of one vaccine compromised the other
In an effort to administer the birth vaccines, i.e., BCG, OPV, and Hep-B, at the same time, unavailability of one vaccine compromised the administration of the other. It was also observed that vaccination was being done only during the clinic hours and not round the clock. As a result, infants delivered during non-clinic hours were often not vaccinated. In

⁶ MCHIP is a USAID-supported project, which, along with other thematic areas, is also providing technical assistance for strengthening routine immunization in two states of Jharkhand and Uttar Pradesh. The project is also piloting high-impact interventions in five focus districts of these two states.

⁷ Ministry of Health and Family Welfare, Government of India. *Immunization Handbook for Medical Officers*, 2009.

some of the facilities, it was observed that there was no structured mechanism for issuing vaccines to the delivery room.

Variability in Records and Reports

An important finding that came to light was non-uniform methods of recording and reporting systems and templates at different health facilities. It was observed that at the majority of facilities, the delivery registers had no space to record newborn vaccinations. Lack of a standardized format compromised the recording and reporting of newborn vaccinations in both Jharkhand and Uttar Pradesh.

- Low percentage of vaccinations in relation to the number of deliveries conducted
Data on newborn vaccination were compiled and analyzed from the records and reports (delivery registers and other available records, e.g., immunization clinic registers) at all 46 health facilities for January to June 2011 and compared to total deliveries conducted. Findings revealed that approximately one-third of newborns being delivered at government health facilities were receiving BCG vaccine and OPV zero dose (36.6% and 33.4% newborn receiving BCG, and 36.8% and 38.8% receiving OPV zero dose in Jharkhand and Uttar Pradesh, respectively). Data were not available for Hepatitis B vaccine because it was not included in the immunization schedule until October 2011.
As per the Coverage Evaluation Survey (CES) 2009, the major underlying reason for partially or unimmunized children was parents' lack of awareness of the immunization schedule and its importance.⁸ This prevailing situation demanded not only action at the health facility level but also a holistic effort at all levels to ensure that an appropriate policy framework and functional monitoring and review mechanisms are in place.

The Intervention

An intervention study was initiated in the same 46 health facilities in five focus districts of Jharkhand and Uttar Pradesh from July 2011 onward. This study provided a roadmap to develop an intervention aiming to strengthen newborn vaccination, specifically for babies delivered at government health facilities. The results from this intervention of improving overall immunization status of the community were demonstrated to policymakers, program managers, and stakeholders.

METHODOLOGY

The initial step was to sensitize district and block-level officials and concerned staff members from the health department during staff review meetings about:

- Key findings from the preliminary assessment,
- Existing policies and operational guidelines regarding newborn vaccination, and
- Steps required to improve newborn vaccination in the facilities.

This step was followed by specific activities in a phased manner over the successive months. These included:

1. Capacity building and conducting on-the-job orientation of staff nurses and Auxiliary Nurse Midwives posted in delivery rooms for birth/newborn vaccination;
2. Developing a mechanism for supplying required vaccines and diluents in vaccine carriers to the delivery room and ensuring their availability round the clock;

⁸ Government of India and UNICEF, Coverage Evaluation Survey, 2009.

3. Incorporating separate columns in the delivery registers for recording vaccinations administered and, if not given, to capture the reason;
4. Ensuring that regular reporting of newborn vaccinations was done along with the ongoing daily reporting of deliveries conducted under *Janani Suraksha Yojna (JSY)*; and
5. Including this practice as an agenda item for regular discussion during the supervisory visits and review meetings.



Picture 1: Demonstrating to the nursing staff how to fill out the MCH Card and update the delivery register for vaccination in the delivery room



Picture 2: Logistics for vaccination placed in delivery room to facilitate newborn vaccination



Picture 3: Nursing staff updating a newborn's vaccination status in the delivery register and MCP Card

Results

The continued advocacy, technical support, feedback, and feed-forward within the health department resulted in gradual adoption of the new practices and improvements in coverage among newborns delivered at these health facilities, as shown in Table 2.

Table 2: Initial Status and Progress of Newborn Vaccination during Intervention

PERIOD	JHARKHAND (2 DISTRICTS, 13 HEALTH FACILITIES)				UTTAR PRADESH (3 DISTRICTS, 33 HEALTH FACILITIES)			
	Total deliveries	BCG coverage	OPV zero dose coverage	Hep B birth dose coverage	Total deliveries	BCG coverage	OPV zero dose coverage	Hep B birth dose coverage
Jan–June 2011	5,638	36.6%	36.8%		30,161	33.4%	38.8%	
Jul–Dec 2011	9,366	66.3%	61.7%	12.0%	46,825	53.1%	53.4%	1.2%
Jan–June 2012	8,692	76.2%	69.6%	69.1%	31,723	55.1%	69.0%	59.4%
Jul–Dec 2012	10,753	79.6%	74.4%	74.3%	43,115	67.1%	78.4%	74.7%
Jan–June 2013	9,349	82.4%	83.9%	81.3%	30,249	60.6%	75.4%	64.2%



Picture 4: Newborn vaccination accounted for on the MCP Card in the delivery room

The coverage data compiled for 6-month periods revealed progressive improvements not only for BCG and zero dose of OPV but also a sharp increase in coverage of Hepatitis B birth dose, as soon as the vaccine was introduced in the immunization schedule in November–December 2011 in both the states.

The intervention resulted in timely vaccination of an additional 26,000 children with BCG vaccine and 30,000 children with zero dose of OPV in the 6 months between January and June 2013, more than the total number of births occurring annually in such countries as Bahrain, Latvia, and Qatar.⁹

⁹ UNICEF, *The State of World's Children*, 2013.

Lessons and Implications

The practice of vaccinating newborns delivered at health facilities as early as possible after birth is easy to implement and replicate in other facilities. Sustaining the ability to carry out the new practices and procedures should ensure improved immunization coverage and protection against targeted vaccine-preventable diseases. The other benefit is early registration of infants in the health facility records for subsequent follow-up for complete immunization.

Some of the hurdles faced initially were because of administrative staff structures and program priorities in different states, including leadership issues, inequitable distribution of service providers and facilities, and a mismatch between demand and supply. Stock-outs of vaccines were one of the issues during the intervention period that limited improvements in coverage.

However, contrary to expectations, resistance from mothers and caretakers to vaccination of their newborns was minimal. Most missed opportunities resulted from mothers not staying overnight or for the required period of time after delivery at the health facilities. This finding indicates the importance of vaccinating newborns delivered at health facilities as early as possible. The outcome of the intervention is the number of newborns vaccinated by adoption of this easy-to-follow practice. Once scaled up, the intervention will lead to improvements in vaccination coverage, early vaccination, and immunity, and ensuring timeliness of vaccinations. The state-level program managers in Jharkhand and Uttar Pradesh issued clear instructions and guidelines to district officials to ensure vaccination of all newborns delivered at government health facilities with the three vaccines (BCG, OPV, and Hepatitis B) before the mother is discharged. To ensure compliance with this instruction, another government order in these states is linked to the ongoing JSY initiative. The latter order instructed district and block-level officials to release the JSY incentive only after ensuring that the newborn is vaccinated and an immunization card is issued to the child.

Conclusion

The importance of early vaccination of newborns with birth doses is well-established. The results of this intervention, in limited geographical areas of the poor-performing states of Jharkhand and Uttar Pradesh, indicate that advocacy and synchronized technical inputs for capacity building, system strengthening, concurrent monitoring, and review can improve the practice and help build early immunity against three vaccine-preventable diseases among the newborns delivered at the health facilities. Implementation and sustainability for ensuring the desired impact over time require timely policy reforms in light of scientific advances and evidence appropriately backed with operational guidelines.

