Experiences From an Implementation Model of ARI Diagnostic Device in Pneumonia Case Management Among Under-5 Children in Peripheral Healthcare Centers in India

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ABSTRACT

OBJECTIVES: To address pneumonia, a major killer of under-5 children in India, a multimodal pulse oximeter was implemented in Health and Wellness Centers. Given the evidence of pulse oximetry in effective pneumonia management and taking into account the inadequate skills of front-line healthcare workers in case management, the device was introduced to help them readily diagnose and treat a child and to examine usability of the device.

DESIGN: The implementation was integrated with the routine OPD of primary health centers for 15 months after healthcare workers were provided with an abridged IMNCI training. Monthly facility data was collected to examine case management with the diagnostic device. Feedback on usefulness of the device was obtained.

SETTING: Health and Wellness Centers (19) of 7 states were selected in consultation with state National Health Mission based on patient footfall.

PARTICIPANTS: Under-5 children presenting with ARI symptoms at the OPD.

RESULTS: Of 4846 children, 0.1% were diagnosed with severe pneumonia and 23% were diagnosed with pneumonia. As per device readings, correct referrals were made of 77.6% of cases of severe pneumonia, and 81% of pneumonia cases were correctly given antibiotics. The Pulse oximeter was highly acceptable among health workers as it helped in timely classification and treatment of pneumonia. It had no maintenance issue and battery was long-lasting.

CONCLUSION: Pulse oximeter implementation was doable and acceptable among health workers. Together with IMNCI training, PO in primary care settings is a feasible approach to provide equitable care to under-5 children.

KEYWORDS: Childhood pneumonia, primary health care, pulse oximeter, front-line health worker, India

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Introduction

Status of pneumonia in India

Pneumonia contributes to 15% of child death across the world with India accounting for 20% of these deaths.[1] India has progressed in reducing under 5 child mortality in the last decade but deaths due to pneumonia is still a challenge. There are state variations with pneumonia and diarrhea being the leading causes of death in states with high under-5 mortality.[2] With the current under 5 mortality rate (U5MR) of 36 (SRS 2018), India needs to aggressively address pneumonia and diarrhea deaths to achieve SDG3 target of 25 by 2030. India launched the ARI program in 1990 and amalgamated it with the Integrated Management of Neonatal and Childhood Illnesses (IMNCI) program since 2005. The Indian Association for Prevention of Pneumonia and Diarrhoea (IAPPD), additionally, aims to reduce pneumonia and diarrhea through integrated protection, prevention, and treatment.

ARI diagnostic devices

WHO recommends counting Respiratory Rate (RR) and recording SpO_2 for effective management of pneumonia. However, pulse oximeter (PO) is currently not available at primary health centers in the country and available evidence indicates a lack of diagnostic precision of childhood pneumonia based only on clinical symptoms.[3] Manually recording respiratory rate (RR) is a challenge and leads to misclassification of the symptoms[3-6] while

chest in-drawing is not adequately recognized.[7] Low knowledge scores were found among providers of government facilities for the management of severe childhood pneumonia.[8] The addition of pulse oximetry (PO) to IMCI guidelines has been found to be cost-effective and to avert 148 000 deaths among children with pneumonia in the top 15 countries with the highest disease burden.[8] A 2-fold increase in referrals for children having low SpO_2, who were earlier missed, confirmed the potential utility of pulse oximetry in primary healthcare (PHC) settings.[9] These findings led to renewed efforts in LMIC to improve pneumonia case management with multi-modal pulse oximeterition of diagnostic devices that measured SpO_2 and respiratory rate. However, implementation studies in primary healthcare settings are demonstrably few.[10-12] Meanwhile, as RR measurement is particularly challenging for frontline health workers, improved RR diagnostic aids have been introduced and evaluated in several LMIC.[13,14] They highlight the usability of certain devices but recommend further evaluation of devices especially from end-users perspectives.

The updated Global Action Plan launched by WHO and UNICEF—*Integrated Global Action Plan for the Control and Prevention of Pneumonia and* Diarrhea—emphasized the criticality of integrating levels of care in reducing deaths from pneumonia and diarrhea. The plan addresses the urgent need for a coordinated and collaborative implementation across communities, clinics, districts, institutions, and countries (Survive and thrive: transforming care for every small and sick newborn. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO).[5] In this context, a continuum of care of under-5 children from the primary to secondary and tertiary level was emphasized wherein strengthening of primary health facilities to deliver quality care to children would be a focus to lessen the burden on higher facilities. Meanwhile, India's efforts toward reduction in under 5 mortality saw the introduction of the national guidelines, "Social Awareness and Actions to Neutralize Pneumonia Successfully (SAANS)" wherein the use of pulse oximeter for improved pneumonia management was recognized and approved. However, apart from tertiary level public and private health facilities and secondary level district hospitals, pulse oximeter was rarely available or used in primary healthcare level, a system that serves 65% of the Indian population.

Community health centers covering 120 000 population and primary health centers covering 30 000 population of a block in a district form the bulk the Indian public health system. Under the Ayushman Bharat scheme of the Government of India (GOI), 150 000 primary health facilities that all along had offered integrated basic curative and preventive health care to the rural population were converted to Health and Wellness Centers (HWC). These offered an expanded range of services including screening, diagnosis and management of non-communicable diseases as well the regular range of services including child, maternal, and neonatal care.[15] The center is headed by a Community Health Officer (CHO)/Medical Officer (MO) supported by Auxiliary Nurse Midwife and Community Health Workers. CHO/MO are AYUSH doctors who are trained in traditional medicine. The center is equipped with 2 to 3 clinical staff supported by at least 2 community health workers and 1 pharmacist. Primary health facilities/Health and Wellness centers are the first point of care for pneumonia cases. Referral facilities handle management of critical cases of pneumonia requiring advanced interventions. It is critical to strengthen primary health facilities as majority of the under-5 population who are most at risk of dying from pneumonia would be enabled to easily and timely access diagnosis and treatment at the nearest center.

Rapid situation assessment to understand current status of ARI case management in primary care

To understand case management protocols of ARI in under-5 children project undertook a rapid assessment of 25 HWC in Aspirational districts of 7 states—Haryana, Jharkhand, Odisha, Uttarakhand, Himachal Pradesh, Punjab, and Chhattisgarh. Aspirational districts are districts that have lagged behind others in health and development indicators and are, thus currently, the focus of the government for accelerated improvement. Review of facility records of 3 months revealed that documentation was poor—very few records reported diagnosis, rest mentioned presenting complaint. There were no records related to signs, classification, and treatment. Nearly 60% of the 2528 children visiting the centers during the 3 months were reported to have ARI symptoms out of whom 8.4% were reported as having pneumonia of which less than 1% was referred and 80% were prescribed antibiotics. Assessment, based on IMCI algorithm, revealed that the majority of the HWC staff lacked knowledge on how to correctly assess a child with cough or difficult breathing. While 75% of them did not know how to count RR 80% did not how to look for chest indrawing. Almost 90% were unable to enumerate all the danger signs of ARI. More than half had not heard of a pulse oximeter and it was not available in any of the facilities. Stock out of drugs was reported at least once during the 3 months in 9 facilities.

Considering the need for improved pneumonia management in HWC, the project decided to pilot an implementation of multi-modal pulse oximeter (PO) in a few selected HWC using IMNCI as the platform for training.

The project had an initial discussion with the GoI child health division and various states about the proposed intervention and how it can be integrated within the existing operational model of HWC. The team conducted a desk review of available pulse oximeter in the market, and found the Masimo Rad-G multimodal device with both RR and oxygen saturation capacity to be promising. The device has rechargeable

battery and LCD display, and comes with a single probe which can be used across all children under 5 years of age. It uses Masimo Measure-through Motion and Low Perfusion™ SET® pulse oximetry technology to measure SpO_2, respiration rate from the Pleth (RRp™), pulse rate (PR), and perfusion index (PI).

To validate its efficacy of RR counting, an initial study was conducted in partnership with the Kalawati Saran Children's Hospital which was already using the device. The results showed strong association (97%, $P < .001$) between a pediatrician's manual counting and the plethysmograph based RR.[16] RR measured by the device had a sensitivity of 95% and specificity of nearly 94%. It was subsequently introduced in 19 HWC in Aspirational Districts of the states of Jharkhand, Odisha, Chhattisgarh, Uttarakhand, Punjab, Haryana, and Himachal Pradesh. The current article reports on the results of 15 months of implementation.

Methods

Objectives of implementation

The broad objective was to examine the implementability and usefulness of the device in the HWC. Specifically, we sought to

(1) establish correct clinical case management procedures of ARI based on age-appropriate classification, identification, and treatment of under-5 children in OPD as per multimodal device reading
(2) examine the usability and durability of the multimodal device.

Selection of implementation site

Based on facility resources, accessibility, and patient footfall, 19 facilities were finalized for implementation in consultation with state government. The facilities were located in the aspirational districts of 7 states.

Process of implementation

The PO implementation started with a shortened version of IMNCI training for service providers from HWC. Three regional trainings were conducted. On the job training was also conducted for supporting PO use. One PO was provided to each HWC free of cost by the manufacturers with the support of the state governments and Child Health Division of NHM.

Data management and monitoring

OPD registers added a few new columns as shown in the format below:

Child's age and sex	Oxygen saturation as per the MMD	Respiratory rate as per the MMD	Chest in-drawing (Y/N)	General Danger Signs (Y/N)	Classification	Action taken-Treated/referred/ others

Clinical data of children were recorded in this standard format and collated at state level from June 2019. Monitoring indicators were as follows:

- % Cases of fast breathing, $SpO_2 < 90$, chest indrawing, general danger signs out of total cases
- % Amoxycillin given in ARI cases out of total cases
- % Referrals out of total cases
- % Reached Higher facility out of referred cases
- % Correct case management

Every month, data was entered in web based portal of Vriddhi project by state project consultants and compiled at national level for analysis and feedback to states and HWCs. Mentoring visits by project consultants were regularly conducted during which skills of service providers were assessed along with performance of the device, time taken to display reading and managing cases, correctness of case management and follow up of the referred cases. Registers were reviewed along with follow up of the children diagnosed with Pneumonia and Severe Pneumonia. The follow up was conducted telephonically usually by the service provider. In those cases that were not followed up, the Vriddhi consultant did the needful.

Qualitative feedback from providers

Midway through the implementation, the project collected feedback from 23 providers—consisting of the total sample of the staff who were using the PO device. Providers who were trained at the pre-service training were the ones to use the device. A structured as well as a semi-structured questionnaire was used by 6 national Vriddhi team members to conduct the interviews. The interviewers were from the project national team who had been oriented with qualitative research techniques in a 1-day training. They visited the HWC individually or in teams of 2. The structured questionnaire was administered first. The participant was asked to measure RR and SpO_2 of the interviewer with the device, and the time taken for reading noted down. The semi-structured tool was used as a guide to probe details on acceptability. Interviews were recorded with permission.

Data analysis

Health providers screened children presenting in the facility with symptoms of ARI with the PO. Based on symptoms, SpO_2 and RR count, the children were classified into 3 categories: severe pneumonia, pneumonia, and no pneumonia. Children with no pneumonia were treated with paracetamol in case of fever and advised home remedies. No antibiotics, anti-histamine,

and cough syrups were prescribed to such children. Children with pneumonia were prescribed antibiotics as per IMNCI recommendation and followed up till recovery. Children with Severe Pneumonia were referred to higher facility and followed up to ensure compliance and record outcome.

Monthly tabulation of cases was done by the project data manager. Data was analyzed at various levels:

1. It was disaggregated by age to find out the proportion of cases that had fast breathing, according to IMCI algorithm.
2. Data on referrals and antibiotic use for general danger signs (GDS) and $SpO_2 \leq 90$ was used to find out correct management of cases:

   GDS or SpO2<=90 is referred = Yes

   Or

   Fast breathing or chest indrawing and amoxicillin given = Yes

   Or

   If above both none then no amoxicillin given = Yes

3. Total ARI cases with diagnosis

For qualitative analysis, transcripts were read, coded, and analyzed by the research advisor using ATLAS ti. An apriori code list was prepared based on topics of the questionnaire. Responses were categorized and compared and a final thematic framework was prepared.

Ethical approval

Permission was obtained at the national level from the Child Health division of NHM, the state governments, and state NHM for the implementation of the intervention. Regular facility data was obtained with multi-modal pulse oximeterition of only 2 new columns on oxygen saturation and RR reading. Anonymity and patients'/clinicians' rights were respected. The data collected came under the category of "research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies" which are waived from voluntary informed consent process.[17]

Results

A total of 4846 children with ARI symptoms visited the facilities over the 15 month period from June 2019 to August 2020. The PO used to assess them was robust and had no maintenance issue except for the probe of 1 device which malfunctioned and was replaced. Readings took about 1 minute for the majority of cases. The PO made the task of diagnosis and treatment easy for the healthcare worker (HW) according to qualitative feedback.

We used the IMNCI classification for children 2 months to 5 years as the following:

Severe pneumonia: $SpO_2 < 90$ or presence of general danger signs.

Pneumonia: fast breathing or chest in-drawing.

No pneumonia: none of the above signs.

The providers were instructed to diagnose and treat children between 2 and 59 months, however, during OPD hours sick infants <1 month were also brought in by parents who could not be refused treatment. Overall, 0.1% of the children were diagnosed with severe pneumonia and 23% were diagnosed with pneumonia. There was no difference in disease severity between male and female children. There is a significant difference in pneumonia status between states (Table 1).

A total of 29 children had $SpO_2 < 90$, 1283 had fast breathing, 141 had chest indrawing, and 38 showed general danger signs (GDS). Hypoxia was correlated with fast breathing in 26 children, danger signs in 8 children, and chest indrawing in 17 children. Two children had hypoxia and no other symptoms.

About 1.1% of all children were referred, 27% were treated with antibiotics, 71.7% were treated with home remedies. Based on correct case management, 77.6% children with $SpO_2 < 90$ or danger signs or any other valid reason were correctly referred (Table 2). We considered the following to be valid referrals: severe malnutrition (n = 3) and to access antibiotic when it was unavailable at the HWC (n = 2). Approximately 76% children were found to have complied with referral, and had positive outcome.

Of all the cases of children given antibiotics, 81% had fast breathing or chest indrawing or other symptoms requiring antibiotics such as local bacterial infection, wound, urine infection, or Possible Serious Bacterial Infection (PSBI). Similarly, 71.7% of children with no difficulty in breathing, danger signs, or hypoxia were not given antibiotics or referred but were provided paracetamol or home remedies (Table 3). A total of 416 children were given incorrect treatment (inappropriate referral, inappropriate antibiotics, inappropriate home remedy) (Table 4). In total, 4430 children (91.4%) visiting the facilities with ARI were correctly managed.

As chest indrawing was the only clinical sign apart from danger signs that was used for classification, we were interested to see it's relationship with SpO_2, RR, and GDS. Among 141 cases of chest indrawing, 133 also had symptoms of fast breathing, 17 cases had $SpO_2 < 90$, and 15 cases had GDS. There were 6 cases (4.2%) of chest indrawing with no other symptom.

Table 1. Characteristics of sample (N = 4846).

STATE	SEVERE PNEUMONIA	PNEUMONIA (%)	NO PNEUMONIA (%)	TOTAL	*P* (χ^2)
Chhattisgarh	20 (2.5%)	204 (25.3)	582 (72.2)	806	.000
Haryana	3 (0.3%)	244 (29.3)	586 (70.3)	833	
Himachal	2 (1.1%)	17 (9.0)	171 (90.0)	190	
Jharkhand	13 (0.8)	505 (29.9)	1170 (69.3)	1688	
Odisha	16 (2.6)	105 (16.9)	499 (80.5)	620	
Punjab	4 (1.2)	125 (35.8)	220 (63.0)	349	
Uttarakhand	1 (0.3)	35 (9.7)	324 (90.0)	360	
Child sex					
Male	28 (1.1%)	651 (25.4)	1888 (73.6)	2567	.670
Female	31 (1.4%)	584 (25.6)	1664 (73.0)	2279	
Age of child					
<2 months	0 (0.0%)	9 (11.5)	69 (88.5)	78	.003
2 month-1 year	23 (1.5%)	357 (23.5)	1137 (75.0)	1517	
1-5 years	36 (1.1%)	869 (26.7)	2346 (72.2)	3251	
Total	59	1235	3552	4846	

Usability of device

The device was durable and portable. A few providers carried the device with them for fear of theft if left in the facility, and reported that it was easy and lightweight to carry. Maintenance problem was not reported. During the course of the intervention, the probe of only 1 was found to be malfunctioning. More than half of the providers took 1 to 2 minutes to take a reading. Battery backup was reported to be good. Majority said it took 1 to 2 hours to charge 50% of battery and that once fully charged, the battery lasted for as long as 1 month given an average monthly patient load of 100 children. Five health providers maintained that they charged the device only twice since they received it. Challenge in taking reading when a child moved was reported by the majority. They overcame this by removing the device from the child and reapplying it or using it on the toe while the child breastfed.

The following themes were identified from qualitative interviews:

Correct classification and timely identification of pneumonia and treatment: The device equipped the providers with confidence about their ability to identify the illness and confirm a diagnosis which they were unable to do before by physically checking respiratory rate and doing chest indrawing. Providers reported that measuring respiratory rate manually was challenging as children aged 16 to 24 months would get frightened or irritated and moved about a great deal. It would take time to check with a stethoscope. Job aids provide healthcare workers with an easy tool to make timely diagnosis and take timely action. Often parents of sick children are referred to higher facilities which cost them time and money in transport. Having the device at hand enabled immediate diagnosis and action.

> "*Earlier we were mentioning cough as diagnosis but now we are maintaining register as pneumonia and no pneumonia. And if oxygen saturation is less than 90% then we refer them as severe pneumonia.*" *(#18, medical officer)*

Ease of use: RR reading in the PO helped providers make timely decision on pneumonia diagnosis and treatment, which was not easy in their previous experience. SpO_2 reading likewise provided a ready reckoner for identifying hypoxic children, Providers with less experience found the automated readings easy to follow and has increasingly become reliant on the device:

> "*It has made our job of detecting pneumonia very easy. This helps in identifying breathing difficulty automatically as fast breathing can easily be detected through this device. It helps in instant and easy diagnosis*" *(#12, CHO).*

Reduced use of antibiotics: Certain other outcomes were reported by the providers. One of them was their usage of antibiotics for treating mild symptoms which they reported commonly doing in their previous experience. Due to non-confirmation of pneumonia diagnosis previously, many cases of cough and fever were treated with antibiotics, which was not the case now. Not overusing antibiotics is a new learning for them which may have come about due to their exposure of the new treatment guidelines in the training.

Table 2. Correct case management of children with severe pneumonia (general danger signs or hypoxia ($SpO_2 \leqslant 90$).

AGE GROUP	TOTAL REFERRAL	TOTAL CASES WITH $SPO_2 < 90$	CASES WITH $SPO_2 < 90$ AND REFERRED	TOTAL CASES WITH GENERAL DANGER SIGN	CASES WITH GENERAL DANGER SIGN AND REFERRED	CASES WITH $SPO_2 < 90$ OR DANGER SIGN AND REFERRED	VALID CASES REFERRED	TOTAL CORRECTLY REFERRED N (%)	REFERRAL COMPLIANCE (%)
2 months to 1 year	21	16	12	10	8	17	2	19 (90.5)	14 (82.4)
1-5 years	28	13	8	28	13	16	3	19 (67.9)	11 (68.8)
Total	49	29	20	38	21	33	5	38 (77.6)	25 (75.8)

Table 3. Correct case management of children with pneumonia (fast breathing or chest indrawing symptoms).

AGE GROUP	TOTAL ANTIMICROBIALS GIVEN	TOTAL CASES WITH FAST BREATHING	CASES OF FAST BREATHING GIVEN ANTIBIOTICS	TOTAL CASES WITH CHEST INDRAWING	CASES WITH CHEST INDRAWING GIVEN ANTIBIOTICS	CASES WITH FAST BREATHING OR CHEST INDRAWING GIVEN ANTIBIOTICS	OTHER VALID REASONS FOR ANTIBIOTICS	TOTAL CORRECTLY GIVEN ANTIBIOTICS N (%)
<2 months	13	9	7	0	0	7	0	7 (53.8)
2 months to 1 year	380	372	299	55	44	299	4	303 (78.7)
1-5 years	927	902	780	86	73	763	0	763 (82.3)
Total	1320	1283	1086	141	117	1069	4	1073 (81.0)

Table 4. Correct case management of all children with ARI.

STATES	ARI CASES	PNEUMONIA (FAST BREATHING/ CHEST INDRAWING)	SEVERE PNEUMONIA (SPO_2<90)	SEVERE PNEUMONIA (GENERAL DANGER SIGNS)	PNEUMONIA (N= 1069), OTHER VALID CASES (N=4) AND ANTIBIOTIC GIVEN* (CONDITION 1)	SEVERE PNEUMONIA (N=33), OTHER VALID CASES (N=5) AND REFERRED (CONDITION 2)	NO PNEUMONIA AND NO REFERRAL + NO ANTIBIOTIC GIVEN (3)	NO OF CHILDREN MISTREATED (UNNECESSARY REFERRAL OR NO REFERRAL WHEN NEEDED; UNNECESSARY ANTIBIOTICS OR NO ANTIBIOTICS GIVEN WHEN NEEDED)
Chhattisgarh	806	204	4	17	198	7	545	56
Haryana	833	244	2	2	241	3	582	5
Himachal	190	16	2	0	11	2	171	6
Jharkhand	1688	506	8	9	402	14	1058	215
Odisha	620	106	12	6	75	6	454	86
Punjab	349	124	0	4	124	5	214	6
Uttarakhand	360	35	1	0	22	1	295	42
Total	4846	1235	29	38	1073	38	3319	416

Increased trust of parents: Providers described how the correct and immediate treatment has led to parental satisfaction. The fact that a machine was used was perceived by parents as implying a more serious and confident check-up of their children. Usage of the device signified that their child was receiving the needed attention which increased their faith in the providers.

> "*Another thing is that people have come to know that there is this machine. They feel happy. It is enough that there is this machine.*" *(#5,CHO)*

Increased utilization of HWC by parents of sick children: Providers highlighted an increase in the flow of sick children in their facilities. They reported that parents spread the news about the device in their village as they were happy to see their child being treated in a timely manner. They gave examples of people from distant villages accessing their facility.

Discussion

The implementation was integrated within the current system of HWC to see whether the device was robust, acceptable, and implementable. Our findings suggest that it can be easily implemented without additional resources except for the cost of a pulse oximeter and a brief pre-implementation training. It leads to classification and identification of disease as per readings of the device and is useful to the health providers.

The pulse oximetry device helped identify 6.5% of hypoxemic children and 26.5% children with age classified fast breathing. A total of 78 young infants less than 2 months visited the HWC and were diagnosed. None of them had hypoxia, 9 had fast breathing out of whom 7 were treated with antibiotics. Even though IMNCI recommendations for PO use are for children 2 months to 5 years, future implementation in public healthcare settings might have to consider infants less than 2 months as HWC, being the nearest health center, is accessed also by parents of young infants. In such situations, health workers may have to be educated on what to do if a young infant has low SpO_2.

With the implementation of PO, we see a marked decrease in antibiotic usage from what was seen in the rapid assessment and slightly higher referral based on classification of disease and appropriate action. Through the pre-service IMNCI training, providers were trained on age appropriate classification of pneumonia which they applied during case management of children with ARI. The majority of children with fast breathing was given antibiotics while those without pneumonia or severe pneumonia were given paracetamol or home remedies or counseled about breastfeeding. A vital IMCI strategy was therefore achieved by reducing antibiotic use among children who do not have pneumonia by reducing selection pressure for antimicrobial resistance.[18] Antibiotic misuse has been evidenced in India[19,20] which could lead to subsequent development of bacterial resistance at both individual and community

level.[21-23] Severe pneumonia was found in 59 children having SpO_2 level of <90 or general danger signs: $SpO_2 < 90$ among 29 children, danger signs among 38 children and both conditions among 8 children. The PO helped in case identification of hypoxia concurring with another study which highlighted the usefulness of PO when it is combined with IMCI algorithm than with IMCI alone.[12] We found 2 children had oxygen saturation <90 but did not meet the IMCI algorithm.

All children with combined $SpO_2 < 90$ and danger signs were referred. However, 9 children out of the 29 hypoxic children were not referred. Among 19 children with $SpO_2 < 90$ and fast breathing symptoms, 12 children were referred which would have been missed if PO was not used; 5 were given antibiotics without referring and 2 were given home remedy. Among the reasons for inadequate referral could be newly appointed staff who may not have had time to receive training and hence lacked the required skills. In another facility, due to task-shifting, a medical doctor had replaced the CHO for a time and during his tenure children with low SpO_2 level were not referred. It could be that the doctor was skeptical about the reading as children may have presented without clinical symptoms. It has been found that when hypoxia is not associated with clinical signs, physicians become skeptical of the reading more than nurses.[24] In an earlier study, the presence of moderate hypoxemia (>96%) with signs of difficult breathing were most associated with pneumonia while vital sign abnormality was not.[25] Health workers, depending on their proficiency and experience, may have made decisions as per their clinical judgment. This highlights the need for refresher training and supervision. It also highlights the critical issue of human resource crunch in the Indian public health setting which often results in re-shifting of staff that creates a backlog of training process. There is a pressing need for trainings to catch up.

Qualitative interviews also revealed cases of hypoxia detected by PO without signs of severe pneumonia raising an important point that without the aid of such devices, critically ill children would have missed referral to higher facility.

Correct case management with the use of short IMNCI training further highlights the need for reducing duration of training as found in other studies.[26,27] The IMCI global survey report indicates that most countries currently use shortened or abridged versions[28] of the original course due to cost of training and prolonged absence of HW from health services.[29] A review of coverage of IMNCI in India had highlighted that in many of the states, training targets could not be reached.[30] The 11 day training course may well be a hurdle in achieving coverage. Future IMNCI implementation can consider an abridged version. In qualitative interviews, we also found providers to be totally reliant on the device which has the risk of the device being utilized in exclusion to clinical examination. Emphasis and refreshers on IMNCI, therefore, needs to be built into the implementation.

Chest indrawing was present along with fast breathing, $SpO_2 < 90$ and GDS in most cases. It was present alone only in a few cases suggesting that severe illness can be detected with the other signs. The rapid assessment revealed that only 4 out of 42 HW had complete knowledge of chest indrawing and that 9 out of them had no idea how to check for chest indrawing indicating that it was a difficult thing to assess. This could be universal in many other primary health facilities. Simplifying IMNCI protocol of chest indrawing may be worth considering, while using a PO may increase diagnostic accuracy of chest indrawing[31]

The PO device was robust and durable. Accuracy of plethysmography based RR of the device was found to have acceptable sensitivity and specificity in a previous study.[16] None of the providers experienced any difficulty in maintaining the device or carrying it with them. Furthermore, the multi-modal feature of the device helped health workers in reducing uncertainty in measuring RR and boosted their confidence in their diagnosis. In contrast to a study in Nigeria[32] the providers found the device an easy tool to make decisions. In the Nigerian study, reminders and motivation along with behavior change training needed to be done to get around providers' misconception of the device that it would add to their burden. Initiation of the implementation with a training followed by active supervision may have contributed to the workers' immediate acceptability of the device.

Regular monitoring helped in addressing technical challenges which continued the workers motivation. Future roll out of the PO, as has already been proposed by 6 of the 7 participating states, may have to consider maintaining regularity of training and supervision for successful integration of PO within primary health units. Barriers to the use of PO in Kenyan hospitals were inadequate supply, broken pulse oximeters, and insufficient training on how, when, and why to use pulse oximeters and interpret their results.[24] Our close partnership with the manufacturer ensured availability. However, scale up of PO by the government needs to consider cost-effective models of similar reliability. Time taken for a single reading was 1 minute among a majority of providers, similar to what was obtained in a feasibility study in Pakistan.[10] Decisive action could thus be taken in time, avoiding delays in initiating treatment and appropriate referral of sick young infants. Similar to that study, we found a high level parental acceptance in the providers' reports. Referral compliance of 75% is another evidence of parental acceptance and satisfaction.

Readings, however, were challenging when a child moved, consistent with findings from Malawi and Bangladesh.[33] While other design specifications were found to be user friendly and acceptable, a redesigning to correct the high sensitivity to movements would be an advantage to the present device. Battery life in the current device, in contrast to that study, was longer lasting. It minimized charging time and hence, the need for electricity backup leading to easy adoption of the device. It confirms findings of another study in which diagnostic pneumonia aids that have long battery life and less reliance on

electricity were perceived by both community based and national stakeholders to be more usable and scalable.[13] Overall, the findings underpin a wide acceptability of the multi-modal device.

Limitations

The results presented here indicate that the diagnostic device helped providers to systematically classify and diagnose conditions of children. A previous study conducted by the project had found a statistically significant correlation between respiratory rate measured by the PO and RR measured by a pediatrician signifying the validity of the device. However, during the implementation, although we had periodic monitoring, we did not have a system to scientifically assess whether the providers were accurately diagnosing the conditions. Future research should look into a rigorous evaluation. Furthermore, social acceptability bias in the qualitative responses cannot be ruled out. As interviewers were from the national project team, the respondents could have wanted to express only views that seemed favorable to the interviewers. Another limitation is that coding of qualitative transcripts was conducted by only the research advisor and may thus carry interpretation bias. However, being an experienced qualitative researcher, she took time to engage with the material, reading, and re-reading before applying the codes.

Conclusion

The pulse oximeter implementation was found to integrate well within a primary healthcare level. The robustness and ease of usability of device is perhaps the biggest advantage observed which has led to some of the states budgeting for PO for scale up in all the districts. A rigorous evaluation in scaled up facilities should be considered by the government. The implementation tentatively demonstrates that a systematic approach to diagnosing pneumonia is likely to improve case management. Considering the importance of hypoxemia and fast breathing as a sign of severe illness, an ideal pulse oximeter is one which functions as a point-of-care device, is durable, affordable, easy to maintain and can deliver rapid, reliable non-invasive SpO_2 measurements. A device that measures respiratory rate should also be considered for wider usage given the difficulty among healthcare workers to measure respiratory rate manually. Improving case management of pneumonia at the primary care level by expanding ARI diagnostic aids, while also increasing coverage of IMNCI, strengthening referral pathways and improving quality of care in referral facilities will contribute majorly to the SDG goal of reducing under-5 mortality.

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Author Contributions

HK conceptualized the intervention, provided technical oversight throughout the implementation period, edited and provided critical feedback of the draft during inception and through the final draft, ES reviewed the literature, analyzed qualitative information, wrote the first and final draft, PS was responsible for overall implementation of intervention and supervision, and provided feedback on draft. AJ wrote sections of the manuscript. NC, JSM, NB, ST, RP, AG supervised implementing state teams and critically reviewed the manuscript, RP conducted quantitative data analysis, AK was responsible for overall data management, SG provided periodic critical review, and VA provided technical guidance on pulse oximetry and pneumonia case management.

Data Availability

Data will be made available upon request.

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