Original Article

Acceptability, usability and efficacy of an automatic respiratory monitor in determining fast breathing: *A pilot study in a tribal tea garden in India*

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Abstract

Background: Childhood pneumonia is one of the leading causes of mortality among under-five children. It is responsible for 15% of all deaths of children U5, killing 808,694 children in 2017 (1). Traditional visual inspection and manual count method is used to detect and classify fast-breathing, a key indicator of Pneumonia. In response to UNICEF's call for a reliable diagnostic tool, Philips was the first to respond with the Children's Automatic Respiratory Monitor for measuring fast breathing objectively. **Aim:** UNICEF and Philips Foundation initiated a field study to test the acceptability, usability and efficacy of the Automatic Respiratory Monitor in Determining Fast Breathing in low resource setting environments. **Settings and Design:** Philips Foundation partnered up with the Directorate of Medical Education in West Bengal, India to conduct the field study amongst community healthcare workers and beneficiaries in a rural district of West Bengal. In collaboration with North Bengal Medical College & Hospital, a community-based study was conducted in a tribal tea garden of Naxalbari block. **Methods and Material:** Acceptability and usability of the device was assessed through structtured interviews and dialogues with community health workers (CHWs), caregivers and local healthcare practitioners. Efficacy of the device was represented by the inter-rater agreement between the traditional visual inspection and manual count method and the device reading. **Statistical Analysis Used:** A descriptive community based mixed method study was conducted. Satisfaction among community healthcare workers (CHWs) and beneficiaries was found to be promising across all study parameters. **Results and Conclusions:** The paper captures the study methods, statistical analysis of the data, the conclusions, areas of further research and recommends community-wide use of the device in objectively measuring fast breathing among children under the age of five years.

Keywords: Automated respiratory monitor, community healthcare workers, pneumonia, respiratory rate

Background

In 2017 alone, 15% of all deaths of children U5 were caused by Pneumonia[1] Despite significant progress, 54% reduction in deaths due to pneumonia since 2000, Childhood pneumonia is the primary infectious killer disease among children under the age of 5 (U5), resulting in more than eight hundred thousand deaths each year worldwide.[2]

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With increased awareness and focus, mortality rate due to pneumonia in children under 5 years of age in India has dropped by 63% between 2000 and 2015. In order to meet the 2030 Sustainable Development Goals for child mortality, continued advancement in protection, prevention, diagnosis, and treatment of pneumonia is needed. Of the 800,000 deaths in children U5 globally, more than 100,000 are in India alone.[3]

UNICEF also notes that the decrease in Pneumonia-related deaths among children has been slower than other preventable diseases, and if current trends were to continue, we will have additional 6.3 million deaths of children under five over the next decade.[4]

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Introduction

In 2009, the World Health Organization (WHO) and UNICEF launched the Global Action Plan for Pneumonia and Diarrhea (GAPPD). To support and aid the community healthcare workers (CHWs) in diagnosing pneumonia, WHO recommended using fast breathing, among other important indicators, as a key indicator.

UNICEF Supply Chain Division and "la Caixa" Foundation initiated the Acute Respiratory Infection Diagnostic Aid (ARIDA) project, which aimed to identify devices capable of automatically counting the number of breaths per minute of children affected by pneumonia.[5]

Philips was the first to respond to the ARIDA call for technology from UNICEF, which resulted in the development and subsequent commercialization of the Philips Children's Automatic Respiratory Monitor—a device that uses an accelerometer to detect the child's chest movements and converts these into a breath count in alignment with the target product profile published by UNICEF.[6]

Children's Automatic Respiratory Monitor, or ChARM, is field-friendly with the primary target users being the CHWs. The profile of CHWs can differ greatly between countries depending on the local program design. They may not have any formal healthcare qualifications and the level of health training they receive ranges from 2 weeks to 1 year. Their basic education levels can differ from uncompleted primary education to high school graduates, and they have varying levels of literacy and numeracy.

The current study is one of the initial field studies to be conducted in India to assess the suitability of Children's Automatic Respiratory Monitor, ChARM as a novel user-friendly alternative to the visual inspection and manual count method currently used to measure breath counts.

Research Context

Despite the proven diagnostic capabilities of ChARM, support from public health administrators for wide deployment of the device requires testing it for usability in representative areas of the country. To this effect, the current study was planned in a tribal community setting so that the device's acceptability, usability, and efficacy can be assessed among the marginal and vulnerable population. The hilly terrains are remotely located and runs a chronic problem of staff shortage. Work overload and difficult-to-reach areas with vulnerable population make the situation more gruesome. Perceived negligence is high in these communities and, due to harsh climates, respiratory problems are commonplace.

Within this context, the current study was undertaken as a pilot project in rural areas of Darjeeling district in West Bengal, India with the following objectives:

a. To assess acceptability of ChARM among community healthcare workers through semi-structured interview of the study subjects
b. To assess the usability of ChARM among community healthcare workers by observing the study subjects, in addition to the interview
c. To determine efficacy, measured through inter-rater agreement, of ChARM among the study subjects

Materials and Methods

A descriptive community-based mixed method study was conducted from November 2019 to February 2020 with data collection period of 2 months in Naxalbari block of Darjeeling district, West Bengal. A tribal-dominated tea gardens, namely, Kiranchandra tea estate and Naxalbari tea estate, in Naxalbari block of Darjeeling district were studied[1].

Study subjects enrolled for study purposes were all eligible accredited social health activists (ASHA) in the tea garden area and block-level nursing staffs (BPHN) were also included in the study. In total, 17 ASHA workers and 2 BPHN were studied. Henceforth, in this study, ASHAs will be referred to as **Community Healthcare Workers (CHW)**. Study subjects also included **Beneficiaries** under 5 years of age, divided into infants (0–2 months and 2–12 months) and toddlers (1–5 years) with their **Caregivers** (who opined on their behalf). A total of 132 beneficiaries were studied. The inclusion criterion was willingness of the participants and the exclusion criterion was cases with severely diseased conditions.

Study tools used were record sheets to record the readings of the two "raters", a pre-designed pre-tested semi-structured schedule for assessing usability and acceptability of the device, and a non-rechargeable battery version of ChARM[2].

Other tools used were stopwatch, Stethoscope, MCPC card, IMNCI booklet, and training tool for CHWs.

The study techniques used a measurement method where RR count was measured and recorded by the CHWs, first through visual inspection and manual count and then with the help of ChARM. Data was later used for comparative analysis.

Interviews of CHWs to assess acceptability, usability, and caregiver cooperation with the use of the device were conducted. Additionally, the use of ChARM by the CHWs was observed to further qualify the usability of the device. Before conducting the study, CHWs were sensitized regarding the use of the device.

[1]Although, the original research intent was to cover a wider area, the study was cut short due to the coronavirus pandemic and subsequent lockdown, which started from March 2020 in India.

[2]ChARM is a measurement device with a monitor that displays recordings of respiratory counts and blinks red in fast breathing cases. It has a comfortable, child-friendly strap to attach it on the torso of the child, while s/he is lying down. The non-chargeable version of the device is used for approximately 2,000 readings. The device was demonstrated to West Bengal health administrators and medical professionals at the 35th IAPSM state conference in NBMCH in 2019 during a main sharing session.

It is to be noted that there were no clinical trials involved as part of the field study.

A. Data Collection and Study Variables

After the required Institutional Ethics clearance and permission from Director of Medical Education (DME), Swasthya Bhavan, local district authority, BMOH Naxalbari and Department of Community Medicine, NBMCH, data was collected for the required study variables.[7] Pre-sensitization was done. Queries were addressed. Anonymity was ensured for participants and it was reinforced that the data will be used for academic purposes only.

After the initial sensitization of CHWs, the basic descriptor variables were collected from them and the caregivers. CHWs then measured RR by visual inspection and manual count method followed by measurement with the help of ChARM, all the while adhering to the user guidelines of the device.

While measuring RR, the CHW was observed to check for the usability of the device.

To assess for acceptability, CHWs and BPHNs were interviewed using a pre-designed, pre-tested semi-structured, validated questionnaire containing the study variables in three different domains, namely:

a. Background descriptors of study participants,
b. Assessing and classifying respiration rate in various age-groups and inter-observer variations, and
c. Assessing perception of the CHWs regarding child position, device position, selecting child age on the device, to name a few.

Furthermore, the caregiver of each beneficiary was interviewed individually for the purpose of the study.

Following operational definitions were used for the study:

Fast breathing: RR count above 60/min in <2 month-old child, above 50/min in 2 month–12 month-old child, and above 40/min in 1–5 year-old child.

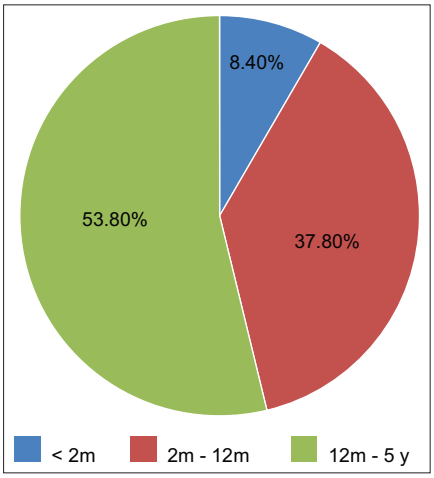

Figure 1: Distribution of study subjects according to age (n = 132)

Acute Respiratory Infections (ARI): IMNCI guidelines were used for appropriate diagnosis and referrals.

Results

A total of 132 eligible beneficiaries up to 5 years of age were studied. 2 BPHN and 17 ASHA were also studied. For the efficacy of the device, inter-rater agreement was used. Usability of the device was checked by observation method and acceptability of the device by interview method. Among health workers, BPHNs performed better than CHWs.

Background descriptors

The majority of the children were males (62.9%), belonging to Socioeconomic class III and Hindus. All of them resided in rural tribal areas and had mothers as their caregivers.

As shown in Figure 1, age range varied and majority of children were above one year of age. There were 11 children (8.4%) less than 2 months of age, 50 (37.8%) children within 2 months to 12 months of age, and 71 children (53.8%) were aged above one year. Among 132 children studied, only 8 were diagnosed with pneumonia and were hospitalized within the last 2 months. Eighty-seven children (65.9%) were having acute respiratory illness (ARI) at the time of data collection. During winter months in the hilly tribal belt, which lack of proper home remedies, the prevalence of ARI remains high.

Efficacy of the device (Inter-rater agreement)

CHWs measured RR of the child using conventionally accepted visual inspection and manual count method followed by reading from the ChARM recorded by the accompanying physician for all 132 beneficiaries. The readings were categorized into fast breathing and normal breathing. Inter-rater agreement between the two rating techniques was analyzed using Kappa statistics, which provides a corrected standardized measure of agreement between categorical scores of the two raters. Here, the readings were categorized into fast breathing and normal breathing according to cut-offs given by IMNCI guidelines.

Overall as shown in Table 1, for the complete set of U5 study subjects (n = 132), the inter-rater agreement was found to be high, a Kappa value of 0.74, which was statistically significant with P = 0.00.

Table 1: Inter-rater agreement and its significance between device and manual use across various age groups using Kappa statistics

Beneficiaries	Agreement value	Approx. Sig.
0-2m (n=11)	0.22	0.06
2m-12m (n=50)	0.620	0.000
12m-5y (n=71)	0.764	0.000
Total (n=132)	0.742	0.000

In the subgroup 12 months to 5 years (n = 71), Kappa value of 0.76 was found, which was statistically significant with P = 0.00. Likewise, in the subgroup 2 months to 12 months (n = 50), Kappa value of 0.62 was found, which was statistically significant with P = 0.00. Hence, the readings in both measurement methods were similar in most of the cases.

Interestingly, while assessing only those children affected with ARI (n = 87), inter-rater agreement was high with a Kappa value of 0.69, which was statistically significant P = 0.00. Hence, the device accurately and appropriately measures similar to the conventional method for ARI cases, as well.

However, for the subgroup 0–2 months (n = 11), the inter-rater agreement was low, and Kappa value was 0.22, which is not statistically significant P = 0.06. Hence, a discrepancy seemed to exist between the two raters for this age sub-group. Reasons for the identified discrepancy may be inappropriate device positioning, small sample size, or the study setting—challenges of breath counting in the field, instead of the calmer surroundings with adequate working space in the sub-centers. Moreover, among infants in the 0–2 month age sub-group fast, and sometimes shallow, chest movements are commonplace. Using ChARM on 0–2 month-old infants has its own challenges as the reading gets stopped midway every time the infant starts making excessive movements.

Usability of the device

Guidelines of WHO and the manufacturer IFU were consistently reinforced during the study. Parameters identified were ability of CHWs on correct child positioning, device positioning, selection of child age on the device, motion of child during device use, and appropriate classification according to the device reading. Most of the sick-child assessments were completed with ChARM on the first attempt. Reasons for few unsuccessful attempts were that the child was feeding or moving during the examination.

During an examination, it was seen that child positioning was appropriate in 52.2% cases, whereas device positioning was correct in 72.1% cases. It was noted that further focused training on device use before wide-scale use will help increase both child positioning and device placement. 78% children were calm during the assessment. For children who were not able to stay calm, their caregivers had to calm them down for the device to perform its measurement. Interestingly, it was noted that correct classification using the device reading was done only in 71.2% cases. Despite available device readings—both the count and the color indicator—there were errors while writing it down in the paper forms provided to the CHWs. The observations were noted and corrective feedback was provided to the CHWs at the time of data recording.

Acceptability of the device

The acceptability of the device was assessed among both BPHN and ASHAs using the qualitative estimates.

Community healthcare workers perspective

All CHWs accepted the device and were of the opinion that it helped in offloading work especially on Village Health and Nutrition days (VHND) and Immunization days. Though there was an initial hesitancy, the majority opined the device was user-friendly and could be used after proper training was imparted. Recording was accurate and the light sensors helped in the classification of the cases. It was easy to communicate the results to caregivers and convince them for appropriate management as per IMNCI classification.

CHWs unanimously opined it was operationally feasible to implement ChARM at community and sub-center level, if supported by the government. As CHWs are over-burdened with multiple tasks, the device seems promising in saving their workload without affecting quality of the recording or classification, potentially leading to referrals that are more authentic.

Table 2 depicts satisfaction regarding usability, acceptability, and receiving caregiver's cooperation. Low outright satisfaction regarding the usability of the device is driven by CHWs' reservations toward using any new device unless they are supported by specific information, education, and communication (IEC) events to sensitize the community, media, and local political party representatives. This is more to do with the context of the study setting—tribal area where access to healthcare-related information is difficult and general literacy levels are low—than the device itself. Likewise, caregivers of the beneficiaries were apprehensive regarding the device, mostly due to their lack of knowledge about the device and concerns with applying a relatively new device on their children. However, once the device was applied, and the reading recorded, they were satisfied with the outcome—especially the light sensor method, which supported the authentication of referrals. Even caregivers who were illiterate could see the signals and understand the clarity of management as per the color-coded classification. Moreover, as the beneficiaries had no complaints or discomfort during and after applying the device, the respective caregivers opined the device was an acceptable alternative to the conventional method.

Table 2: Levels of satisfaction of CHWs regarding device use (n=132)

Device Variables	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied
Acceptability	13 (10.1%)	28 (21.5%)	91 (68.4%)
Usability	17 (12.6%)	42 (32.2%)	73 (55.0%)
Caregiver cooperation	19 (14.2%)	16 (12.1%)	97 (73.7%)

Discussion

The study found inter-rater agreement to be high, except for the less-than-two months' age sub-group. The small sample size and the study setting being at field-level, where proper lying position of the child cannot always be ensured, could have influenced the finding. Manual errors could also be a plausible reason. Another study in Ethiopia also found similar results. However, the need for a global consensus on the most acceptable method is still debatable and needs further study.[8]

Regarding acceptability among CHWs, the present study noted interest and positive intent among them because the majority were literate and trained. Studies in sub-Saharan countries, similar to the current one, had previously noted that some CHWs had expressed initial concerns about their lack of confidence to operate ChARM. In a study in Ethiopia, age and illiteracy of CHWs were seen as constraints for appropriate device use, but the light sensors aiding classification was appreciated, similar to the present study.[9] Other contextual factors in sub-Saharan countries, similar to the present study like numeracy, training, remote study setting, and marginalized vulnerable population are also key variables in every study. Majority of studies observed CHWs opining saving of overall workload with use of ChARM. However, one study in Uganda concluded that the workload saving could only be realized after adequate training on the device has first been delivered. For the current study, caregiver acceptance of ChARM may partly be due to their inherent trust in provisions from the Indian government and due to the device attributes. CHWs felt that having ChARM available encouraged caregivers to visit the health post and that the caregivers were accepting of the device and would be comfortable for it to be used on their children again.

ChARM is a new device in the Indian community health setting, with known use only in Maharashtra. During the current field study, it was found to be operationally feasible to train CHWs in a relatively short period of time and the CHWs were able to demonstrate acceptable adoption and use of the device in the presence of the principal investigator.

Conclusion

The study concludes that the device is of comparable efficacy to the traditional methods given the capacity and skill of the CHWs. ChARM can be considered an acceptable alternative to the conventional visual inspection and manual count method as the inter-rater agreement between them was high in comprehensive age group evaluation and in majority of age sub-groups.

ChARM is a novel user-friendly alternative that was found to be acceptable among beneficiaries, caregivers, and CHWs. Additionally, it shows initial promise in saving time and helps build confidence among caregivers. The device comes in two variants—rechargeable and "use and throw"—either of which will be a good addition to the CHW toolkit in clinics and in the field.

Recommendation

A larger study with a more representative sample is warranted, where interviewing caregivers and recording of breath count by them in their own setting can be done, along with conducting focus group discussions to probe into barriers and facilitators of implementing the device at the field level.

A specific focus on children under 2 months of age will be helpful to confirm the efficacy of the device in this age sub-group. This will require the study to be performed at the district hospitals, instead of in the communities, to reach higher populations of 0–2 month infants.

Furthermore, the assumption that BPHNs, due to their higher educational qualification, are more likely than ASHAs to use ChARM correctly needs to be further explored in future usability studies.

Additionally, interviewing BMOH and other senior officials for their perspective is needed to keep documented evidence of an increase in appropriate classifications and authentic referrals.

Further study will be needed to conclusively determine if the use of ChARM changes the workload of the CHWs. Time and motion studies—to ascertain if a designated, trained CHW operating the device in pre-consultation room saves any consultation time—will be beneficial.

Limitations

Logistical constraints, difficult terrains, limited time and resources for the study, along with the sudden occurrence of Coronavirus pandemic and subsequent lockdowns affected the sample size number that was chosen.

Acronyms

Acronym	Definition
ANM	Auxiliary Nurse Midwives
ARI	Acute Respiratory Illness
ARIDA	Acute Respiratory Infection Diagnostic Aid
ASHA	Accredited Social Health Activist
BMOH	Block Medical Officer of Health
BPHN	Block Primary Health Nurse
ChARM	Children's Automatic Respiratory Monitor
CHW	Community Healthcare Worker
DME	Director of Medical Education
GAPPD	Global Action Plan for Pneumonia and Diarrhea
IEC	Institutional Ethics Committee
IAPSM	Indian Association of Preventive and Social Medicine
IEC	Information, Education, and Communication
IMNCI	Integrated Management of Neonatal and Childhood Illness
MCPC	Mother and Child Protection Card
NBMCH	North Bengal medical College and Hospital
RR	Respiratory Rate
UNICEF	United Nations Children's Fund
VHND	Village Health Nutrition Days
WHO	World Health Organization

An additional limitation of the study was the lack of a "gold standard" review of the CHWs management of the child, as done in similar studies. The silent observations of the CHWs by the research team could have caused some "Hawthorn effect." Some systematic bias could be associated with the convenience sampling of the CHWs and the results may therefore not be generalizable to the overall CHW population in the most remote areas. Additionally, because the interviewees were government employees, the responses may have been measured.

Acknowledgement

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Conflicts of interest

There are no conflicts of interest.

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