malaria consortium
disease control, better health

RESEARCH BRIEF

Usability and acceptability of two automated pneumonia diagnostic aids

Findings from Ethiopia and Nepal

Key messages

- Using an automated respiratory rate counter (Philips ChARM) and a multimodal pulse oximetry-respiratory rate device (Masimo Rad-G), community health workers (CHWs) in Ethiopia were able to adhere to World Health Organization pneumonia case management requirements for managing children with cough and/or difficulty breathing and manufacturers' instructions for use. Practice improved their ability to take respiratory rate and oxygen saturation level readings.
- In Nepal, CHW adherence to these requirements using the ChARM device, was lower and did not improve over time. CHWs felt that their capacity constraints — including low literacy levels — adversely impacted ChARM's usability. ChARM did not sufficiently support CHWs to assess and classify children under five with symptoms of pneumonia. Our findings suggest that focused training on all pneumonia case management steps is needed for CHW cadres with low literacy before new automated devices are introduced.
- Caregivers and frontline health workers — both CHWs and health facility workers — were accepting of the devices in Ethiopia and Nepal.
- Further research on the devices' performance, cost-effectiveness and implementation is warranted to inform policy decisions in countries with a high burden of childhood pneumonia.

Introduction

Pneumonia, a preventable, treatable and curable disease, remains the leading infectious cause of death among children under five. In 2016, it was responsible for 16 percent of the 5.6 million under-five deaths worldwide: roughly 2,400 every day, concentrated within the poorest populations.[1-2]

The current method of diagnosing pneumonia in low-income countries requires the CHW to manually count a child's breaths for one minute, which is challenging and can lead to misdiagnosis and inappropriate treatment. Management of pneumonia could be improved by increasing the availability of new tools to support frontline health workers and by improving access to treatment with amoxicillin dispersible tablets and oxygen therapy. However, investment in pneumonia research and development remains low.[3]

The Acute Respiratory Infection Diagnostic Aid project

The Acute Respiratory Infection Diagnostic Aid (ARIDA) project aimed to identify and introduce automated respiratory rate (RR) counting aids that can be used by frontline health workers — CHWs and health facility workers — in resource-limited community settings and health facilities to classify fast breathing: a symptom of pneumonia. It was funded by a €5,000,000 (£4,498,000) investment from "la Caixa" Foundation in partnership with United Nations Children's Fund's (UNICEF) Supply Division, and the research components were implemented by Malaria Consortium in Ethiopia, and in partnership with HERD International in Nepal.

Following a call for new devices, two manufacturers responded with products that met the Target Product Profile: the Philips ChARM device and the Masimo Rad-G device. The ARIDA field trial design included a number of research stages: i) UNICEF technical and commercial evaluation to assess whether the device meets the technical specifications required; ii) evaluation of device agreement with a reference standard; and iii) assessment of their usability by CHWs and acceptability to users and caregivers through field testing (see Figure 2).

Prior to the usability and acceptability testing, an agreement study was completed at St Paul's hospital in Addis Ababa, Ethiopia, between April and May 2017 (see Figure 1). The second study was the ChARM usability and acceptability field trial, which was conducted in the Southern Nations, Nationalities, and Peoples' Region (SNNPR) of Ethiopia between May and August 2018. The ChARM device was then tested in Jumla district, Nepal, between August and December 2018. The fourth field trial sought to determine the usability and acceptability of Rad-G and took place in the Sodo Zuria, Damote Gale and Damote Sore districts of the SNNPR between September and December 2018.

The design of the ARIDA usability and acceptability studies was informed by a conceptual framework that outlined factors that might affect a frontline health worker's adherence to requirements for integrated community case management (iCCM) or integrated management of newborn and childhood illnesses (IMNCI) when using ARIDA devices, and how these factors are related (see Figure 3).

The framework proposes that the degree to which frontline health workers accept a device — along with their skills, abilities and other environmental factors — will affect their intention to adhere to iCCM/IMNCI requirements and their behaviour over time.

ChARM is a device that uses an accelerometer to calculate a child's RR — a measure that indicates whether the child has fast or normal breathing.

Rad-G is a multi-modal device that calculates a child's RR and oxygen saturation (SpO2) level. Low oxygen saturation is a symptom of severe pneumonia.

Figure 1: ARIDA timeline

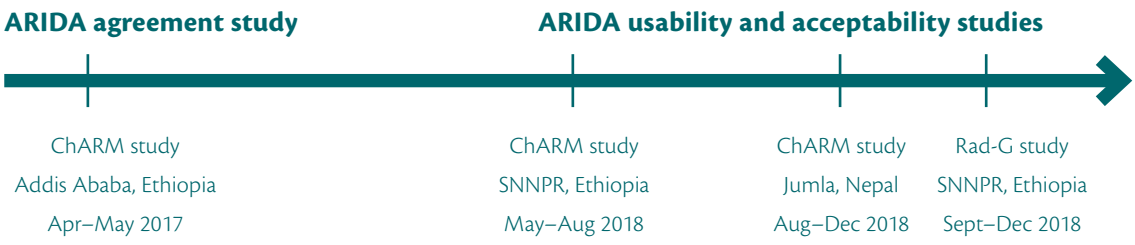
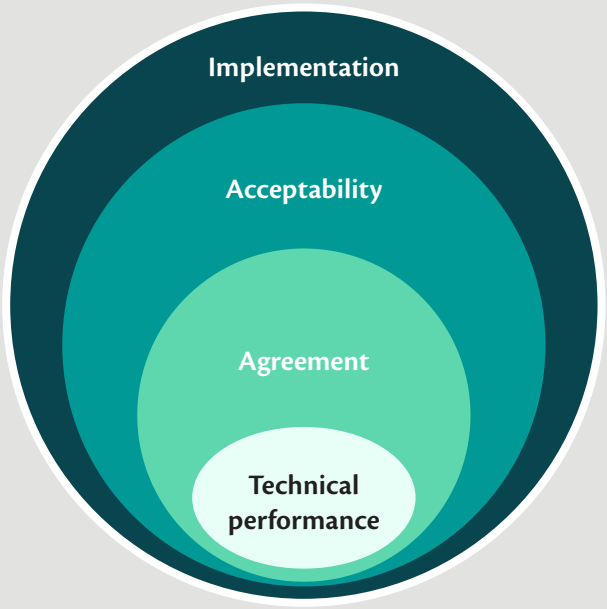


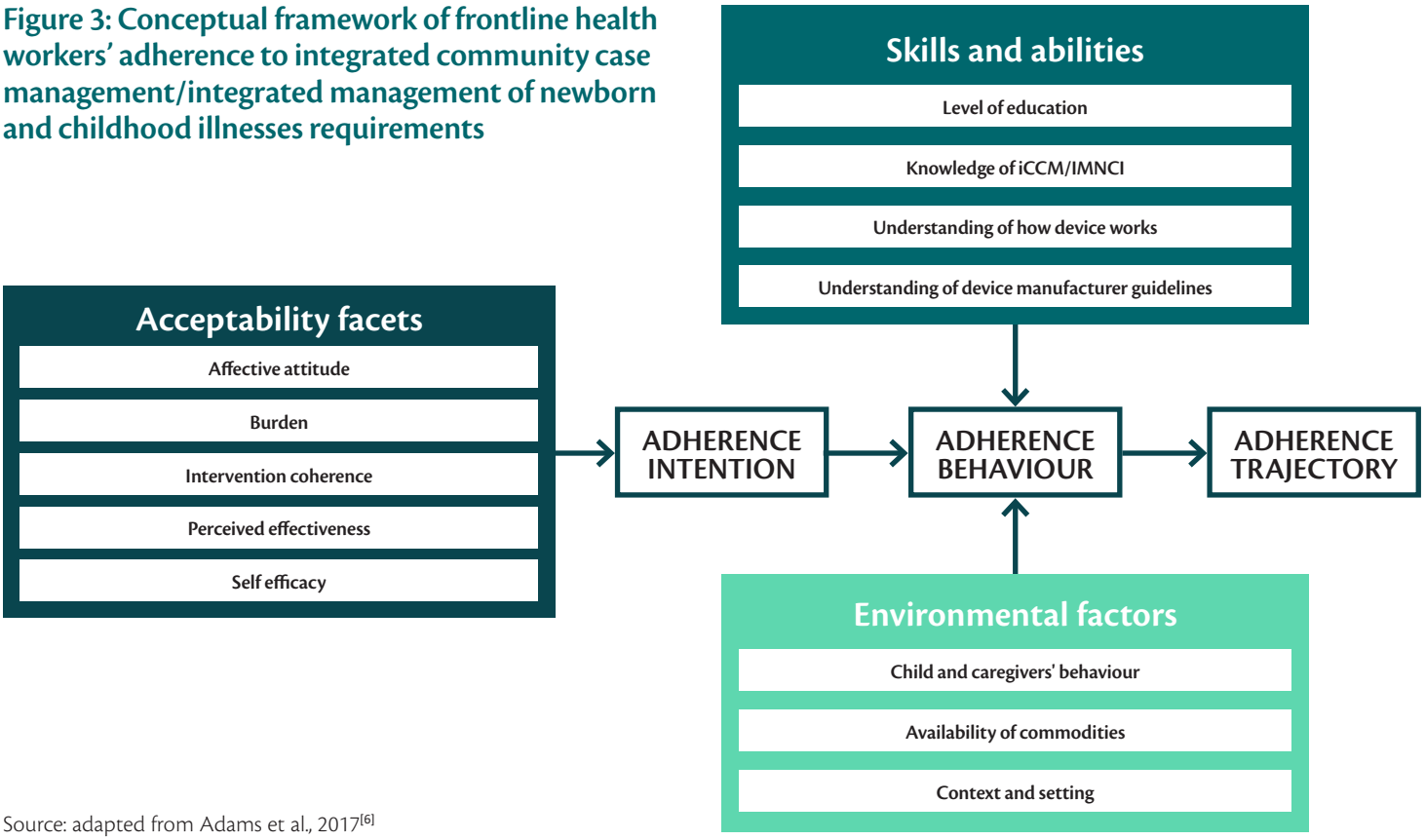
Figure 2: Core stages of introducing a new technology to a healthcare setting

ARIDA project phases	Areas to address
Implementation research	▶ Inform how best to plan for the integration of ARIDA devices into the national health system and help identify the practical, health system-level lessons that emerge to inform future scale up.
ARIDA acceptability study	▶ Can CHWs correctly adhere to the iCCM algorithm and assess and classify children under five with cough and/or difficulty breathing using an ARIDA device? ▶ Are ARIDA devices acceptable to community and frontline health workers in this setting? ▶ Are ARIDA devices acceptable to caregivers of children under five in this setting?
ARIDA agreement study	▶ Do ARIDA devices agree with a reference standard to classify children with cough and/or difficulty breathing?
Regulatory approval	▶ UNICEF technical and commercial evaluation to assess whether the device meets the technical specifications required.



Source: adapted from World Health Organization, 2011[4] and Mytton et al., 2010[5]

Figure 3: Conceptual framework of frontline health workers' adherence to integrated community case management/integrated management of newborn and childhood illnesses requirements



Source: adapted from Adams et al., 2017[6]

Research objectives

1. To determine the usability of the ChARM and Rad-G devices for CHWs seeking to assess and classify under-fives with cough and/or difficulty breathing
2. To document the user experience of the devices in a sick child consultation
3. To explore the acceptability of the devices to frontline health workers and caregivers

Methods

Malaria Consortium trained frontline health workers for two days to use ChARM in Ethiopia and Nepal, and Rad-G in Ethiopia, and provided them with a device-specific job aid. All frontline health workers received a refresher training on iCCM; those trained to use Rad-G in Ethiopia and ChARM in Nepal also received a refresher training on IMNCI. Research assistants observed the CHWs assessing sick children using the devices twice: once after initial training (observation one) and again after two months of routinely using the device in their health post (observation two).

We collected baseline data on when CHWs last received routine iCCM refresher training and supportive supervision, and on the number of years they had been working as qualified CHWs.

Additionally, we conducted semi-structured interviews with frontline health workers and caregivers of children under five to understand their perceptions of the devices.

Female community health volunteers participating in ARIDA training, Nepal

Results: usability

Ethiopia: ChARM

A total of 133 CHWs — known in Ethiopia as health extension workers (HEWs) — and 20 health facility workers — known as first-level health facility workers (FLHFWs) — were trained to use ChARM. HEWs took part in the usability and acceptability studies, while FLHFWs only participated in the acceptability study.

All HEWs were literate and had completed secondary school plus at least one year of tertiary education. On average, they had eight years' experience as an HEW. They all received salaries from the Ethiopian state and were based in a health post.

When we observed participants for the second time:

- HEWs evaluated 337 children using ChARM, 72 of whom (21 percent) were less than two months old.
- HEWs correctly adhered to all eight assessment and classification steps when using ChARM in 74 percent of child consultations (see Table 1). This is a 19 percent increase from when they were observed immediately after training (p=<0.001).
- HEWs correctly adhered to the device manufacturer's instructions (steps one to three) in 77 percent of child consultations.
- HEWs correctly adhered to the World Health Organization's (WHO) pneumonia-related iCCM requirements (steps four to eight) in 94 percent of child consultations.
- HEWs successfully acquired a RR reading with ChARM within three attempts more than 99 percent of the time, and on the first attempt 92 percent of the time.
- On average, it took HEWs 3 minutes and 17 seconds to get a RR reading from when they started attaching the device (inclusive of up to three attempts).

During the two months of routine use in 60 health posts, HEWs completed 933 child assessments. This is 96 percent of all sick children who visited the health posts with pneumonia symptoms.

There was no significant association between the time since an HEW's last routine iCCM integrated refresher training and supervision, her qualification as an HEW, and her ability to correctly adhere to iCCM algorithms with ChARM after two months of routine use (p=>0.05).

Table 1: Child consultation steps correctly performed by health extension workers in Ethiopia when using ChARM

Consultation steps	Number of consultations (total = 337)	Percentage	95 percent confidence interval
1. Correct child position	273	81.0	76.8–85.2
2. Correct device position	319	94.7	92.3–97.1
3. Correct belt attachment	337	100.0	98.9–100
4. Correct age group	332	98.5	97.2–99.8
5. Child calm immediately before ChARM attempt	326	96.7	94.8–98.6
6. Child not eating/feeding during successful ChARM attempt	336	99.7	99.1–100
7. Child calm during successful ChARM attempt	332	98.5	97.2–99.8
8. HEW classified the child's breathing status correctly using ChARM during 'successful' attempt	333	98.8	97.7–100
9. Correct assessment and classification (steps 1–8)	250	74.2	69.5–78.9
10. Correct treatment decision	331	99.1	98.1–100
11. Manufacturer instructions for use correctly performed (steps 1–3)	259	76.9	72.4–81.4
12. iCCM requirements correctly performed (steps 4–8)	318	94.4	91.9–96.8

Child being assessed for fast breathing using ChARM, Ethiopia

Nepal: ChARM

A total of 130 CHWs — known in Nepal as female community health volunteers (FCHVs) — and 20 health facility workers were trained to use ChARM. Only FCHVs took part in the usability study.

On average, they were 42 years old and had 15 years' experience as a FCHV. The majority (71 percent) had received a community-based IMNCI refresher training within the previous three years and just over half (55 percent) were literate, but with little formal education. They were all home-based.

When we observed participants for the second time:

- FCHVs completed 253 child consultations using ChARM, seven of whom (three percent) were less than two months old.
- FCHVs correctly adhered to all eight assessment and classification steps when using ChARM in 53 percent of child consultations (see Table 2). This is a three percent increase from when they were observed immediately after training (p=0.49).
- FCHVs correctly adhered to the device manufacturer's instructions (steps one to three) in 79 percent of child consultations.
- FCHVs correctly adhered to WHO's pneumonia-related community-based IMNCI requirements (steps four to eight) in 66 percent of child consultations.
- FCHVs successfully acquired RR readings with ChARM within three attempts 99.6 percent of the time and on the first attempt 83 percent of the time.
- On average, it took FCHVs 4 minutes and 26 seconds to get a RR reading from when they started attaching the device (inclusive of up to three attempts).

HEWs completed 571 child assessments between September and November 2018: 430 (75 percent) were completed with ChARM, 33 (six percent) with FCHVs' standard practice device and 108 (19 percent) with an unknown device.

There was no significant association between the time since a FCHV's last community-based IMNCI refresher training (p=0.80), the number of years she had been qualified (p=0.62), her level of literacy (p=0.05) and her ability to correctly adhere to community-based IMNCI algorithms with ChARM after two months of routine use.

Table 2: Child consultation steps correctly performed by female community health volunteers in Nepal when using ChARM

Consultation steps	Number of consultations (total = 253)	Percentage	95 percent confidence interval
1. Correct child position	215	85.0	80.0–88.9
2. Correct device position	238	94.1	90.4–96.4
3. Correct belt attachment	246	97.2	94.2–98.7
4. Correct age group	225	88.9	84.4–92.3
5. Child calm immediately before ChARM attempt	213	84.2	79.1–88.2
6. Child not eating/feeding during successful ChARM attempt	231	91.3	87.1–94.2
7. Child calm during successful ChARM attempt	219	86.6	81.7–90.3
8. FCHV classified the child's breathing status correctly using ChARM during 'successful' attempt	244	96.8	93.7–98.4
9. Correct assessment and classification (steps 1–8)	133	52.6	46.4–58.7
10. Manufacturer instructions for use correctly performed (steps 1–3)	200	79.1	73.6–83.7
11. IMNCI requirements correctly performed (steps 4–8)	168	66.4	60.3–72.0

Child being assessed for fast breathing using ChARM, Nepal

Ethiopia: Rad-G

A total of 133 HEWs and 20 FLHFWs were trained to use Rad-G. HEWs took part in the usability and acceptability studies, while FLHFWs only participated in the acceptability study.

All HEWs were literate and had completed secondary school plus at least one year of tertiary education. On average, they had eight years' experience as an HEW. They all received salaries from the Ethiopian state and were based in a health post.

When we observed participants for the second time:

- HEWs evaluated 259 children using Rad-G, seven of whom (three percent) were less than two months old.
- HEWs correctly adhered to all eight assessment and classification steps when using Rad-G in 85 percent of child consultations (see Table 3). This is a 19 percent increase from when they were observed immediately after training (p=0.02).
- HEWs correctly adhered to the device manufacturer's instructions (steps two, four and five) in 97 percent of child consultations.
- HEWs correctly adhered to WHO's pneumonia-related iCCM requirements (steps one, three, six, seven and eight) in 80 percent of child consultations.
- HEWs could get successful RR and SpO2 readings with Rad-G within three attempts in 92 percent of consultations. This is an improvement of 18 percent from the first observation.
- On average, it took HEWs 5 minutes and 42 seconds to get RR and SpO2 readings from when they started attaching the probe to a child (inclusive of up to three attempts).

HEWs completed 579 child assessments between observations one and two (October–December 2018) in 74 health posts: 486 (84 percent) were completed with Rad-G, 57 (10 percent) with HEWs' standard practice device and 36 (six percent) with an unknown device. A total of 208 pneumonia assessments were completed over the same period in 2017.

For every year an HEW had been qualified, the odds of her correctly assessing and classifying children increased by 1.13. However, there was no significant association between the time since an HEW's last routine iCCM integrated refresher training and supervision and her ability to correctly adhere to iCCM algorithms with Rad-G after two months of routine use (p=>0.05).

Table 3: Child consultation steps correctly performed by health extension workers in Ethiopia when using Rad-G

Consultation steps	Number of consultations (total = 259)	Percentage	95 percent confidence interval
1. Child calm before Rad-G attempt	248	95.8	92.5–97.6
2. Correct mode selected	258	99.6	97.3–99.9
3. Correct age group	246	95.0	91.5–97.1
4. Correct probe position	258	99.6	97.3–99.9
5. Correct probe direction	254	98.1	95.4–99.2
6. Child not eating/feeding during Rad-G attempt	257	99.2	96.9–99.8
7. Child calm during Rad-G attempt	251	96.9	93.9–98.5
8. Correct classification using Rad-G	229	96.2	92.9–98.0
9. Correct assessment and classification (steps 1–8)	203	85.3	80.2–89.3
10. Manufacturer instructions for use correctly performed (steps 2, 4, 5)	252	97.3	94.4–98.7
11. Revised iCCM requirements correctly performed (steps 1, 3, 6, 7, 8)	208	80.3	75.0–84.7

Child being assessed for fast breathing using Rad-G, Ethiopia

Results: acceptability

Ethiopia: ChARM

We conducted semi-structured interviews with 14 HEWs to explore their experience using ChARM. These revealed that they found it easy to count RRs and classify cases using the device, and were relieved that it provided a consistent reading when they tested it against their standard practice device. However, they also found that HEWs had sometimes struggled to adjust the device's belt, especially when using it on older children. This does not appear to have impacted demand; interviewees expressed a strong desire for ChARM to be available for use in the future and reported feeling that the availability of ChARM had encouraged caregivers to visit the health post.

We also conducted semi-structured interviews with 14 caregivers to explore their experience of having their child assessed with the device. Very positively, these revealed that caregivers were accepting of ChARM, would be comfortable for it to be used on their children again and would recommend it to others.

The first-level health facility worker's perspective

"Before ChARM, we counted RR manually. Now, ChARM counts for us and shows the result and the classification. If the child has fast breathing, a red light shows; if his/her breathing is normal, a green light shows. It makes things easier. When following the training instructions, using the device is not difficult. I see no barriers; the community is also willing."

Esther, Goyda health centre, Ethiopia

Nepal: ChARM

We conducted semi-structured interviews with 15 FCHVs on their perceptions of the barriers to and facilitators of using ChARM. These revealed that many FCHVs said they were "anxious" or "frightened" when they first saw the device. For most, this initial reaction was short-lived and FCHVs said they got used to the device and were comfortable using it with time. However, FCHVs were concerned they were not able to practise enough due to a low patient load and indicated that they would have liked more refresher trainings.

The majority of FCHVs across all districts preferred ChARM over the previously used 'timer' device. They noted that the possibility of miscounting or forgetting the count was high with the timer — in particular for illiterate FCHVs who found it difficult to count beyond 20. They agreed that ChARM's automated counting and coloured indicators helped overcome this challenge.

Many FCHVs linked their ability to use the device with their age or education level. Interviewees indicated that educated FCHVs "learned quickly", whereas those without formal education tended to "lose interest" and could only "understand simple things". While low literacy levels impacted the FCHVs' ability to read the values displayed, many interviewees felt the red and green indicators helped illiterate FCHVs interpret the results correctly nonetheless.

A few FCHVs mentioned that they felt more confident when referring a child to the health facility based on results obtained with ChARM. However, FCHVs from all districts said it was difficult to share the results with caregivers when the indicator was red and the child had a high RR.

We also interviewed 15 caregivers on their acceptance of ChARM. Caregivers appeared unconcerned about the use of the device; many said they were curious or felt "nothing" when the device was attached to their child. Many caregivers trusted the device because of their good relationship with the FCHV, who always helped their child get better, which was their main concern. They appreciated that the device helped diagnose pneumonia, and found it safe and useful. Caregivers also mentioned that the FCHV would communicate the result of the assessment by showing them the green or red light indicators.

The female community health volunteer's perspective

"Older and uneducated FCHVs were often not able to count childrens' breaths manually. We also sometimes forgot the count if the child was crying or screaming. We were supposed to count either the breaths in or the breaths out, which made it more difficult. But now that we use ChARM, the device counts the RR on its own."

FCHV, Lamra, Nepal

Ethiopia: Rad-G

We conducted semi-structured interviews with 15 HEWs and 15 FLHFWs to explore their experience of using the device. These revealed that both types of health workers preferred Rad-G compared with previous manual counting methods, as they found it easier to use and said they trusted the result provided by the device.

FLHFWs said they had initially been fearful or hesitant to use Rad-G as it seemed complicated and/or difficult to operate, but they explained that these concerns had been alleviated with practice.

Interviewees also reported having encountered several challenges when using the device. Firstly, they indicated that caregivers being unaware of children's ages had precluded them from using Rad-G during assessments as it required them to select an age category on screen. Secondly, they mentioned being concerned that measurement errors may occur due to children moving around during assessments and thus having resorted to manual RR counting in those cases. Both FLHFWs and HEWs felt that it was hard to prevent such motion, noting that some children aged 0–2 months had been distressed and that some aged two years and above had been concerned by Rad-G's red light. Promisingly, they reported that the animal images present on the device's screen had diverted older children's attention from the ongoing assessment.

Both types of health workers also said they had found the job aid provided by Malaria Consortium easy to use and felt that it had helped with classification. Some FLHFWs specifically reported being able to refer cases onto hospitals based on SpO2 readings and noted that assessment with the device avoided the unnecessary use of antibiotics. HEWs mentioned that they had previously treated cases based on observation only, which they recognised was inaccurate.

We also interviewed 15 caregivers to evaluate their acceptance of Rad-G. Many described having initially feared that the red light that the device's probe emits would burn or puncture their child's finger. However, most mentioned that HEWs had helped allay these fears by explaining that the device was not harmful.

Caregivers unanimously reported accepting the device, saying that the time it took to conduct the assessment was reasonable and that they trusted the results. They described being satisfied with the device because it had helped identify the disease, said they would recommend the device to others, and expressed that assessment of their child with Rad-G had been better than with observation alone.

The caregiver's perspective

"My daughter was scared of the previous device, but today she was a lot calmer. Maybe the little animals on the screen distracted her and made the assessment seem quicker. I recommended the device to other caregivers in the village and am happy to bring my other children to the health post to be tested with Rad-G as well."

Selamawit, Ethiopia

Conclusions

Usability

CHWs in Ethiopia were able to adhere to the required steps when using ChARM and Rad-G.

Due to capacity constraints, CHWs in Nepal had lower levels of adherence to the required steps when using ChARM after two months. Their adherence to WHO's case management requirements was significantly lower than to manufacturer's instructions for use. This could be due to their lower level of literacy, numeracy or training and/or the remote location of the study.

Contextual differences need to be considered when introducing automated pneumonia diagnostic aids. CHWs in Ethiopia had a higher literacy level and were on average younger and more accustomed to new technology than CHWs in Nepal. Therefore, they were able to adhere to the required steps more easily. They also received more frequent IMNCI training and supervision than CHWs in Nepal, and had more practice using ChARM as they saw more patients.

Across the three studies, there is not currently enough data to make recommendations about the usability of devices for children in specific age groups, or for children with fast-breathing or hypoxemia.

Acceptability

Both ChARM and Rad-G were acceptable to frontline health workers and caregivers in Ethiopia and Nepal.

Future research

The findings from the ARIDA field trials support the rationale for further studies on performance, cost-effectiveness and implementation of RR and RR-SpO2 devices to inform policy decisions in countries with a high burden of childhood pneumonia.

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