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ARIDA field trials – update on ARIDA device agreement and acceptability studies in Ethiopia and Nepal

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Child Health Task Force – Implementation Science sub-group, September 26th 2018

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Overview of pneumonia and ARIDA field trials

Overview of pneumonia and ARIDA field trials

Problem

- Pneumonia is the leading cause of death from infectious disease in U5 children worldwide
- Pneumonia is under-diagnosed and inaccurately treated
- Pneumonia deaths are concentrated within poorest populations
- Investment in pneumonia R&D is low

Potential solutions

- Increase availability of improved tools to support frontline health workers diagnose pneumonia
- Improve access to treatment: antibiotics and oxygen therapy

Overview: Acute **R**espiratory **I**nfection **D**iagnostic **A**ids

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Image: Philips ChARM device: automated respiratory rate counter

Image: Masimo Rad-G device: fingertip pulse oximeter

Diagnostic agreement study: ChARM

St Paul's Hospital Addis Ababa, Ethiopia, April – May 2017

Diagnostic agreement study: ChARM

Study objectives:

- To assess the agreement* between the respiratory rate (RR) count of ChARM and the RR count of the reference standard, a video expert panel (VEP)

- To assess the agreement* between two ChARM devices counting RR for the same child at the same time

- To assess the agreement* between the on-the-spot RR count by an expert clinician (EC) and the RR count of the reference standard, a video expert panel (VEP)

- To assess the agreement* between two ECs counting RR for the same child at the same time

*Agreement is presented in terms of:
1) mean absolute difference in **RR counts** (root mean square difference);
2) binary **classification** of children to the 'fast breathing' and 'normal breathing' groups.

Diagnostic agreement study: ChARM

Reference standard:

Video expert panel (VEP)

60-second video of the child's chest movements taken at the same time as the ChARM and EC evaluation

VEP respiratory rate (RR) compared to ChARM and EC RR

Image: Diagnostic agreement study pre-test – a child is being assessed by the ChARM device and by an expert clinician using the MK2 ARI timer. The assessment is being recorded on video

Diagnostic agreement study: ChARM

Inclusion criteria:

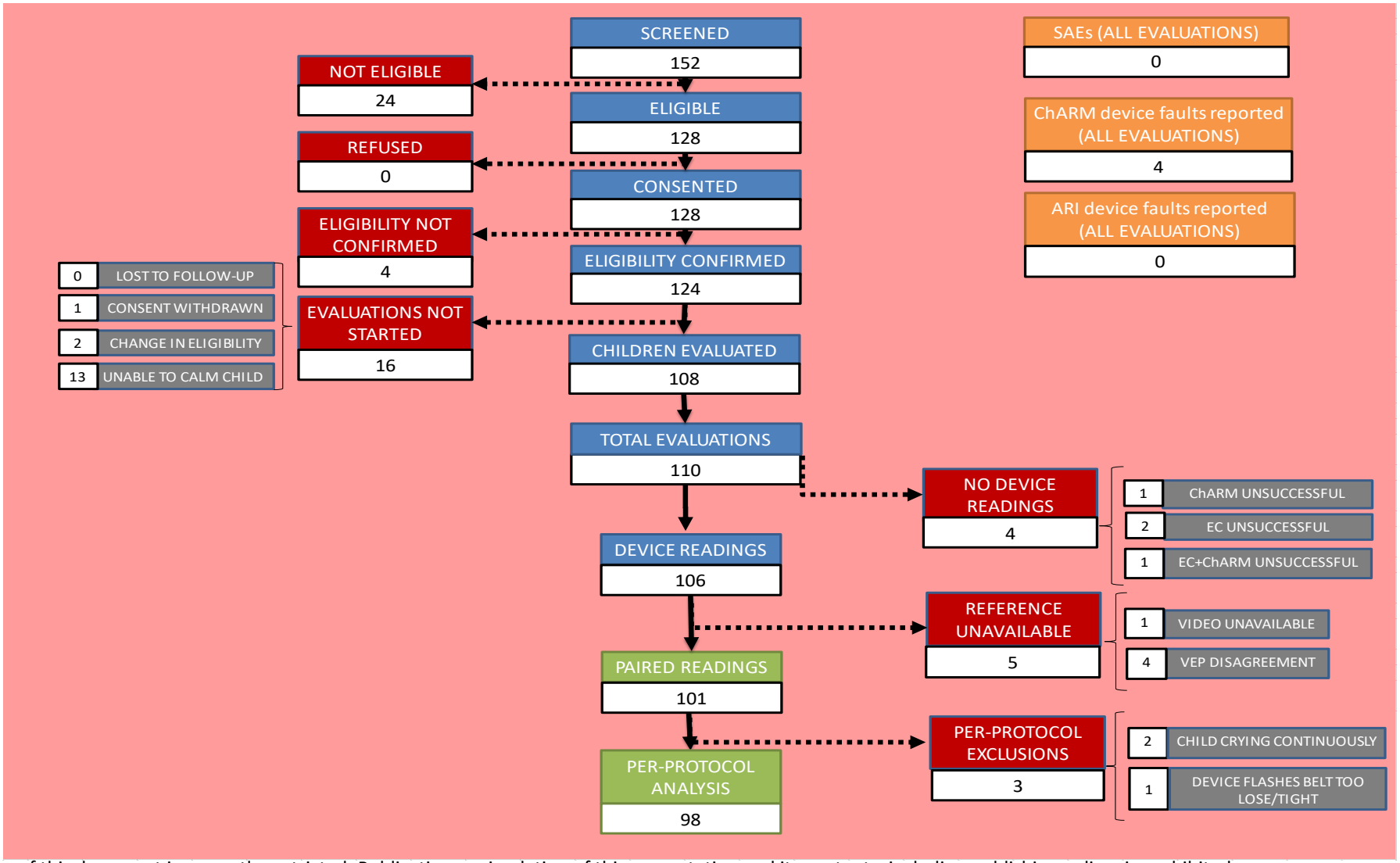
- Child aged 0-59 months presenting
- Parent or guardian consent
- Cough and/or difficulty breathing for 2-59 month olds

Exclusion criteria:

- Child with general danger signs
- Child with signs of severe pneumonia
- Child with IMNCI pink referral signs for severe disease
- Parent/guardian under 16 years
- Device manufacturer safety exclusion criteria

The study also enrolled a 3:1 ratio of fast:normal breathing cases

Diagnostic agreement study: ChARM



Results:

Table 1: ChARM and expert clinician agreement with video expert panel

	Root mean square difference	Positive percent agreement (%) (95%CI)	p-value	Negative percent agreement (%) (95% CI)	p-value	Kappa (interpretation)
ChARM agreement with VEP (n=98)	9.3	81.5 (68.6, 90.7)	1	84.1 (69.9, 93.4)	1	0.65 (moderate)
EC agreement with VEP (n=98)	5.3	92.6 (82.1, 97.9)	0.076	75 (59.7, 86.8)	0.3	0.69 (moderate)

Based on agreement between **respiratory rate counts**:

- **the ChARM device agrees less with human experts than humans agree with each other** (RMSD 9.3 vs. 5.3)

Based on the binary **classification** of children to the 'fast' and 'normal' breathing groups,

- **ChARM is not significantly different from the EC at classification of RR** in both fast (p=0.076) and normal (p=0.3) breathing cases.
- Overall **agreement in classification with the VEP was moderate** for both ChARM (K=0.65) and EC (K=0.69).

Results:

Table 2: Interrater agreement between two ChARM devices, two VEP members and two ECs

	Root mean square difference	Positive percent agreement (%) (95%CI)	Negative percent agreement (%) (95% CI)	Kappa (interpretation)
ChARM vs. ChARM (n=37)	4.2	84.2 (60.4, 96.6)	100 (81.5, 100)	0.84 (strong)
VEP 1 vs VEP 2 (n=105)	4.2	92.9 (82.7, 98)	91.8 (80.4, 97.7)	0.85 (strong)
EC vs. EC (n=37)	6.6	82.4 (56.6, 96.2)	100 (83.2, 100)	0.83 (strong)

Based on agreement between **respiratory rate counts**:

- **Human expert counters do not agree with each other perfectly**, but agree more when assisted with videos (RMSD=6.6 and 4.2 bpm)
- **Inter-ChARM agreement is similar to two VEP members** (4.2 bpm)

Based on the binary **classification** of children to the 'fast' and 'normal' breathing groups:

- Human inter-rater agreement and inter-ChARM agreement in RR classification is strong

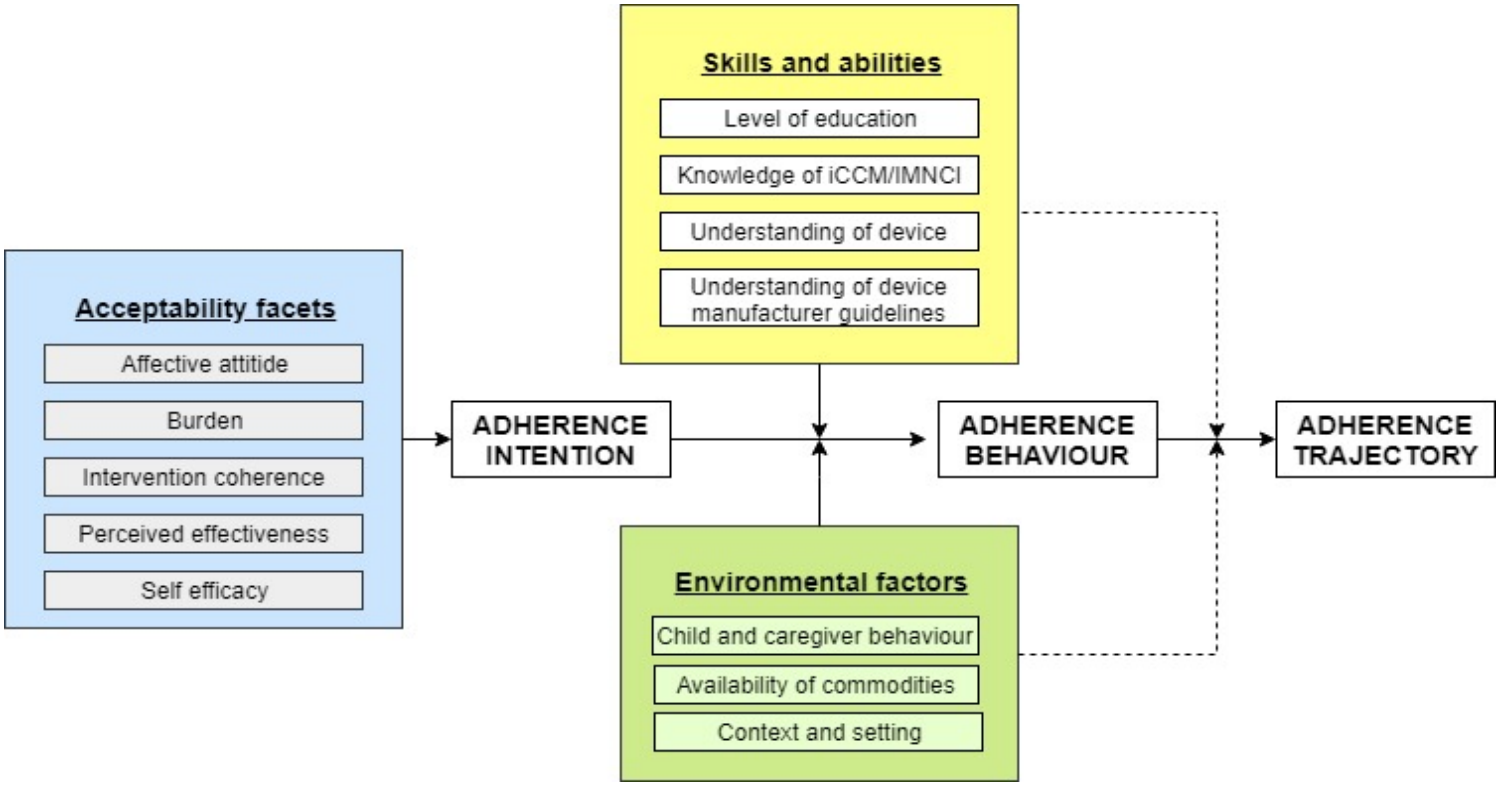
Diagnostic agreement study: ChARM

Conclusions

- ChARM is not significantly different from the EC at RR classification - you can replace a human counter with this device.
- The findings from this study cannot support or challenge ChARM accuracy:
  - Large differences observed between human expert counters. Neither VEP or EC can be used as a reference standard.
  - ChARM measures a slightly different breath sequence (mean time taken for RR=79 seconds)
  - ChARM adjusts for non-breathing movement
- Further work is needed to refine reference standards for new RR devices
  - *Video annotation software*
  - *Larger panel of experts*

Acceptability study: ChARM and Rad-G

Acceptability study: ChARM and Rad-G

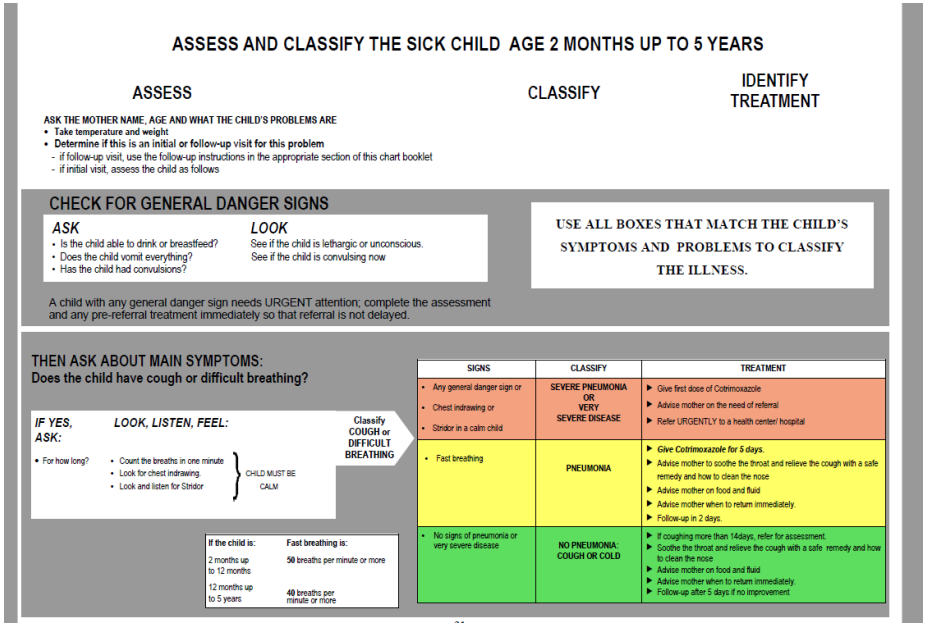


Conceptual framework of frontline health workers' adherence to iCCM/IMCI guidelines, adapted from Adams et al., 2017

Acceptability study: ChARM and Rad-G

Specific objectives:

1. To determine if CHWs using an ARIDA adhere to iCCM algorithms and correctly assess and classify children under-five with cough and/or difficult breathing after two months of routine use.



ASSESS AND CLASSIFY THE SICK CHILD AGE 2 MONTHS UP TO 5 YEARS

ASSESS | CLASSIFY | IDENTIFY TREATMENT

ASK THE MOTHER NAME, AGE AND WHAT THE CHILD'S PROBLEMS ARE
- Take temperature and weight
- Determine if this is an initial or follow-up visit for this problem
  - if follow-up visit, use the follow-up instructions in the appropriate section of this chart booklet
  - if initial visit, assess the child as follows

CHECK FOR GENERAL DANGER SIGNS

ASK
- Is the child able to drink or breastfeed?
- Does the child vomit everything?
- Has the child had convulsions?

LOOK
See if the child is lethargic or unconscious.
See if the child is convulsing now

USE ALL BOXES THAT MATCH THE CHILD'S SYMPTOMS AND PROBLEMS TO CLASSIFY THE ILLNESS.

A child with any general danger sign needs URGENT attention; complete the assessment and any pre-referral treatment immediately so that referral is not delayed.

THEN ASK ABOUT MAIN SYMPTOMS:
Does the child have cough or difficult breathing?

IF YES, ASK:
- For how long?

LOOK, LISTEN, FEEL:
- Count the breaths in one minute
- Look for chest indrawing.
- Look and listen for Stridor

CHILD MUST BE CALM

Classify COUGH or DIFFICULT BREATHING

If the child is:	Fast breathing is:
2 months up to 12 months	50 breaths per minute or more
12 months up to 5 years	40 breaths per minute or more

SIGNS	CLASSIFY	TREATMENT
• Any general danger sign or • Chest indrawing or • Stridor in a calm child	SEVERE PNEUMONIA OR VERY SEVERE DISEASE	▸ Give first dose of Cotrimoxazole ▸ Advise mother on the need of referral ▸ Refer URGENTLY to a health center/ hospital
• Fast breathing	PNEUMONIA	▸ Give Cotrimoxazole for 5 days. ▸ Advise mother to soothe the throat and relieve the cough with a safe remedy and how to clean the nose ▸ Advise mother on food and fluid ▸ Advise mother when to return immediately. ▸ Follow-up in 2 days.
• No signs of pneumonia or very severe disease	NO PNEUMONIA: COUGH OR COLD	▸ If coughing more than 14days, refer for assessment. ▸ Soothe the throat and relieve the cough with a safe remedy and how to clean the nose ▸ Advise mother on food and fluid ▸ Advise mother when to return immediately. ▸ Follow-up after 5 days if no improvement

Acceptability study: ChARM and Rad-G

Specific objectives:

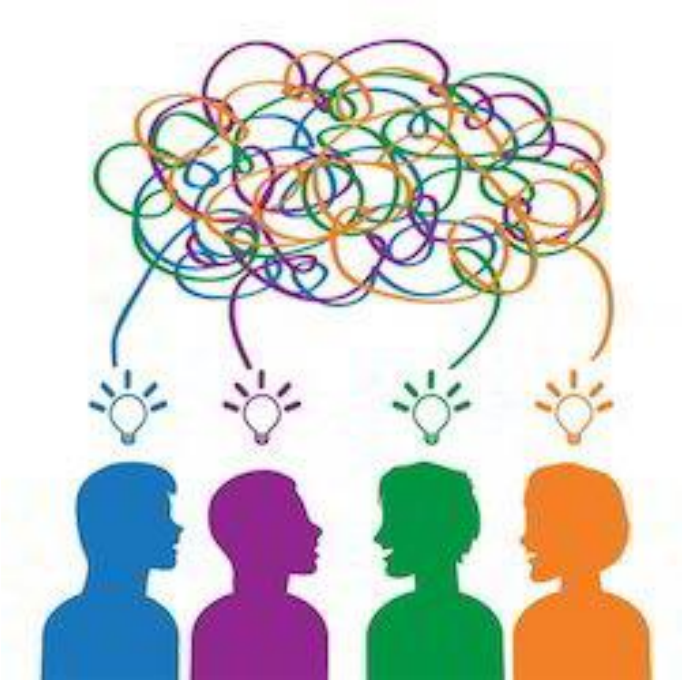
2. To document the user experience of ARIDA in a sick child consultation**.**

- Number and type of errors made during the management of the sick child using ARIDA (assessment, classification, treatment, referral)
- Mean time taken to complete the sick child assessment
- Number of unsuccessful attempts and failures using ARIDA
- Number of children assessed by health workers s with ARIDA during routine care

Acceptability study: ChARM and Rad-G

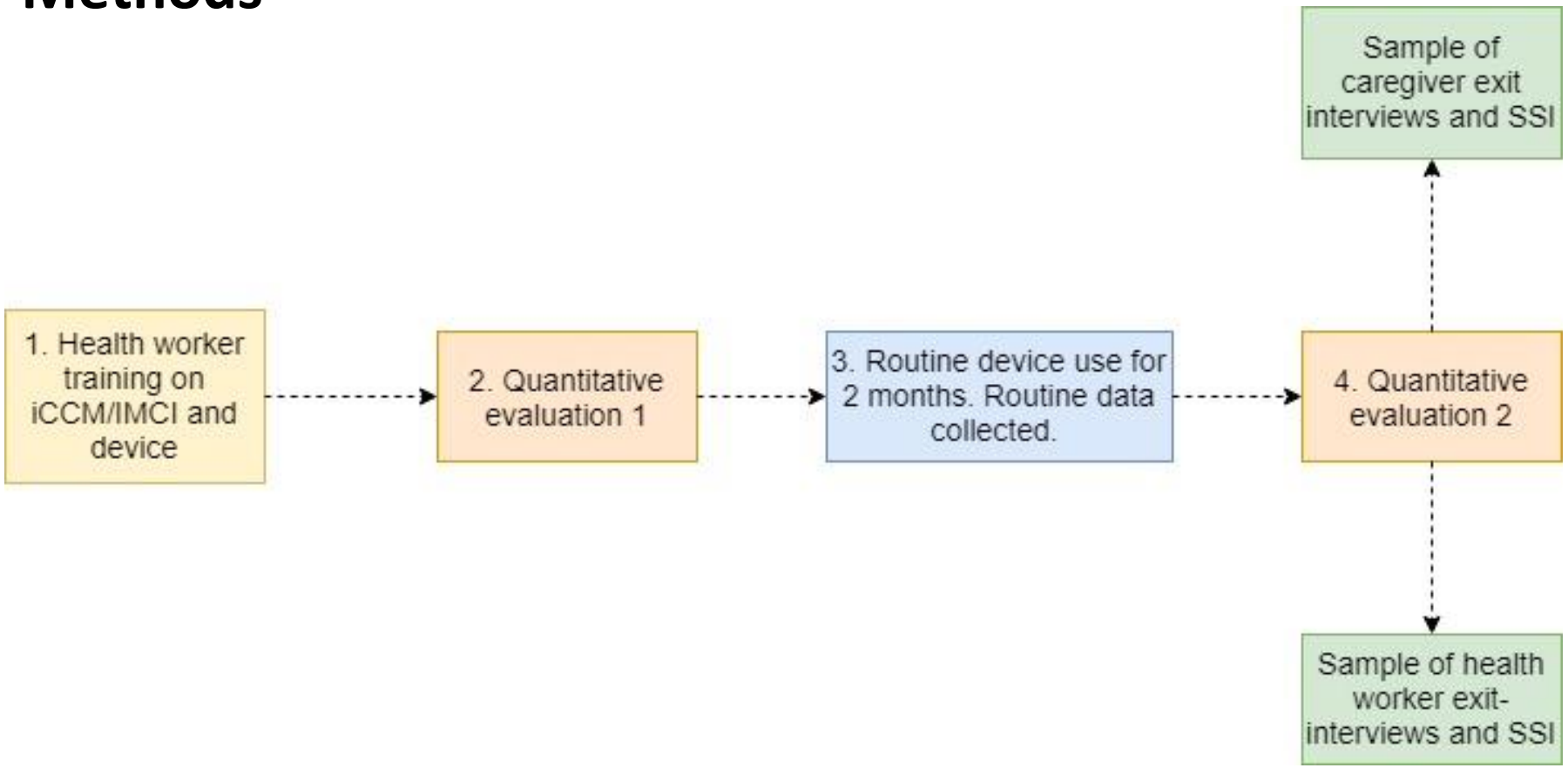
Specific objectives:

3. To explore the acceptability of the ARIDA to frontline health workers and caregivers



Acceptability study: ChARM and Rad-G

Methods



Acceptability study: ChARM, SNNPR, Ethiopia

Image: ARIDA ChARM acceptability training, Hawassa, Ethiopia, April 2018

Acceptability study: Rad-G, SNNPR, Ethiopia

Image: mother and child waiting for the Rad-G assessment, Ethiopia, July 2018

Acceptability study: ChARM, Jumla, Nepal

Image: Female community health volunteer, Jumla district, Nepal, September 2018

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Thank you

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