

Children's Automated Respiration Monitor (ChARM):

an innovative easy to use pneumonia screening tool for low resource settings





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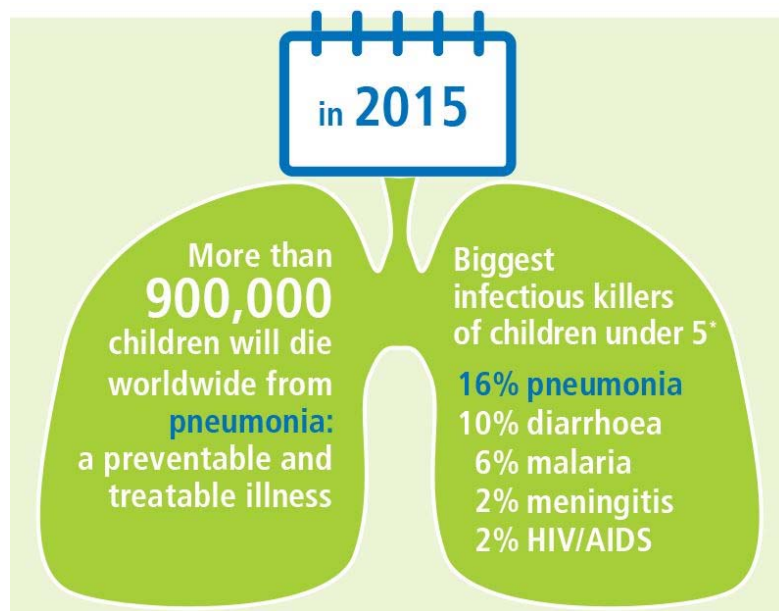
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Background

Pneumonia – the leading child killer



WHO estimated 5.9 million children under age five died in 2015

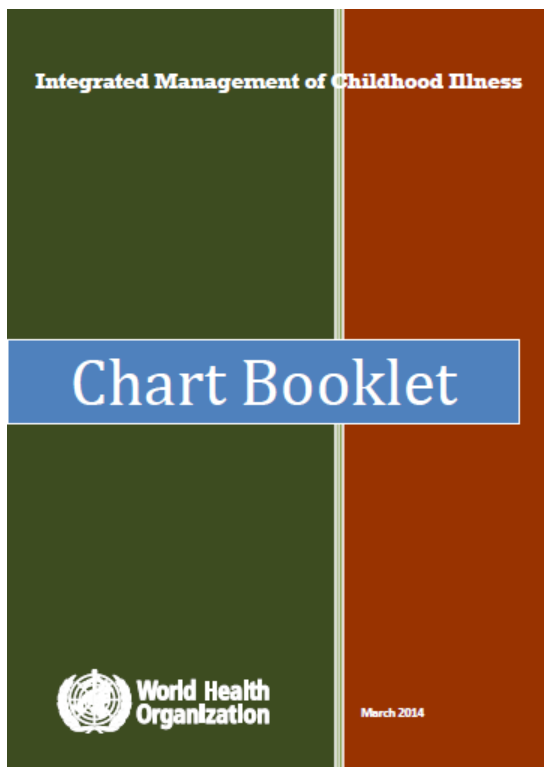
Pneumonia kills more than 900,000 children under five every year

More than all child deaths from malaria, AIDS and measles combined

Source: WHO And Pneumonia Innovation Summit 2015

Pneumonia diagnosis

WHO defined pneumonia



- **Not easy task in low-resource settings**
- **WHO IMCI fast breathing cut-offs**
 - <2 months - ≥ 60 breaths/min
 - 2-11 months - ≥ 50 breaths/min
 - 12-59 months - ≥ 40 breaths/min
- **Assessing fast breathing is crucial for diagnosing children's pneumonia**

Children's Automated Respiration Monitor (ChARM)

- In response to UNICEF's call for innovation for improved pneumonia diagnostics
- In consultation with SC - on needs and specifications

Philips developed ChARM



Children's Automated Respiration Monitor (ChARM)

ChARM is designed to -

- be placed around the child's belly,
- measure automatically respiratory rate, and
- classify fast breathing according to WHO guidelines

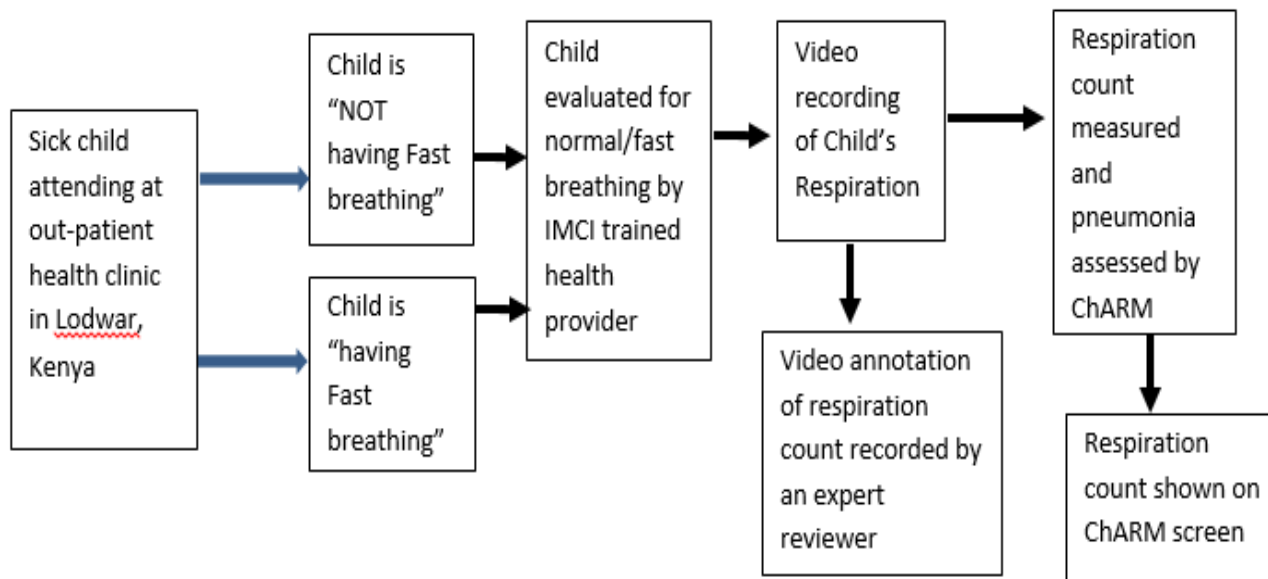


Field study



- Prospective study following observational design
- To assess accuracy, usability and acceptability of ChARM
- At 4 health centers in Lodwar county, Kenya
- During January – July 2016
- Included Under 5 years children with or without fast breathing
- Obtained approval from IRB/KEMRI and ERC/SC-US

Study procedure



Study Sample

- **We enrolled 110 children**
 - 18 were excluded because of excessive movement which made difficult to obtain a reliable reference count during video annotation.
- **Thus, data from 92 study children were analyzed and presented in our results.**

Enrolled child's Age group	Without Fast breathing	With Fast breathing	Total
0 – 2 months	8	10	18
2-11 months	18	23	41
12-59 months	13	20	33
Total	39	53	92

Respiration counts

- Respiration count was measured by -
 - Physicians' count – was measured for first full minute for each child
 - Annotation of video clips

We took the respiration count on video annotation as the 'reference count'

- Each child's video clip was annotated, frame by frame, by an expert reviewer.
 - Each video clip was played forward and backward with various speeds until every breath moment was marked.

Respiration counts

- During video annotation, respiration counts were measured with two reference boundaries:
 - **Reference – Low**: represents the actual counts during a full minute
 - **Reference – High**: represents respiration counts during calm phase
- The calmer the child, the more these two counts move towards each other.
- We consider any value between Ref-Low and Ref-High counts as good and have 0 error
- “Uncertainty” was calculated by subtracting ‘Reference-Low’ count from ‘Reference –High’ count
 - We included data with uncertainty level <20 RPM

Statistical analyses

- For estimating performance of ChARM, we employed
 - **RMSE (Root Mean Squared Error)** – shows how good a set of measured values approach the ideal “reference” values.
 - **Percentage below 2 RPM** – **≥80 %** is indicative of a better performance than an average physician.
- Based on UNICEF’s 2014 Target Product Profile for child’s breath counting device, the accuracy for a device should be close to ± 2 breaths from the ‘reference standard’.
 - Thus, the ChARM device should have a count close to this limit (± 2), compared to the ‘reference’ boundaries (Low and High), to be considered as an ‘accurate’ alternate method.

Study results: RMSE and % <2 RPM for ChARM

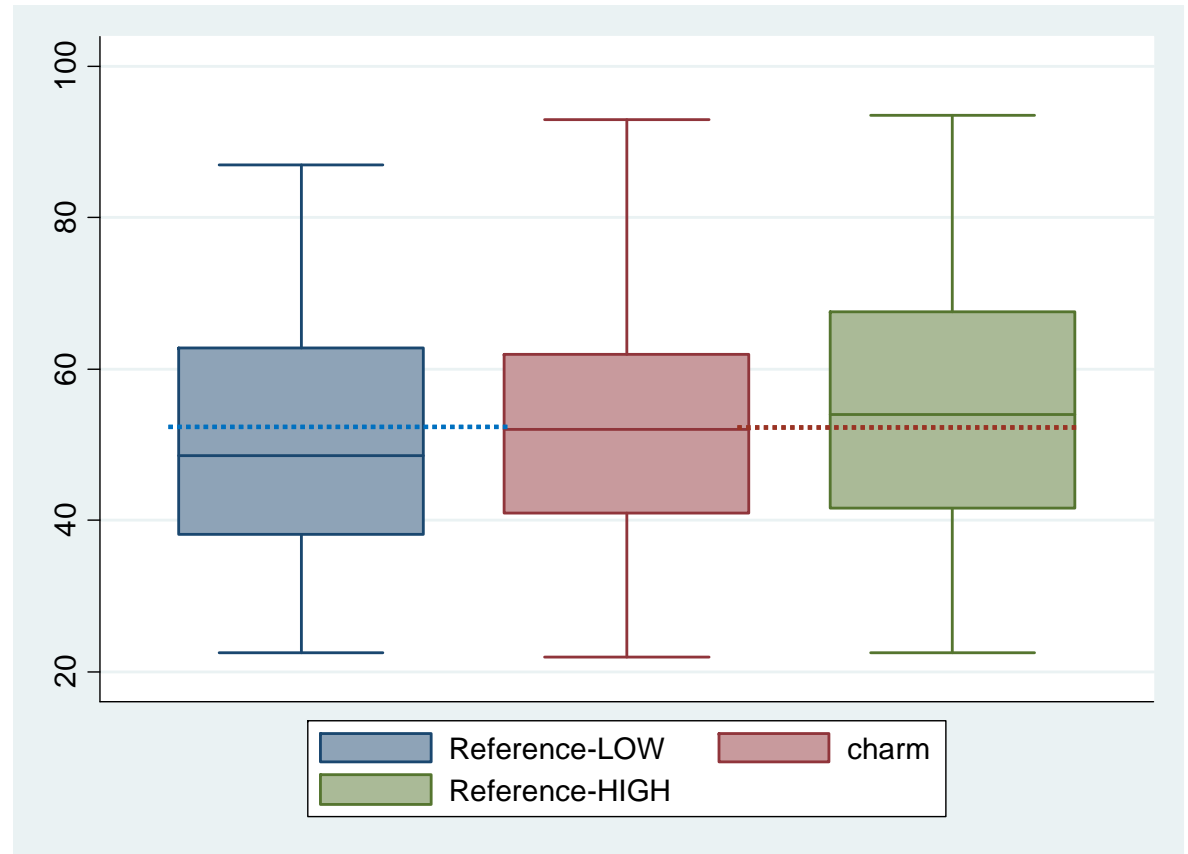
	N	RMSE	% 2 RPM
Overall value	92	1.9	83.7
Age groups			
0-2 months	18	3.0	72.2
2-11 months	41	1.6	85.4
12-59 months	33	1.6	87.9
Status of fast breathing			
with Fast Breathing	53	2.3	77.4
Without Fast Breathing	39	1.2	92.3
Combined categories			
0 – 2 m, with Fast breath	10	3.8	60.0
0 – 2 m, without Fast breath	8	1.7	87.5
2 – 11 m, with Fast breath	23	1.8	82.6
2 – 11 m, without Fast breath	18	1.3	88.9
12 – 59 m, with Fast breath	20	1.9	80.0
12 – 59 m, without Fast breath	13	0.7	100.0
Balanced value	92	2.1	83.2

We estimated RMSE for ChARM device which measured close to 2. Our estimated balanced % <2 RPM (83%) is also found higher than the same estimates for physicians (which was 64% and 73% for physicians)

These comparative % <2 RPM estimates reveal that **ChARM device is at least as good as a trained physician for measuring breath count.**

Study results

ChARM count in relation to reference count boundaries



Expected benefit and impact

- **Locally relevant, easy to use automated RR measurement device for low-resource settings**
- **Will help reducing overtreatment with antibiotics by accurate diagnosis of pneumonia**
- **Estimated 40% of Community care (CHW's) and 30% of Primary care facility segment to be addressable in LMIC's.**

This represents an estimated 3M units as addressable market volume globally.

- **Estimated measurement cost per patient/case- USD 0.02 to USD 0.05**

