One-arm safety intervention study on management of chest indrawing by CORPs, Niger state, Nigeria

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Rationale for study

- **Pneumonia** is a leading cause of death in children 2-59 months

- Many children with symptoms of severe pneumonia, such as chest indrawing**, do not reach referral facilities** due to a range of barriers – geographic, financial and socio-economic

- In Nigeria, **appropriate care seeking for pneumonia happens in under 40% of cases**, typical of more rural areas such as Niger state

- **Improved care seeking, along with appropriate training, support and supervision of community health workers (CORPs)** to assess, classify and manage fast breathing and chest indrawing pneumonia using oral antibiotics, can reduce pneumonia-related mortality

Can CORPs safely and appropriately manage chest indrawing pneumonia in children 2-59 months old?

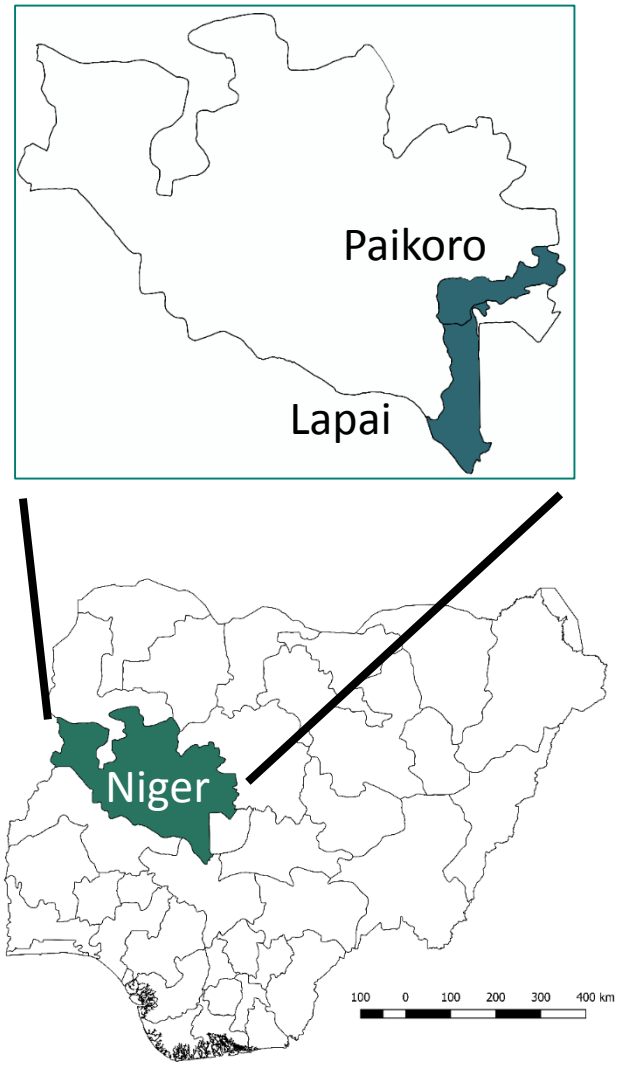
Primary outcomes

- Proportion of children under five classified with chest indrawing pneumonia who are managed appropriately by CORPs
- The clinical treatment failure rate of chest indrawing pneumonia by day 6

Secondary outcomes

- Proportion of children classified with chest indrawing who were followed up by CORPs on day 3
- Clinical relapse of pneumonia between day 7 to 14 among children whose signs of pneumonia disappeared by day 6
- CORPs' acceptability of and caregiver satisfaction with community level management of chest indrawing pneumonia

Study location



- **Two local government areas** (districts) in Niger state, Nigeria, within RAcE iCCM project
- **308 children with chest indrawing** to be enrolled (to estimate the prevalence of the main outcome with ±7% precision and 95% CI – based on conservative estimate of 50% prevalence)
- **350 CORPs in total** – all gave consent to participate in study

CORP job aid to assess child for chest indrawing study

Ask about danger signs

If danger signs present or other condition CORP is unable to treat, REFER

If NO danger signs, continue with assessment. Assess child for cough/difficulty breathing, fast breathing and chest indrawing

No chest indrawing, treat child using normal iCCM guidelines

If chest indrawing present, ask for caregiver consent to enrol child in study

Treat with oral amoxicillin according to WHO guidelines

Research Assistants (RAs)

- 12 in total, resident in the two study LGAs

- Profile: retired or non-working health professionals, mainly nurses

- Responsible for verifying CORPs' original assessment of enrolled child with chest indrawing by completing full IMCI-based assessment within 12 hours
- Do outcome re-assessments on days 6 and 15
- The verification includes videotaping the chest indrawing child

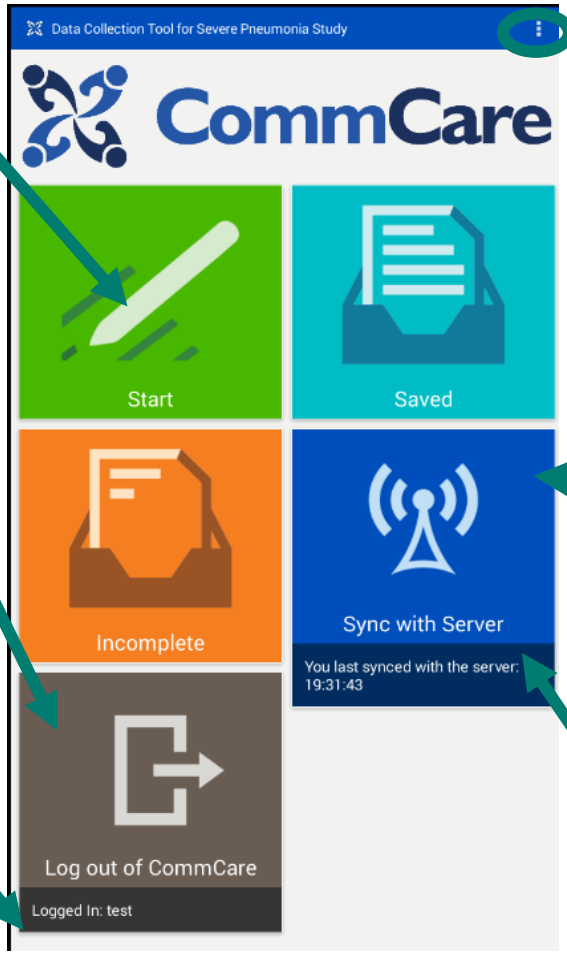
- **RAs use tablets with customised CommCare app to complete re-assessment**

The CommCare application

Start- Select here to enter the application and fill out the data collection forms

Log out - When you want to exit the application, select this button

Logged in - This tells you which account you are submitting data from



Update app – This will manually check for updates to the app. However the app should also automatically check for updates on a daily basis

Sync with server - Select this button at least once each day to send any pending forms on the tablet to Malaria Consortium. However the app should automatically send the forms to the server if there is signal

Last sync - This information is to notify you of the number of outstanding forms to send (if any) and the last time you sent data to Malaria Consortium's server

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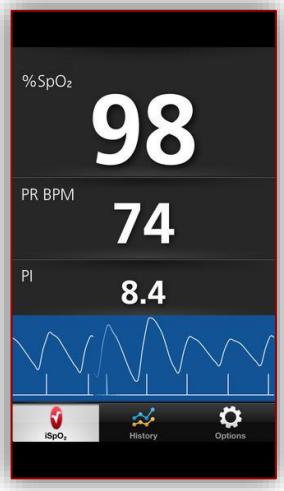
- **RAs use the Masimo iSpO2 phone pulse oximeter linked to app on tablet**



MASIMO iSpO2 phone pulse oximeter

Job aid

malaria consortium
disease control, better health

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- **RAs support CORPs involved in the study and referrals if required – and for linking with CORP supervisors**

Follow up visit schedule for children enrolled

Day	0	0-1	3	6	15
Activity	Screening and enrolment	Re-assessment (IMCI) including pulse oximeter*	Re-assessment	Re-assessment as for Day 0-1	Re-assessment as for Day 0-1
Person	CORP	RA	CORP	CORP and RA	CORP and RA
Outcomes		•CORP performance to manage chest indrawing •Health status of child	•Health status of child	•Health status of child •Treatment failure •Treatment adherence	•Health status of child •Clinical relapse
Location	CORP	Household	CORP or household	Household	Household

**Pulse oximeter reading taken if child has signs of chest indrawing and/or fast breathing, as per IMCI guidelines*

Treatment failure criteria

- Appearance of a danger sign (unable to drink or breastfeed, convulsions, vomiting after ingestion of food or drink, and abnormally sleepy or difficult to wake)
- Hypoxemia (oxygen saturation ≤90%)
- Temperature ≥37.5°C and chest indrawing on day 3
- Temperature ≥37.5°C or chest indrawing alone on day 6
- Change of antibiotic
- Death

Study implementation

- **Training and orientation of research personnel**: oversight provided by FMoH, SMoH and WHO — **July/Aug 2016**
- **RAs:** pulse oximeter and tablet installed with CommCare and Masimo iSpO2 apps — **Aug 2016**
- **DSMB** established; **study site** visit — **Oct 2016** — **April 2017**
- Identification of **referral centres**; assisted referrals
- **Data collection**: case identification, consent, enrolment and case management — **Started Oct 2016**
- **Monitoring and evaluation** including real-time data management
- Continuous **community mobilisation**
- **Competency quality assurance sessions** for research personnel

Issues detected

Enrolment rate

- By June 2017, only 71 children with chest indrawing had enrolled
- Based on an observed lower prevalence of main outcome (5% prevalence, ±2.5% precision and 90% CI), revised sample size down to 200 children

Capacity of CORPs and RAs

- Monitoring visits to study site detected issues with capacity of CORPs to assess chest indrawing and danger signs (both rare occurences)

Measures to increase enrolment rate

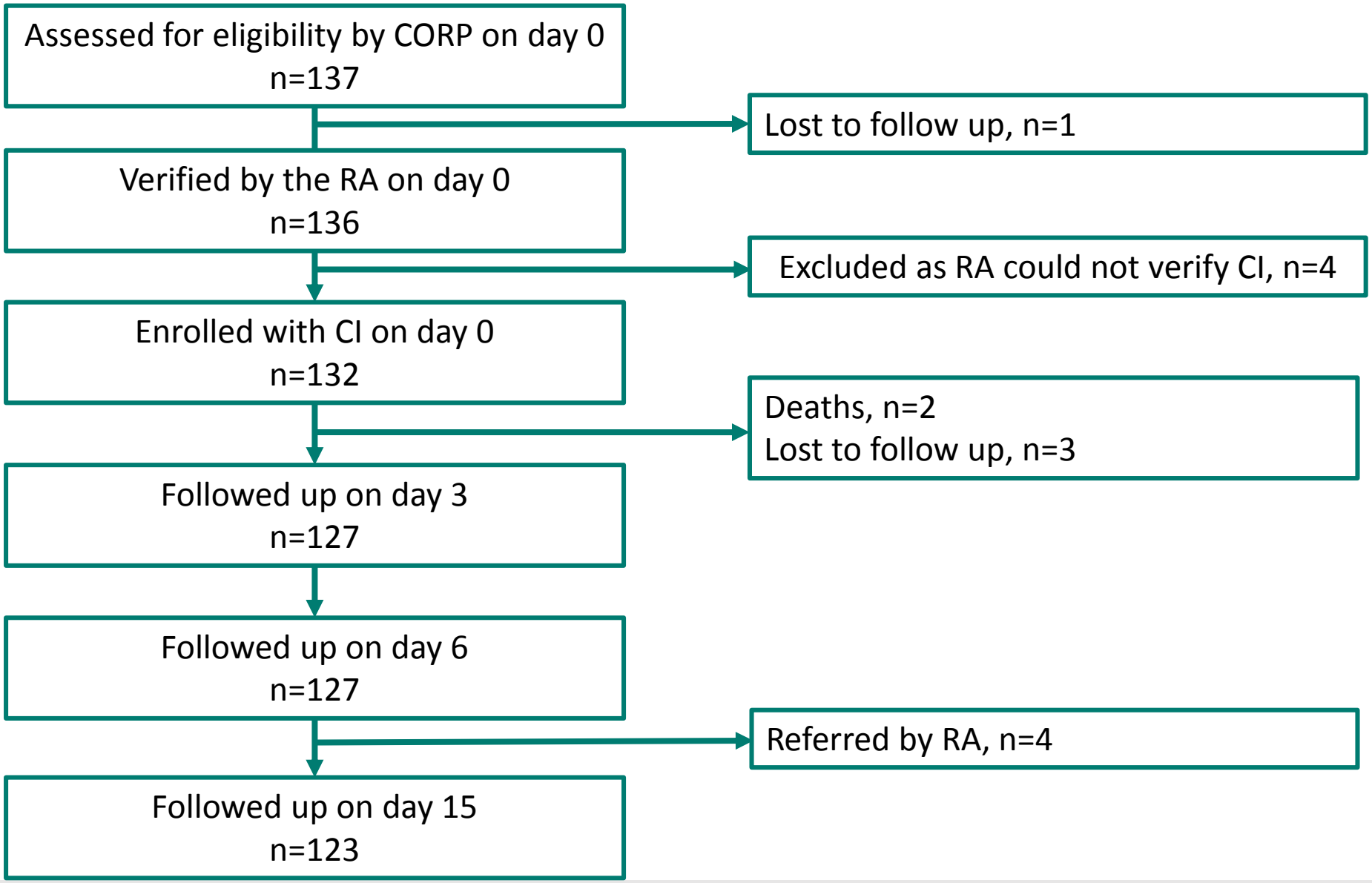
Community engagement and sensitisation

- **Focused messages** by social mobilisers
- **Delivery of messages by religious leaders** – both Muslim and Christian
- **Meetings** with traditional healers
- **More posters and banners** on CORPs' services
- Mothers of children with chest indrawing **treated in study as champions**
- **Media campaign** on radio

Measures to strengthen CORP and RA capacity

- **Refresher training of CORPs and RAs** and strengthened follow-up

Trial profile



Next steps

- Acceptability and satisfaction data being collected – from both caregivers and CORPs
- Continue social mobilisation for higher enrolment rates
- Continue enrolment into Dec 2017
- Analysis to be completed by Feb/Mar 2018

Lessons learnt

- **Frequent refresher training of CORPs and RAs post-initial training is necessary** to achieve required quality and capacity to appropriately manage chest indrawing cases

- **Scaling up would require focused and sustained strengthening** of CORP and supervisor capacity to recognise chest indrawing as well as other danger signs

- **Conducting community engagement and mobilisation** will increase cases of chest indrawing presented to CORPs

- **Using the app on tablet for study data** entry enables effective real-time monitoring of progress

Thank you

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