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
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

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

Treat with oral amoxicillin according to WHO guidelines

No chest indrawing, treat child using normal iCCM 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 also 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
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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

<table>
<thead>
<tr>
<th>Day</th>
<th>0</th>
<th>0-1</th>
<th>3</th>
<th>6</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity</strong></td>
<td>Screening and enrolment</td>
<td>Re-assessment (IMCI) including pulse oximeter*</td>
<td>Re-assessment</td>
<td>Re-assessment as for Day 0-1</td>
<td>Re-assessment as for Day 0-1</td>
</tr>
<tr>
<td><strong>Person</strong></td>
<td>CORP</td>
<td>RA</td>
<td>CORP</td>
<td>CORP and RA</td>
<td>CORP and RA</td>
</tr>
</tbody>
</table>
| **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 occurrences)
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**

- Assessed for eligibility by CORP on day 0, n=137
  - Verified by the RA on day 0, n=136
    - Enrolled with CI on day 0, n=132
      - Followed up on day 3, n=127
      - Followed up on day 6, n=127
      - Followed up on day 15, n=123
        - Lost to follow up, n=1
        - Excluded as RA could not verify CI, n=4
        - Deaths, n=2
          - Lost to follow up, n=3
        - Referred by RA, n=4
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