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Understanding the outcome and management of children aged 2–59 months with chest indrawing pneumonia: a study protocol for an observational study in Ethiopia, India, Nigeria, Pakistan, Uganda and Zambia

Chest Indrawing Pneumonia Management (CIPAM) Study Group

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ABSTRACT

Introduction Childhood pneumonia is a leading cause of morbidity and mortality among children aged 2–59 months, particularly in low-income and middle-income countries (LMICs), where healthcare providers face significant challenges in diagnosing and treating childhood pneumonia. Many LMICs have taken steps to address this issue by revising their national policies and aligning them with WHO's revised guidelines for pneumonia management. These revised guidelines aim to facilitate the outpatient management of children aged 2–59 months chest indrawing pneumonia. Despite these efforts, there is limited empirical evidence regarding the management and outcomes of these children in primary-level healthcare settings. This study aims to assess the survival status of children aged 2–59 months with chest indrawing pneumonia presenting at primary healthcare facilities.

Methods and analysis A prospective, observational cohort study will be conducted in Ethiopia, Nigeria, Uganda, Zambia, India and Pakistan on children aged 2–59 months presenting at selected primary-level healthcare facilities with chest indrawing pneumonia. Eligible participants will be enrolled and managed by facility healthcare providers who are trained in Integrated Management of Childhood Illness and will be followed up on day 15 to record the treatment-related information and vital status, including conducting verbal autopsies in case of child death. The sample size for each site will be 310. The analysis will involve exploring site-specific trends before conducting a pooled analysis of de-identified data from all sites. The first data collection started at the Ethiopian site in September 2022, followed by other sites. The data collection will continue until June 2025.

Ethics and dissemination The study protocol, enrolment forms and consent forms will undergo ethical review by the Institutional Review Boards of the University of Gondar, Gondar, Ethiopia; the INCLEN Trust International Independent Ethics Committee, New Delhi, India; Ethical Review Committee of the University of Ibadan, Ethical Review Committees of Lagos State and Ethical Review Committee of University College London, UK; Institutional Review Board, International Research Force, Islamabad, Pakistan; Institutional Review Board, People's Primary Healthcare Initiative-Sindh, Karachi and National Bioethics Committee, Islamabad, Pakistan; Makerere University School of Biomedical Sciences Research Ethical Committee, Kampala, Uganda; University of Zambia Biomedical Research Ethics committee, Lusaka, Zambia and Ethical Review Committee of WHO, Geneva, Switzerland. Ethical procedures include WHO and local review board evaluations, parental consent in the local/national language, permits enrolment, follow-up, and, if required, clinical video recording for children with chest indrawing pneumonia, ensuring their eligibility. Adherence to local regulations encompasses precollection ethical approvals, risk management strategies and secure, de-identified data storage. Findings will be disseminated through seminars, publications and meetings, engaging diverse stakeholders to foster collaborations.

Trial registration number ISRCTN12687253.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The proposed study is a comprehensive observational longitudinal study with detailed assessment and follow-up to evaluate the management and outcomes of childhood pneumonia in selected low-income and middle-income countries in sub-Saharan Africa and South East Asia, which have the largest burden of pneumonia in children aged <5 years.
⇒ The proposed study will be performed and overseen by an experienced international research group, combining expertise from all areas of research.
⇒ We had to limit the inclusion of enrolled children where follow-up was feasible due to the limited technical and financial resources, which might systematically exclude the geographically marginalised population that is more vulnerable to poor outcomes.
⇒ Being an observational nature of the study, the impact of certain unmeasured confounding variables cannot be excluded.

INTRODUCTION

Pneumonia in children aged <5 years is a major public health problem and is one of the leading causes of childhood deaths worldwide,[1] mostly in low-income and middle-income countries (LMICs). In 2021, pneumonia claimed the lives of 725 557 children aged <5 years, primarily in LMICs.[2]

The Democratic Republic of Congo, Ethiopia, India, Nigeria and Pakistan contribute a substantial proportion of pneumonia cases and related deaths.[3 4] Furthermore, beyond mortality, childhood pneumonia contributes to long-term respiratory complications and impaired lung function.[5] The Global Burden of Disease Study reported over 97 million disability-adjusted life years lost globally in 2019, with children aged <5 years bearing a substantial portion of this burden.[6]

Effective management of childhood pneumonia is crucial for reducing morbidity and mortality in children.[3] WHO revised pneumonia management guidelines in 2012, recommending outpatient treatment of chest indrawing pneumonia with oral amoxicillin based on findings from clinical trials.[7–10] The WHO Integrated Management of Childhood Illnesses (IMCI) chart booklet was revised in 2014.[11] The IMCI proposes a comprehensive approach to the management of childhood pneumonia, including prompt assessment and classification, appropriate treatment with antibiotics, supportive care and referral for severe cases.[11] In 2018–19, a WHO survey reported that 45 (30%) out of 154 countries had embraced the revised WHO pneumonia guidelines. Among them, 39 (87%) recommended oral amoxicillin as the primary treatment for chest indrawing pneumonia.[12]

It is essential to consider the broader context of childhood pneumonia management in LMICs. Childhood pneumonia takes a significant toll on children's health and places a substantial economic burden on families. This burden arises from healthcare expenses related to frequent healthcare visits, hospitalisations and productivity losses resulting from recurrent illnesses. A study conducted in India, for instance, estimated that the direct out-of-pocket cost of hospitalised acute respiratory infections consumed approximately one-third (34%) of the annual per capita income.[13] Implementation of the revised WHO pneumonia management guidelines has been shown to reduce 39.5% of treatment costs, alleviating the significant financial strain on both families and healthcare systems, particularly in nations facing resource limitations.[13]

In addition, healthcare challenges in LMICs are multifaceted and often daunting. These regions grapple with inadequate access to essential healthcare services, resulting from a lack of healthcare infrastructure and geographic barriers.[14] Moreover, the burden of preventable diseases, inadequate sanitation and malnutrition persists, contributing to high rates of morbidity and mortality, particularly among vulnerable populations such as children and pregnant women.[15 16]

These financial and healthcare challenges are exacerbated by a range of systemic issues in LMICs. These challenges include pervasive poverty, limited access to healthcare facilities, a shortage of trained healthcare providers and suboptimal quality of care.[17] Moreover, concerns persist about the overuse and misuse of antibiotics, which undermine treatment effectiveness and contribute to the development of antimicrobial resistance (AMR).[18] The AMR compounds the healthcare challenges in LMICs. The overuse and misuse of antibiotics in these regions have led to a growing threat of AMR, making previously treatable infections increasingly difficult to manage. This poses a serious public health risk, as it limits the effectiveness of essential antibiotics and threatens the success of medical interventions, including surgeries, chemotherapy and the prevention of infections in childbirth.[19] Addressing AMR is a critical component of improving healthcare in LMICs, and it necessitates prudent antibiotic use and investments in infection control and surveillance.

Against this backdrop, the implementation of revised guidelines for the management of WHO-defined pneumonia in an outpatient setting holds immense promise. By addressing these challenges head-on, the revised guidelines have the potential to alleviate the economic burden on families, improve access to quality care and promote judicious antibiotic use, ultimately benefiting children's health outcomes.

In 2018, a retrospective analysis of data concerning hospitalised children with pneumonia in Kenya revealed a notably elevated mortality rate among children who exhibited mild to moderate palmar pallor, had a weight-for-age z-score below −3 SD and displayed lower chest indrawing.[20] These findings raised concerns among the authors and other experts, prompting a recommendation for these children to receive hospital-based treatment, diverging from the outpatient approach advocated by the revised WHO guidelines.

Therefore, it is important to evaluate the current management and outcomes status of children aged 2–59 months with chest indrawing pneumonia in a few selected LMICs using the updated WHO pneumonia guidelines. This prospective observational study in selected primary healthcare facilities in selected countries in Africa and Asia where the burden of disease is the highest would enable us to collect data about outpatient management of children with chest indrawing pneumonia and its associated outcomes.

OBJECTIVES

Primary objective

- To determine the case fatality rate outcome of children aged 2–59 months who present at a primary-level healthcare facility with chest indrawing pneumonia assessed at day 15 postenrolment.

Secondary objective

- To determine the prevalence of antibiotic use (along with mode of administration and duration)

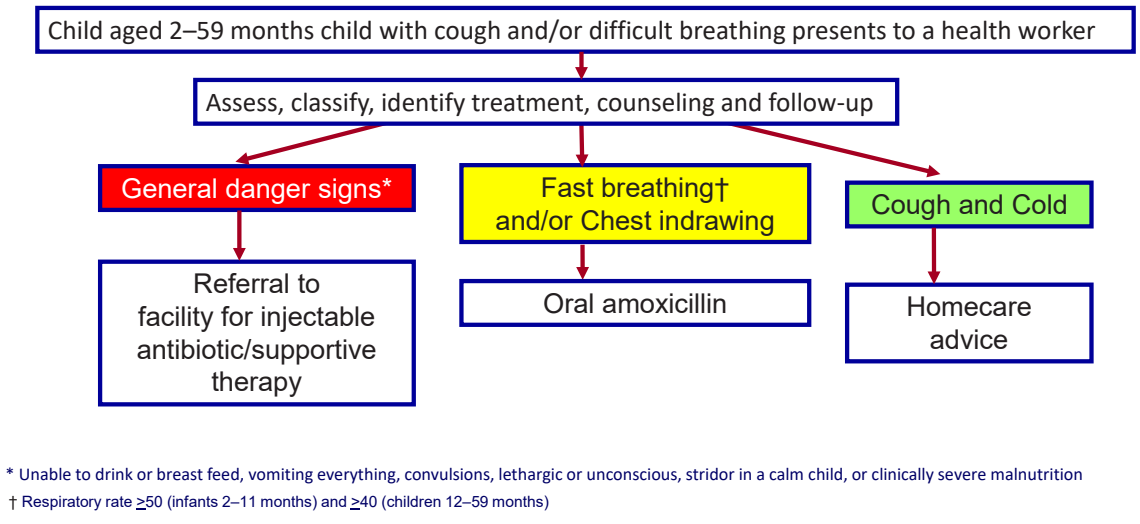

Figure 1 Current Integrated Management of Childhood Illnesses clinical guidelines pneumonia standard case management.[11]

among children aged 2–59 months who present at a primary-level healthcare facility with chest indrawing pneumonia.

- To determine the proportion of hospital admissions (along with the duration of admission) among children aged 2–59 months who present at a primary-level healthcare facility with chest indrawing pneumonia.
- To determine the treatment adherence after discharge among hospitalised children aged 2–59 months who present at a primary-level healthcare facility with chest indrawing pneumonia.

METHODS AND ANALYSIS

Study design and setting

This is a prospective, observational cohort study in six countries, four in Africa (Ethiopia, Nigeria, Uganda and Zambia) and two in Asia (India and Pakistan). These countries were selected due to the high prevalence of childhood pneumonia, and they have updated national policies that recommend oral amoxicillin at the outpatient level for the treatment of chest indrawing pneumonia in children aged 2–59 months. Moreover, these countries have functional primary-level health facilities with staff trained according to the updated WHO IMCI case management tool (figure 1).[11] Tables 1 and 2 show the details of each study site.

Study population

Children aged 2–59 months presenting to selected primary-level healthcare facilities with cough and/or breathing difficulty and presence of lower chest indrawing will be enrolled. Written informed consent will be obtained from parents when the child has been diagnosed with chest indrawing pneumonia, and treatment has been initiated by the healthcare provider. Children will be excluded if they are aged <2 months or >5 years, displaying any general danger sign (eg, convulsions, inability to drink or breast feed, persistent vomiting, lethargy, unconsciousness), stridor when calm, severe malnutrition oxygen saturation (SpO_2) levels below 90% (where pulse oximeter is available),[11] live in an area where the follow-up is not feasible or currently enrolled in another study.

The study investigators at each site, in agreement with the Ministry of Health, will select a suitable number of facilities to achieve the sample size.

Participant and recruitment

The recruitment process involves both the initial assessment and subsequent follow-up evaluations of the outcome.

Initial assessment

At the primary-level healthcare facility, healthcare providers will follow the IMCI chart booklet to assess children presenting with cough and/or breathing difficulty. Based on the assessment, children aged 2–59 months will be classified as having no pneumonia, fast breathing (respiratory rate above the age-specific cut-off per minute), chest indrawing or severe pneumonia.[11] Video recording of children with chest indrawing pneumonia may be done with

Table 1 Details of Ethiopia, India and Nigeria study sites

	Ethiopia	India	Nigeria
Study area	Rural districts of the North Gondar zone, one of the 11 zones in the Amhara region. The zone has 24 districts (Woredas). Estimated population of 4 066 517.[21]	Palwal district of Haryana state (India), at INCLEN-SOMAARTH Demographic, Developmental and Environmental Surveillance Site comprising a population of 223 488 in 51 villages of 3 administrative blocks (Hathin, Hodal and Palwal)	Project in Ikorodu local government area (LGA) of Lagos, Nigeria.[22] The LGA is a peri-urban setting with an estimated population of 15 387 600 and a total area of 245 km^2 (including 145 km^2 of water). The LGA is subdivided into 6 local council development areas (LCDAs) with 28 primary health centres (PHCs) in all.
Characteristics of health facilities	Five health centres (HC) of the Dabat district, that is, Dabat HC, Wokin HC, Dara HC, Gedebye HC and Ambagiorgis HC. Each HC has a catchment population of about 25 000 (about 5000 households). The HCs provide 24-hour outpatient services without any inpatient service.	Three Community Health Centres (CHCs) (Hathin, Hodal and Aurangabad) and three PHCs (Uttawar, Kot, Nagaljaat). The CHCs provide round-the-clock services, including inpatient care throughout the week, whereas the PHCs only provide outpatient services.	Implemented in 16 PHCs, 7 of which were 'flagship' PHCs, 1 in each LCDA, provide 24-hour service with doctors on duty. The other 9 PHCs were selected due to patient load open for 8 hours (08:00–16:00 hours) from Monday to Friday. Only outpatient care is provided. PHCs may observe severe or emergency cases for 2–6 hours, pending referral or discharge on ambulatory care.
Health facility staff	1–2 clinical nurses working in the under-5 clinics. Nurses working in the under-5 clinics have grade 12 education with an additional 4 years of university training in nursing. HC staff trained in Integrated Management for Newborn and Child Illness (IMNCI).	Medical and paramedical staff consisting of medical graduates, graduates in alternate medicine (AYUSH), nurses and pharmacists who are trained in national IMNCI and have the capacity and skill required to appropriately identify, treat and refer cases of cough and cold and/or difficult breathing.	Community health extension workers (CHEWs) and doctors ('flagship' PHCs only). CHEWs are trained in colleges/schools of health technology for at least 2 years. They are licensed and regulated by the Community Health Practitioners Registration Board of Nigeria. All healthcare workers in all study PHCs were trained in IMCI.
Supplies and commodities	Respiratory rate timers, thermometers, weighing scales and height measuring scales (stadiometers). Pulse oximeters and oxygen are not available.	All HCs are equipped with weighing scales and stadiometers. Pulse oximeters and oxygen are available at the CHCs for inpatients. Respiratory rate timers are not available.	All PHCs had respiratory rate timers, mid-upper arm circumference tapes, weighing scales, stadiometers as well as PPEs and medical consumables. The 'flagship' PHCs had pulse oximeters and oxygen concentrators.
Pharmacy	All HCs have dispersible oral amoxicillin tablets.	Oral amoxicillin formulations of 125 mg/5 mL suspension, non-dispersible tablets in 250 mg, 325 mg, 500 mg and 625 mg preparations.	Both oral amoxicillin dispersible tablets and suspension are available at the PHC facilities. However, the suspension is more commonly available.
Laboratory	Rapid diagnostic test for malaria and basic blood and urine examination services are available.	Basic blood and urine examination services are available.	Basic blood and urine examination services are available.
Data collection	Data are collected on outpatient registers and transferred to be entered into the District Information Management System (DHIS) and maintained centrally through the Health Information Management System (HMIS).	Data are collected on outpatient registers and transferred into the electronic repository of health records maintained centrally through the HMIS.	Data are collected on outpatient registers. And is later transferred to the district for entry into DHIS/HMIS.
Referral facilities	District hospitals	District hospitals. Special newborn care units with specialist care exist in district hospitals.	Secondary level or tertiary care level hospitals.
Year of Integrated Management of Childhood Illnesses (IMCI) adaptation with revised pneumonia guidelines	2021	2017	2019

parental consent to evaluate the providers' assessments. The face of the child will not be videographed to protect the privacy of the study patients. Healthcare providers will attend to all patients seeking care in routine and record all essential patient information, such as patient name, age, address, caregivers' phone number, clinical findings and diagnosis, in the daily outpatient register. Additionally, the healthcare

Table 2 Details of Pakistan, Uganda and Zambia study sites

	Pakistan	Uganda	Zambia
Study area	Three geographically diverse sites in Pakistan: the rural Thatta district in Sindh province, the urban district of Lahore in Punjab province and the rural and peri-urban Islamabad Capital Territory (ICT). Thatta district has an approximate population of 982 138.[23] ICT and Lahore have populations of approximately 2 million and 11 million, respectively.[24 25]	Eight selected primary healthcare centre III facilities in the rural Kamuli district in Eastern Uganda that included Bugulumbya, Bulopa, Balawoli, Kitayunjwa, Butansi, Mbulamuti, Nabirumba and Namasagali. The catchment area population varies but ranges from 25 000 to 45 000 people in each subcounty.	Of eight selected primary health centres, four are RHCs; the catchment population is 10 682 for RHC Chikobo, 9652 for RHC Mwachisopola, 14 775 for RHC Chainda and 5616 for RNC Chalimbana. Four are urban HCs; the catchment population is 90 953 for Chaisa Clinic, 47 030 for Chazanga Clinic, 84 700 for Kanyama West Clinic and 94 759 for Mtendere. Clinic.
Characteristics of health facilities	In Thatta, Basic Health Unit (BHU) Dhabeji, Rural Health Centre (RHC) Varr and RHC Jungshahi are selected. These health centres (HCs) have a catchment population ranging from 15 000 to 30 000 and operate round-the-clock. The four selected HCs in Lahore are BHU Ali Raza Abad, BHU Attoki Awan, BHU Jallo Pind and RHC Manga Mandi. In ICT RHC Bara Kahu, RHC Tarlai, RHC Sihala, CHC Rawat and BHU Sohan were selected. The RHCs and CHCs extend services to 100 000 and 150 000 people. RHCs and CHCs operate 24/7. The HCs provide outpatient care, routine healthcare services, maternal, newborn and child health services, routine immunisation services and nutrition services.	The HCs provide services from Mondays to Fridays from 8:30 hours to 17:00 hours. Skeleton staff are available to handle any emergency and refer beyond 17:00 hours and on weekends. Maternity services are available 24/7. The focus is the provision of primary healthcare services—including antenatal care, maternity, postnatal care, family planning, immunisation (static and outreaches), laboratory and dispensing. Circumcision, incision and drainage, superficial soft tissue repair, etc are also carried out.	All the sites work 24 hours every day. Health workers work in two shifts—a morning shift from 7:30 hours to 16:30 hours and a night shift from 16:30 hours to 7:30 hours.
Health facility staff	The healthcare providers serving at these facilities are qualified medical graduates, Trained medical assistants (qualified in allied health sciences and/or dispensers) and nurses. Most were trained in Integrated Management of Childhood Illnesses (IMCI) tools and those who were untrained were trained in IMCI.	Staff include Medical Clinical Officers (Assistant Physicians) who train for 3 years at the diploma level as the highest-trained staff to provide any high-level clinical services. Other staff include midwives, nurses, laboratory assistants and dispensers who are trained for 2 or 3 years at diploma or certificate levels.	Clinical officers, registered nurses, and environmental health technologists each hold a diploma after 3 years of training. The Community Health Assistants are certificate holders with 1 year of training. Healthcare providers in the facilities have been trained in IMCI tools.
Supplies and commodities	Respiratory rate timers, infant pulse oximeters, weighing scales and length/height measuring scales are available at these facilities. Pulse oximeters, and mid-upper arm circumference (MUAC) tapes were supplied by the research team.	Weighing scales, length/height boards, MUAC, thermometer, microscope, drip stands, delivery beds, wheelchairs and stretchers are available. Pulse oximeters and oxygen are not available.	Respiratory rate timers, infant weighing scales, length/height measuring scales and MUAC tapes are available. Pulse oximeters and oxygen are not available. Oral amoxicillin is available.
Pharmacy	Essential medicines including oral amoxicillin suspension are available at the facilities.	Amoxicillin tablets are available but the paediatric preparations are rarely available.	All health centres have dispersible oral amoxicillin tablets.
Laboratory	Basic blood and urine examination services are available.	Rapid diagnostic test (RDT) for malaria and basic blood and urine examination services are available.	RDT for malaria is available at all HCs. The Mtendere Urban Clinic has a laboratory for conducting basic blood and urine examinations.
Data collection	Data are collected on outpatient registers in Thatta and ICT. In ICT it is also entered electronically. In Lahore data are entered electronically. Immunisation services data are entered directly into an electronic database through an application linked directly to the provincial database.	Routine data are collected on hard copies using outpatient registers for children and older patients. No specific IMNCI register exists. Specific registers exist for maternity services, HIV, tuberculosis (TB), etc. Data are later transferred to be entered into the DHIS/HMIS.	Routine data are collected on hard copies using outpatient registers for children and older patients. Specific registers and data collection tools exist for well-baby clinics, maternity services, HIV, TB, etc. Data are later transferred to the district for entry into the DHIS/HMIS.
Referral facilities	Secondary level or tertiary care level hospitals.	District hospitals.	District hospitals.
Year of IMCI adaptation with revised pneumonia guidelines	2019	2021	2019

providers will also be involved in screening children aged 2–59 months who present with cough and/or breathing difficulty and will use the IMCI tool for assessing, classifying and managing children and will enrol those eligible with chest indrawing pneumonia. During this process, the healthcare provider will be assisted by the research staff, who will collect basic demographic information and will also obtain consent for the enrolment procedure.

Follow-up and outcome assessment

On day 15 after enrolment, the independent data collector (not involved in the diagnosis and treatment of the enrolled children) will contact the parents or caregivers using the provided phone number or mobile number that was obtained at the time of enrolment. The outcome data collectors will introduce themselves and inquire about the possibility of conducting an outcome assessment visit or call. Based on this phone call, the research team will visit the child's home or any facility/hospital where the child is admitted or follow-up telephonically (figure 2). During the visit, the data collector will gather details regarding the child's treatment during the illness, including the name, route of administration, duration, frequency of antibiotic use, treatment adherence and whether the child was treated on an outpatient basis or referred for hospitalisation. If the child was hospitalised, then the name, route of administration, frequency and duration of antibiotic therapy will be recorded. The survival status (outcome) of the child will be recorded. The window period for the follow-up is within the range of ±2 days. An Outcome and Treatment Record Form will be completed. In the unfortunate event of child death, a verbal autopsy will be conducted to determine the apparent cause of death. The hospital notes about the death will be prioritised over verbal autopsy whenever they are available. Online supplemental table S1 details

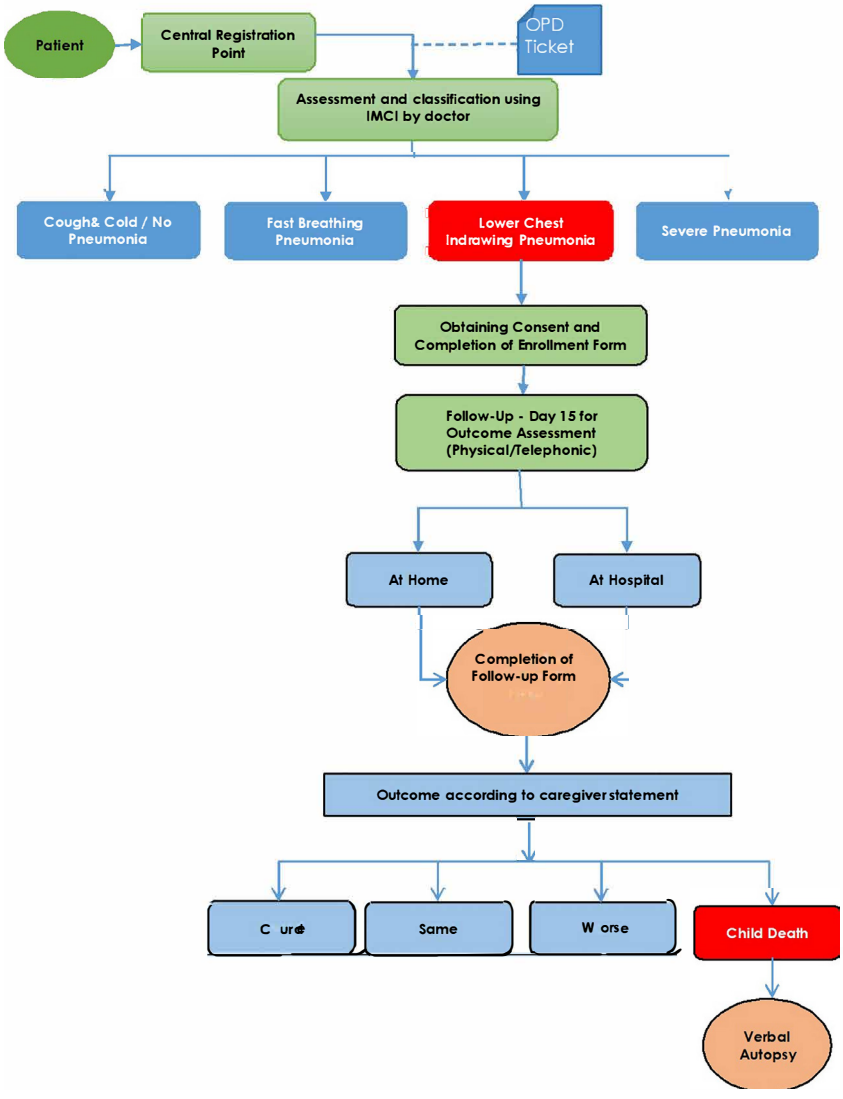

Figure 2 Visual representation of the study data collection process. IMCI, Integrated Management of Childhood Illnesses.

the implementation strategy of all the research study sites in the selected countries.

IMCI refresher training

Before implementing the study, all healthcare providers at selected primary-level facilities will undergo a 2-day to 3-day refresher training programme based on the IMCI chart booklet. The training will focus on assessing and classifying children aged 2–59 months presenting with cough and/or difficult breathing.[11] Subsequently, it will be ensured that health workers have an IMCI chart booklet and facilitation materials, including pictorial guides, to assist them in their daily work. An orientation of all health workers on the study's objectives, design, methods, consent forms, ethical considerations regarding data collection, etc will be done to facilitate enrollment.

Sample size

The sample size for the descriptive analysis has been calculated to be 292 for each study site (not each health facility at each study site). This calculation is based on assumptions of a 5% case fatality ratio for chest indrawing (5% taken from primary care data from Malawi, personal communication), with a margin of error of 3% and a confidence level of 95%. Accounting for a 5% loss to follow-up, a total of 310 children aged 2–59 months with chest indrawing pneumonia will be enrolled and followed up at each study site.

Statistical analysis

The analysis will be performed using STATA V.17. The analysis will start with the calculation of frequency and percentage distributions for categorical variables, including sex, clinical signs, treatment received and vital outcomes based on IMCI.[11] The case fatality risk and 95% CIs will be calculated and reported separately for each study site. Additionally, we will conduct a pooled analysis to estimate the case fatality risk with 95% CI for all children enrolled in this study. Additionally, continuous variables such as age and duration of treatment will be evaluated by calculating the mean and median, accompanied by measures of dispersion such as SD and IQR, respectively. The site-specific data analysis will be conducted, followed by a pooled analysis of de-identified data from all sites using predefined core variables. The selection of these core variables will occur in the subsequent phases of the study.

Ethics

The study protocol, enrolment forms and consent forms will undergo ethical review by the Institutional Review Boards of the University of Gondar, Gondar, Ethiopia; The INCLEN Trust International Independent Ethics Committee, New Delhi, India; Ethical Review Committee of the University of Ibadan, Ethical Review Committees of Lagos State and Ethical Review Committee of University College London, UK; Institutional Review Board, International Research Force, Islamabad, Pakistan; Institutional Review Board, People's Primary Healthcare Initiative-Sindh, Karachi and National Bioethics Committee, Islamabad, Pakistan; Makerere University School of Biomedical Sciences Research Ethical Committee, Kampala, Uganda; University of Zambia Biomedical Research Ethics committee, Lusaka, Zambia and Ethical Review Committee of WHO, Geneva, Switzerland approved the study.

Written informed consent will be obtained from the parent or guardian of each child with chest indrawing pneumonia for enrolment, follow-up and video-recording of clinical examination. Apart from Nigeria, the healthcare provider will present the consent document to the parents/caregivers of eligible children in the local language to ensure their understanding of the study and its procedures. Parents/Caregivers of the eligible child will receive comprehensive information about the study and will be invited to provide consent for their child's participation. Children meeting the eligibility criteria will be enrolled if their parents/caregivers provide informed consent. In cases where parents/caregivers are illiterate, they will be asked to make a thumbprint on the consent form in the presence of a witness, while literate parents/caregivers will be requested to sign it. Children diagnosed with chest indrawing pneumonia requiring hospitalisation will either be admitted or referred to the appropriate hospital for treatment, and the quality of the care they receive will not be influenced by whether they provide consent for video recording or their participation in the study. Participation in the study will be voluntary, and participants will be allowed to withdraw if they are not comfortable with the study. The study will adhere to all local and national regulations concerning research involving human subjects by obtaining approval from the relevant ethical review committees before commencing data collection. Potential risks to the participating children and their families will be identified and addressed by the research teams in the study design to ensure an ethically responsible approach throughout the research process.

Confidentiality

All collected data will be de-identified and stored securely in a location accessible only to the site-specific research team to ensure privacy and confidentiality. Participants will be assured of the confidentiality of the data collected from them. Any data shared beyond the research team will be presented in aggregated form, with no identifiable information included.

Dissemination

The findings of this study will be disseminated locally, nationally and internationally to various stakeholders, including government officials, policymakers, academics, researchers, the local community and voluntary organisations involved in community-based services. Dissemination efforts will include a

district-level seminar for healthcare staff, providers and local non-governmental organisations. Meetings with community leaders and members will directly communicate findings, raise awareness and encourage discussions. The study's results will also be published in open-access, peer-reviewed journals, with local researchers as lead authors, promoting local expertise. Additionally, key findings will be summarised in abstracts for national and international conferences, expanding the reach and fostering collaborations with experts from diverse backgrounds.

Patient and public involvement

The development of the research question was informed by the high pneumonia-related mortality. Patients neither were advisers in this study nor were involved in the design, recruitment or conduct of the study. Results of this study will be made publicly available through open-access publication where study participants may access them.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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