UPTAKE OF THE NEW NATIONAL OUTPATIENT PNEUMONIA GUIDELINES FOR THE MANAGEMENT OF CHILDREN AGED 2 TO 59 MONTHS AT THE KENYATTA NATIONAL HOSPITAL, OUTPATIENT DEPARTMENT.

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DECLARATION

I declare that this proposal is my original work and has not to the best of my knowledge been presented to any another university for the award degree.

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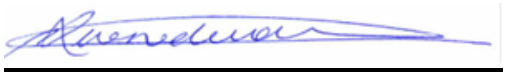
Signature:  **Date 4th May, 2022**

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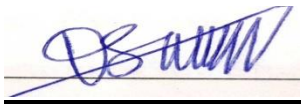
Signature:  **Date: 4/05/2022**

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LIST OF ABBREVIATIONS

ARI	Infections Acute Respiratory
AOR	Adjusted Odds Ratio
CI	Confidence interval
ETAT	Emergency Triage Assessment and Treatment
GAPPD	Global Action of Pneumonia and Diarrhoea
GRADE	Grading of Recommendations Assessment Development and Evaluation
HIV	Human Immunodeficiency Virus
HIC	High Income Countries
IMNCI	Integrated Management of Newborn and Childhood Illnesses
IMCI	Integrated Management of Childhood Illnesses
LMIC	Low and Middle Income Countries
KNH	Kenyatta National Hospital
MoH	Ministry of Health
OR	Odds Ratio
PEU	Pediatric emergency unit
UNICEF	United Nations Children's Emergency Fund
RTI	Respiratory Tract Infection
URTI	Upper Respiratory Tract Infections
W.H.O	World Health Organization

DEFINITION OF TERMS

Age–specific tachypnea or fast breathing- Respiratory rate≥ 50 breaths / minute (age 2-11months), respiratory rate≥ 40 breaths/minute (age 12-59 months).

AVPU- A simple scale used by health professionals to assess and record the level of consciousness: Alert, response to Voice, response to Pain, Unresponsive/ Unconscious

Danger sign(s) – These are MoH 2018 IMNCI guidelines signs and symptoms that point to severe pneumonia. They include: AVPU less than A / not alert, inability to drink/breastfeed, central cyanosis or oxygen saturation <90% (to be used in this study). These are adapted from the 2014 revised WHO IMCI pneumonia guidelines. Additional danger signs in WHO IMCI guidelines include convulsions, stridor in a calm child, grunting, persistent vomiting, lethargy or unconscious and severe malnutrition.

IMCI pneumonia guidelines- These are the 2014 WHO IMCI guidelines for outpatient management of pneumonia in children aged 2-59 months.

2018 MoH IMNCI pneumonia guidelines. These are guidelines currently used in Kenya for outpatient management of pneumonia. These guidelines were adapted from the 2014 WHO IMCI guidelines.

No pneumonia or upper respiratory tract infection- History of difficulty breathing or cough without lower chest wall in drawing or age-specific tachypnea and without danger sign(s).

Pneumonia- History of cough or difficulty breathing with age specific tachypnea and or lower chest wall in drawing without any associated danger signs.

Increased respiratory rate for age- is respiratory rate of more than 50 for children aged 2-11 months, more than 40 for children aged 12-59 months counted in one full minute in a sleeping or feeding child.

Severe pneumonia- History of difficulty breathing or cough with age-specific tachypnea and or lower chest wall in drawing and danger sign(s).

Adherence/ uptake- This is the overall indicator that will be used to determine clinicians' documentation of correct assessment (history taking and examination),

correct classification and appropriate treatment and counseling done during a consultation in a child presenting with cough and or difficulty in breathing.

Adequate assessment-

Clinicians' documentation of all symptoms (history of difficulty breathing and or cough) and signs (alert, ability to drink/breastfeed, age-specific tachypnea and or lower chest wall in drawing, absence of cyanosis or oxygen saturation ≥90%, no grunting) to enable pneumonia severity as pneumonia.

Health care workers full documentation of history of difficulty breathing or cough in absence of lower chest wall in drawing or age-specific tachypnea and without danger sign(s) to allow for classification as no pneumonia.

Correct classification.

Health workers documentation of the correct classification of pneumonia according to all the documented symptoms (history of difficulty breathing and or cough) and signs (age-specific tachypnea and or lower chest wall in drawing. The patient should be alert, able to drink/breastfeed, no cyanosis or oxygen saturation ≥90%) to allow for classification as pneumonia.

No pneumonia - Documentation of history of difficulty breathing or cough in absence of lower chest wall in drawing or age-specific tachypnea and without danger sign(s) to allow for classification as no pneumonia.

Correct treatment-

Pneumonia **-** Health workers documentation of the correct antibiotic prescription of high- dose oral amoxicillin dispersible tablet(s) (4kg–<10kg:250mg, 10kg–<14kg:500mg, 14kg – <19kg:750mg) with the correct 12 hourly dosing frequency and correct treatment duration of 5 days.

No pneumonia- Supportive treatment to sooth the throat with a safe cough remedy; breast milk for those on exclusive breastfeeding and hot water with lemon or honey for children aged above six months.

Counseling done – A patient with a diagnosis of pneumonia and allowed home on high dose dispersible amoxicillin tablets should return for follow up in 2 days, or the mother to return immediately she notices the following: The child becomes sicker, unable to drink or breastfeed develops fever. Patients with cough should be brought back if they develop fast breathing or difficult breathing (1)

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ABSTRACT

Background

Pneumonia is the second highest infectious cause of death among children aged below five years accounting for 15% deaths annually. Case management is the corner stone of pneumonia control strategies. It consists of assessing and classifying severity of illness using simple clinical signs and symptoms then treating appropriately(2). In 2014, the World Health Organization revised the original IMCI guidelines prompted by new evidence, to re-classify childhood pneumonia from the former four severity categories to the current three severity categories. In addition, use of oral high dose amoxicillin was recommended to manage non-severe pneumonia(3). The MoH updated the National Integrated Management of Newborn and Childhood Illnesses pneumonia guidelines and introduced oral high-dose amoxicillin for outpatient management of pneumonia in 2018 following a local study (1).

Primary Objective: To determine the proportion of patients that presented with cough and or difficulty in breathing who received documented complete assessment, documented correct classification and given the appropriate treatment consistent with the current IMNCI national guidelines.

The Secondary Objective: To determine factors associated with poor uptake of the new national pneumonia case management guidelines.

Methodology This was a quantitative hospital based Cross sectional survey conducted on patients aged between 2 to 59 months with cough and or difficulty in breathing presenting in the Paediatrics Emergency Unit of Kenyatta National Hospital, between 1st of February and 10th of April 2022. Adherence to guidelines was assessed based on performance and documentation of three main areas of care; assessment to allow for correct classification and treatment prescribed in tandem with the new Kenyan pneumonia guidelines.

Results We reviewed records of 377 eligible patients visiting the outpatient department during the study period. The median age was 20 months IQR (8-36) and a male to female ratio of 1.33:1. The overall guideline adherence during assessment was less than 1%, documented correct classification 48.0% and none of the patients correctly classified as pneumonia got the guideline recommended high dose of dispersible amoxicillin tablets. Ninety six percent of the patients correctly classified as no pneumonia received an antibiotic. Age greater than one year was significantly associated with non-adherence to correct classification OR 1.29 95% CI (1.03-2.19), p=0.03.

Conclusion Overall guidelines adherence was low at all levels. None of the patients diagnosed as non-severe pneumonia received the MoH IMNCI guideline recommended high dose amoxicillin dispersible tablets.

CHAPTER I: INTRODUCTION AND LITERATURE

1.0.1 Background

Pneumonia is an acute form of lung inflammation that is caused by bacteria, viruses or fungi. It can be life threatening particularly to children(4). The W.H.O case management strategy developed in the 1980s based on evidence achieved in the 1970s and early 1980s was the foundation of the Acute Respiratory Infection (ARI) programme. This was later blended into the Integrated Management of Childhood Illnesses (IMCI) guidelines in 1995 (5). IMCI consists of the community component and the facility component. Case management is the corner stone of pneumonia control strategies and it consists of assessing and classifying severity of illness using simple clinical signs and symptoms then treating appropriately(2).

1.0.2 Etiology

Streptococcus pneumoniae and Haemophilus influenzae type b (Hib) were the commonest pathogens causing pneumonia before introduction of Hib and pneumococcal vaccines in the 1980s. A study conducted in Kenya, showed that the causative organisms attributed to pneumonia in HIV uninfected children were the respiratory syncytial virus (37%), rhinovirus (29%), streptococcus pneumonia (5%) and Hib (6%) (6). Atypical pathogens such as Chlamydia pneumonia, Mycoplasma pneumoniae, or Legionella pneumophila also cause pneumonia mainly in patients with compromised immunity(4).

1.0.3 Burden of Disease

It is the highest infectious cause of death among children under the age of 5 years. The disease accounts for 15% of all under-five deaths killing more than 800,000 children annually or 2200 daily including 153,000 newborns(7). Sadly, a child succumbs to pneumonia every 39 seconds (7)(8). Recent estimates show that eight children die every minute due to preventable illnesses with pneumonia accounting for 21% of these mortalities (9). Kenya is one of the top thirty contributors to 84% of under 5s global mortalities from pneumonia(7). Pneumonia affects children and families everywhere, but the disease is most prevalent in South Asia and Sub-Saharan Africa(10).

Less than 60% of children suspected to have pneumonia receive appropriate care and only 35% receive antibiotics in LMIC (11,12). Early detection of pneumonia during its initial stages of cough and difficulty in breathing coupled with appropriate therapy stops its progression. Without timely intervention, even intravenous antibiotics rarely avert associated complications resulting to high case fatalities(12).

1.0.4 Efforts towards Pneumonia Case Management

WHO and UNICEF Global Action Plan for Pneumonia and Diarrhoea (GAPPD) strategies to hasten pneumonia control entails: protecting children from pneumonia by promoting exclusive breastfeeding and adequate complementary feeding, preventing pneumonia with vaccinations, hand washing with soap, reduction of household air pollution, HIV prevention and cotrimoxazole prophylaxis for HIV-infected and exposed children and treating pneumonia making sure that every sick child has access to quality care (11).

Uptake of the new pneumonia guidelines in the outpatient department has barely been explored in low income nations, who were meant to be the main beneficiaries (13).

The simplified stepwise algorithms have also been utilized by community health workers. This has evidently been shown to reduce pneumonia related mortality in Asian countries by 35% and recently in Kenya (14–16). Malawi was the first Sub Saharan Africa nation to implement community IMCI(17).

The revised IMCI guidelines have benefits such as; cost effectiveness to the patient, hospital and ultimately the government ensuring that resources are directed to more serious illnesses. They allow use of simple clinical signs and symptoms where diagnostic laboratory and radiology resources are limited(18). The guidelines also recommend use of dispersible amoxicillin tablets that are cost effective, less bulky, do not require refrigeration as well as better adherence of the twice daily doses for management of pneumonia(19) .

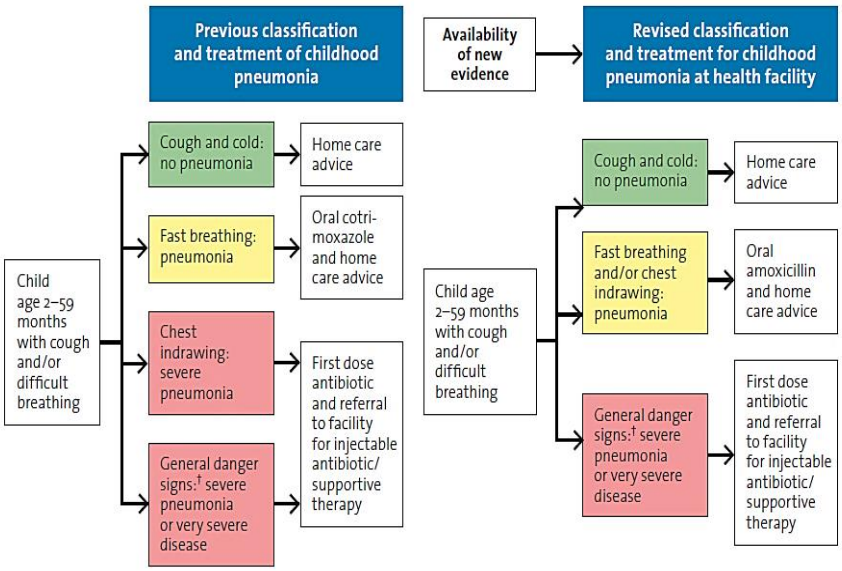

Figure 1: Comparison of previous and revised classification and treatment of childhood pneumonia at a health facility. Adapted from World Health Organization, Revised WHO classification and treatment of childhood pneumonia at health facilities–Evidence summaries

The World Health Organization had not revised pneumonia case management guidelines for more than two decades until 2014. Revision of these IMCI guidelines was prompted by new research-based evidence assessed by a panel of experts using GRADE methodology (Grading of Recommendations Assessment, Development and Evaluation) to determine quality and certainty. The main symptom (lower chest wall in drawing) previously used to identify severe pneumonia was downgraded and harmonized with fast breathing to identify non-severe pneumonia (cough or difficulty breathing with age specific tachypnea and or lower-chest wall in-drawing without any danger sign). This changed the management of lower chest wall in drawing pneumonia from injectable penicillin to oral high dose amoxicillin. Hence, classification changed from three pneumonia severity categories; very severe pneumonia, severe pneumonia and non-severe pneumonia to two; severe pneumonia and non- severe pneumonia(hereafter referred to as pneumonia) (13).

The old WHO IMCI guidelines recommended that non-severe pneumonia defined as; History of difficulty breathing or cough, age-specific tachypnea, without lower chest wall in-drawing or danger signs be treated with oral cotrimoxazole.
Severe pneumonia defined as ; History of difficulty breathing or cough, age-specific tachypnea plus lower chest wall in-drawing but without any danger signs and very severe pneumonia defined as; History of difficulty breathing or cough with danger signs be remedied with injectable penicillin only and penicillin with gentamycin respectively(3).

However, this encountered several hurdles in low and middle income countries where transportation to the referral facility was either costly or unavailable(18). Management with injectable treatment also carried its own risks such as nosocomial infections; injection site abscesses and spread of blood Borne diseases(10). High cost to the hospital and family, drug and administration equipment unavailability were added disadvantages(18). To ward off pneumonia related deaths, irrational use of antibiotics and cough remedies, research to ascertain effectiveness of oral amoxicillin for management of chest in drawing pneumonia was necessary. The evidence gained from initial clinical trials was termed non generalizable and of moderate quality citing monotony in study settings and the participants' Asian descent predominance(20). This was also considered unsafe for most African countries including Kenya, where pneumonia related childhood deaths are higher(14). Prevalent comorbidities such as HIV and malnutrition contribute to high childhood pneumonia related mortality in LMIC(21). Clinical trials were therefore conducted in different geographical regions, urban and rural settings with diverse cultural backgrounds to determine generalizability and applicability of new evidence (10,18,20–23).

In 2010, a Kenyan team comprising of experts from clinical, policy and academic backgrounds reviewed and discussed evidence from prior clinical trials. The evidence was again declared ungeneralizable and hence unadoptable. Agweyu et al, 2015 conduted a study to ascertain effectiveness of oral amoxicillin for management of pneumonia in Kenyan children. The randomized clinical trial enrolled 527 participants aged between 2 to 59 months. Children with common commorbities were included to simulate daily encounters. Inpatient and post discharge follow up was done at 48hours, 5 days and 14 days post enrollment. The results were treatment failure of 7.7% and 8.0% in the amoxicillin arm and injectable benzyl penicillin arm respectively, with a risk difference of 0.3% 95% CI -5.0-4.3% at 48 hours. The risk difference of treatment failure between the two groups was also <7% at all follow up points.

Non Inferiority of high dose amoxicillin to injectable penicillin was confirmed hence the Kenyan MoH IMNCI guidelines on the use of high-dose oral amoxicillin for outpatient management of pneumonia (current classification) were updated in 2018(1)

1.0.5 Barriers and Challenges of Revised guidelines implementation

Challenges facing Kenya leading to poor guidelines adherence include; procurement inefficiencies such as weak commodity management systems that cause stock outs and unavailability of dispersible amoxicillin tablets, Inadequate synergy and child health funding across programs, human resource and poor governance at national and county levels (19). Clinicians disbelief in monotherapy, high patient volume, poor provider motivation, limited availability of drugs and diagnostic aids have also been suggested as barriers to guidelines adherence (19,24,25). The guidelines focus more on sensitivity rather than specificity as they are incapable of differentiating between bacterial and viral causes of pneumonia(26)(23). Concerns have been raised whether there is unnecessary use of antibiotics risking drug resistance as some authors attribute reduction of pneumonia related mortality and morbidity to high global uptake of the pneumococcal and haemophilus influenza type b conjugate vaccines(27,28).

1.1 Literature review

Complete assessment through focused history taking and examination, correct classification and appropriate treatment ensures child survival(12). Pneumonia case management guidelines were revised to reduce the burden on hospital services, improve equity allowing for quality care for all children and improve case management skills of healthcare workers(12). They provided simple stepwise algorithms and standardized protocols for managing common conditions with several treatment options. Severe Pneumonia is one of the commonest reasons for admission in public hospitals and more often than not, a parent will have sought prior treatment during the early stages of the disease (29).

1.1.2 Cost Effectiveness of the Guidelines in Pneumonia Management

Treatment of pneumonia puts a huge economic burden on households and the already constrained hospital and national resources in the LMIC. A study done by Ayieko et al. 2009, demonstrated that caretakers of admitted children are often unable to raise money for hospital charges(29). This either leads to extended hospital stay or waiving of the charges which the hospital is often unable to recover. A study was done in Uganda by Ekirapa E et al 2021, to estimate the average costs associated with an episode of pneumonia from the household, government, and society in children aged less than 5 years. The study showed that to treat an episode of pneumonia the cost incurred by the society was 42 dollars across all sectors. The cost of inpatient and outpatient management of pneumonia was 62 US dollars and 16 US dollars respectively(30). A study was done in Zambia to estimate and compare the average cost incurred in inpatient and outpatient management of childhood pneumonia and diarrhoea. The urban based health center was majorly funded by the ministry of health and donors. Every outpatient visit cost was US$48 while every inpatient cost per bed day was US$215 for management of under-five childhood pneumonia(31). A systemic review conducted by Shanshan Z et al, 2016 on 34 cost analysis studies containing data on more than 95,000 children from LMIC and HIC showed that the total cost incurred per episode of severe pneumonia management was US$ 4.3 (95% CI 1.5–8.7), US$ 51.7 (95% CI 17.4–91.0) and US$ 242.7 (95% CI 153.6–341.4)–559.4 (95% CI 268.9–886.3) in community, out–patient facilities and in–patient settings in LMIC(32).

One of the ways to ensure rationalized utilization of hospital resources is by following simple guidelines that enable early identification of pneumonia before complications set in(29). We review studies done to show uptake of pneumonia case management guidelines in the outpatient.

1.1.3 Quality of Care in Patients Seen in the Outpatient

It has been found that there is poor IMCI guidelines adherence when assessing febrile children in outpatient departments of first level facilities (33–35). Poor guidelines adherence has also been shown even when patients are admitted for pneumonia management (5). A retrospective cross-sectional study done in Kenya by Mutinda et al 2014, to determine the level of adherence and factors affecting adherence to the national guidelines in management of pneumonia among children aged two to fifty nine months, found that there was 42.9% mean guideline adherence to clinical signs and symptoms, 56.6% correct classification and 27.7% had the correct guideline recommended treatment indicated on the records of 91 patients reviewed (5). A cross-sectional study done in Malawi to determine adherence of IMCI guidelines by clinical officers in an outpatient department of a district level clinic showed that less than 1% of consultations received optimal assessment. This was evaluated against16 elements required to assess for pneumonia in patients who presented with cough or difficult breathing and fever. The clinicians correctly classified 61% of the 695 patients who presented with cough or difficulty in breathing as non- severe pneumonia. Twenty four percent (168/695) identified as no pneumonia were found to have pneumonia after a pediatrician's (taken as the gold standard) re-evaluation. Only 16% of the 695 patients had a respiratory rate counted. Correct antibiotic prescription and pneumonia care was provided to 20.9% and 22.3% of the patients respectively while the rest had missed an antibiotic prescription(36).

Clinicians often follow clinical logic to manage children in busy outpatients. A febrile child may not have a full history taken or assessment for pneumonia without the worried caregiver reporting history of cough or difficulty in breathing (25). A cross sectional study done in Tanzania to determine the assessment of under-fives for acute respiratory tract infections found that, among the 1,081 outpatient consultations, 84% had a full history taken beyond what the care taker reported. Among the 554 children presenting with a history of cough or difficulty in breathing, 5% had their respiratory

rate counted, and 14% had adequate chest exposure i.e up to the nipple to elicit lower chest wall in drawing. The odds ratios (OR) of having the respiratory counted was 4.28 (95% CI 1.75-10.47), 2.57 (95% CI 1.67-3.95) for adequate chest exposure and 18.91(95% CI 9.52-37.57) for auscultation (37). A study was done by Johansson et al, 2017 in Malawi to determine factors that influence IMCI non severe pneumonia classification and care among 3149 eligible patients seen in the outpatient. After re-evaluation by a pediatrician, 590 (18.7%) patients were discovered to have non–severe pneumonia classification. Eighteen percent of the patients with cough or difficulty in breathing had a one minute respiratory rate counted while 228 (38.7%) of the non –severe pneumonia cases received oral amoxicillin as a first–line antibiotic. One hundred and fifty nine (26.9%) of these patients had no antibiotic prescription. The Odds ratio of having a respiratory rate taken was higher when a patient was seen by a health worker with IMCI training (OR 2.37, 95% CI 1.29–4.31). Patients with a negative rapid diagnostic test result for malaria had higher odds of having a respiratory rate assessment OR 3.21, (95% CI: 1.45–7.13). Children above the age of one year had lower odds of a full assessment compared to infants (OR, 0.35, 95% CI: 0.16–0.75). Children with a coexisting comorbidity were less likely to be correctly assessed for pneumonia. A prescription of high dose amoxicillin was more likely if the patient presented with fever (OR=3.26, 95% CI: 1.24–8.55). RDT confirmed malaria was a strong predictor of not getting an amoxicillin prescription (OR=10.65, 95% CI: 2.39–47.36).

The frequency of personal encounters with a certain disease, IMCI training and provision of diagnostic equipment also determines the quality of patient assessment(38). A Malawian study done in outpatient departments of 11 health facilities to determine implementation of W.H.O guidelines for pneumonia assessment in under-fives showed that only 7% (12/176) of encounters had all pre-set evaluation tasks completed by the 23 clinical officers. To enhance implementation, 3 monthly ETAT refresher courses were offered as well as provision of Thermometers, pulse oximeters, respiratory timers and antibiotics. History of convulsions had the least frequency of enquiry 17% (30/176) while pulse oximetry was the least performed examination task 35% (62/176). When assessed for IMCI knowledge, the clinical officers had a median score of 75%.

Better guideline adherence has been shown with severe pneumonia compared to non -severe pneumonia (5,39). A retrospective study, with the aim of assessing pneumonia management among 60,919 children aged less than five years, in a malaria endemic zone of Mozambique was conducted. The study was done between January 2008 to June 2011 in the outpatient departments of one district hospital and five peripheral health centers. 3,448 (5.7%) were correctly classified as severe pneumonia, 42,331 (69.5%) as non-severe pneumonia. 15,140 (24.9%) were not classified since they had insufficient information documented in their medical records. Close to 90% of the severe pneumonia cases had the correct diagnosis matching with their clinical criteria compared to 80% of the non-severe pneumonia cases. 92% and 70% of the severe pneumonia cases attended in the district hospital and the health centres respectively were correctly diagnosed and appropriately referred. Among those who had non-severe pneumonia, only 45.7% (352 / 16,094) received antibiotics as recommend. Coexistence of Comorbidities such as malaria (OR 0.20, 95% CI 0.19 to 0.22), pallor (OR 0.62, 95% CI 0.54 to 0.70) or gastroenteritis (OR 0.38, 95% CI 0.35 to 0.42) with pneumonia increased the likelihood of missing antibiotic prescription. Infancy and abnormal auscultatory findings were positively associated with an appropriate antibiotic prescription(39).

Failure to accurately count the respiratory rate is a common error yet it is the starting point in the guidelines for pneumonia classification and correct treatment(7,28,30). A study in Benin showed that failure to classify and diagnose pneumonia preceded incorrect treatment or no antibiotic prescription. Clinicians often counted respiratory rates for half a minute resulting to high respiratory rates in even numbers (41), leading to misuse of antibiotics as well as unnecessary referrals and admissions (33,42). Contextual factors such as a noisy environment can also cause respiratory rate variations. This is more common in infants than older children hence misclassification and over treatment(43). WHO / UNICEF recommends counting respiratory rates for one full minute in a calm sleeping or feeding child since high rates persist in a child who has pneumonia(13). Adequate exposure of the chest for patients presenting with cough or difficulty in breathing is also a common omission by clinicians working in busy outpatient clinics(44). Age of the patient may influence completeness and appropriateness of assessment and treatment(25,45).The consequences of such

omissions, is having patients with bacterial chest infections missing antibiotics in the mild stages of illness(41)

Febrile patients seen in busy outpatients are often over diagnosed and treated with antimalarials in absence of parasitological evidence (14,37,39). Providers working in malaria endemic zones are likely to prescribe antibiotics based on a negative malaria test. Co-existence of non-severe pneumonia with illnesses presenting with overlapping signs and symptoms appear to affect the diagnosis and management of pneumonia without danger signs. A caretaker is more likely to report fever only in an older child as opposed to the common tendency of reporting more symptoms in a child younger than one year. This may prompt the clinician to diagnose malaria in an older child due to incomplete assessments(25). A cross sectional study done in New Papua Guinea to determine use of antibiotics within the IMCI guidelines in outpatient settings demonstrated under treatment (40%) among patients who had both pneumonia and rapid diagnostic test confirmed malaria. However, among those with pneumonia,77.5% had antibiotics prescribed (41). This demonstrates substitution of complete assessments for rapid diagnostic tests where false positive results may occur(35).

1.1.4 Determinants of Guidelines Adherence

Lack and inadequate implementation of available technologies and diagnostic aids such as pulse oximetry gadgets (46) has been attributed to non- adherence of guidelines towards pneumonia care despite hypoxemia identifying as a risk of death (27,19). Even a highly skilled physician can only detect oxygen saturations below 80% by observation(48). This portable non-invasive device gives an indirect estimation of the arterial oxygen saturations by showing oxygen saturations in hemoglobin. Pulse oximetry has a 2% difference in accuracy when compared to the arterial oxygen saturation(49). Relying on clinical signs alone to detect hypoxemia is insufficient both for facility based health workers and community health workers (42). Nonspecific danger signs such as head nodding, severe lower chest wall in-drawing and respiratory rates above 70 albeit not mentioned in the guidelines require clinicians to be vigilant as they indicate presence of hypoxemia(50). 97 surveys were done in 19 countries with limited resources settings located in Africa (contributed 52% of the participants), Asia and South America. 71% of the participants reported to have pulse

oximeters in their facility. 59% reported to have the gadget majority of the times while 48% reported having a non- functional device. Other barriers reported include high competition for use (53%), lack of training in use (46%), perceived high cost (35%) and lack of policies and guidelines (54%) (51). A multi-center study done in Malawi with the aim of investigating outpatient use of pulse oximetry among children in Malawi showed that availability of pulse oximeters increased the number of referrals by 27% (p value < 0.001). The study was done in 18 health centres and among 38 community health workers. Researchers provided pulse oximeters as well as training on proper use of the gadgets. Availability of pulse oximeters identified hypoxemia of less than 90% in 68.7% (390/568) and 61.9% (52/84) children seen at the study health centers and CHWs respectively(52). These were patients who had pneumonia plus in drawing without danger signs deemed ineligible for admission based on the current WHO pneumonia case management guidelines. A cluster randomized controlled trial was conducted in 24 health centres between September 2018 and April 2019, southern Ethiopia. The aim was to determine and compare if pulse oximetry and the current WHO algorithms improve health workers performance in diagnosing pneumonia in children aged between two and fifty nine months who presented with cough and or difficulty in breathing. 928 children were allocated to the intervention arm (pulse oximetry) while 876 were allocated to the control group (IMCI / WHO guidelines). 135/928 (14.5%) had oxygen saturation of less than 90%. Severe pneumonia diagnosis was made in 148/928 (15.9%, 95% CI 4.7 to 27.2) of the children allocated to the intervention (pulse oximetry) group. Only 65/148 (43.9%) met the WHO guidelines for severe pneumonia and had oxygen saturation of <90%. 70 (47.3%) did not meet the IMCI algorithm, but had oxygen saturation > 90% While 13/148 (8.8%) met the IMCI guideline but had oxygen saturations of >90%. 34/876 (3.9%) 95%CI 1.2 to 6.6) were diagnosed with severe pneumonia in the IMCI guidelines group. The likelihood to make a severe pneumonia diagnosis was more in those who had pulse oximetry done with an odds ratio of 4.7 (95% CI 1.9 to 11.8; p value <0.001 compared to those whom only IMCI guidelines were used (53).

Non-clinical factors such as cadre, years of practice, frequency of IMCI refresher training, supportive supervision as well as salary scales have been shown to determine likelihood of a full assessment among clinicians(45). Contextual factors such as time

of consultation, facility setting such as rural, urban, public or private have also been found to determine the level of guidelines adherence (54).

1.1.5 Concerns and Loopholes of New Guidelines Failure in the Outpatient Department

Despite the presence of research based evidence on effectiveness and generalizability of WHO revised pneumonia guidelines, concerns have been raised particularly in HIV-endemic clinical settings like the Sub Saharan Africa where HIV accounts for 10% of child pneumonia deaths(55). Only a third of HIV exposed infants routinely receive the DNA Polymerase Chain Reaction (PCR) test by the age of two months(56). In Kenya, the number has stagnated at 50% since 2011(57). The other concern is clinicians' likelihood of missing children with risk factors of mortality managed as outpatients (58,59). A retrospective study by Agweyu et al, 2018 with an aim of demonstrating the risk of death among children who might have been considered eligible for outpatient management according to the new guidelines between March 2014 and February 2016 was done in 14 Kenyan hospitals. 2.7% (322/11930) children diagnosed as non-severe pneumonia succumbed whereas 14.2% (488/3434) of severe pneumonia died with a risk ratio of 5.3 (95 CI 4.6-6.0). 83% (9968/12025) of the children classified as non- severe pneumonia, had a factor that increased their risk of mortality(59). Factors such as incomplete immunization, infancy, seeking care in a hospital located in malaria endemic zones, axillary temperature>39^0c, respiratory rates >70/min, moderate to severe acute malnutrition, dehydration and pallor showed higher risks of mortality (21,60).

Lack of strong outpatient services and inadequate follow up mechanisms are additional reasons thought to cause low guidelines adherence in poor countries. However, with proper safeguards and strategies such as enhanced follow up of patients, ability to identify high risk groups and educating caregivers on danger signs and symptoms, these guidelines are feasible, effective and applicable in low risk groups.(22)

1.1.6 Conceptual Framework

The conceptual framework as illustrated shows the relationship between the independent and dependent variables. In order to have a successful or effective adherence to the pneumonia treatment guidelines, assessment, classification and treatment have to be made based on the pre-developed guidelines.

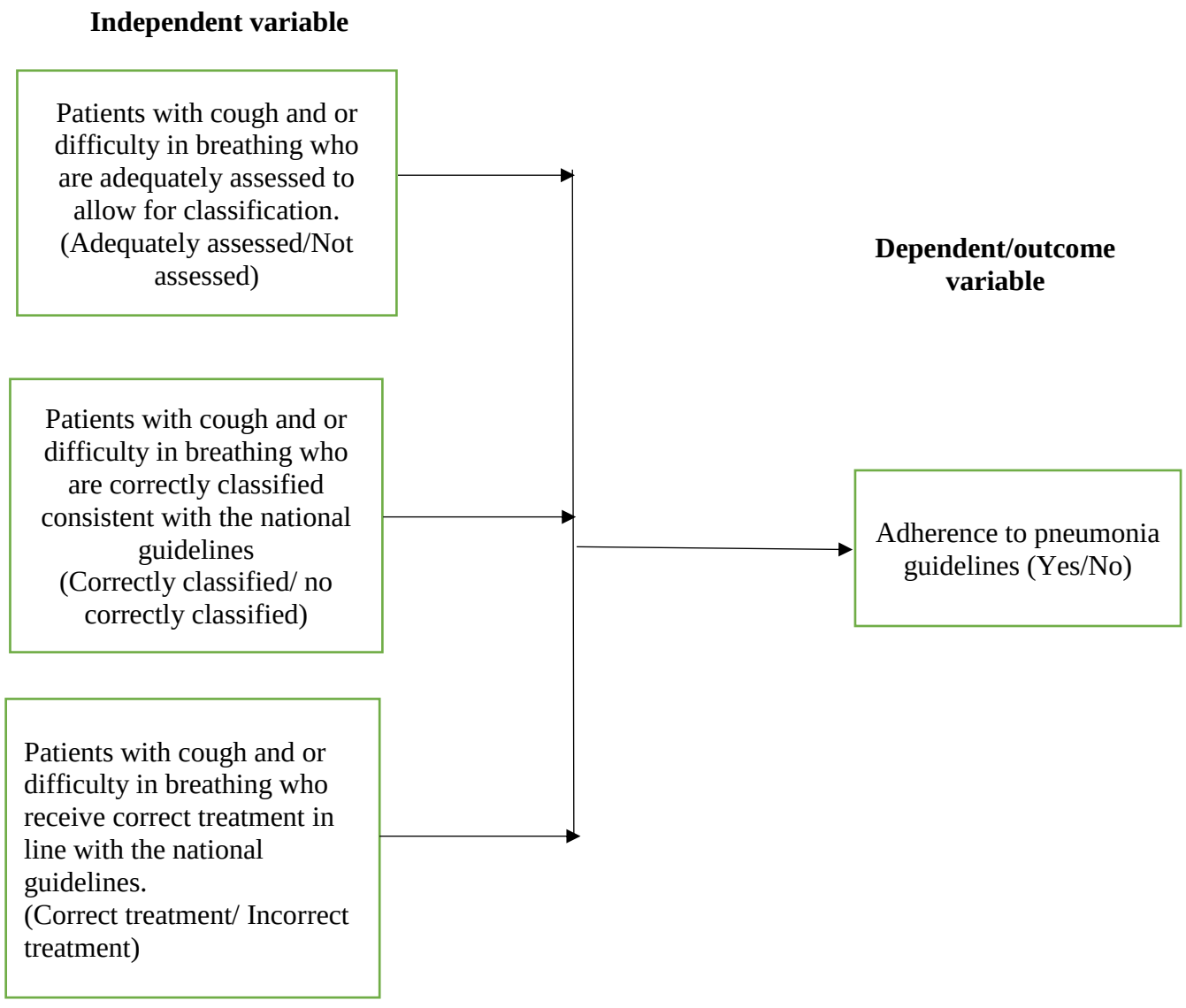

Figure 2: Conceptual Framework Showing the Relationship between Independent and Dependent Variables

CHAPTER 2: STUDY JUSTIFICATION, RESEARCH QUESTIONS AND STUDY OBJECTIVES

2.1.1 Study Justification

Research has shown that guidelines are not implemented as expected(54). Non-adherence to guidelines leads to suboptimal treatment, irrational use of antibiotics and other cough remedies deemed unsafe for children. Guidelines development and revision occurs after evidence is generated by intense research to; ensure equitable, safe and quality care of patients, improve health workers skills and provision of cost-effective management for all patients. Most studies that have been done on adherence of clinical guidelines are based in inpatient settings, yet the outpatient is the first point of contact of a sick child to the hospital. Most children are only seen in the outpatient department without necessarily being admitted. This study would evaluate how the guidelines are utilized where most patients are seen at the point of first contact. Few studies have been done in Africa; none in Kenya despite the fact that the new guidelines were meant to ensure that majority of children suffering from non-severe pneumonia have access to cost effective treatment from the outpatient where feasible. Therefore, this project seeks to find the uptake of revised WHO/Kenyan guidelines in the management of pneumonia among under -fives at the Kenyatta National Hospital outpatient department. If the level of adherence is found to be low, necessary measures tailored towards enhanced implementation shall be put in place to ensure that patients receive quality care as deserved.

2.1.2 Study Question

What is the level of adherence to the revised W.H.O/Kenyan pneumonia clinical guidelines in the management of children aged between 2 months to 5 years in the outpatient department of Kenyatta National Hospital?

2.1.3 General Objective

To investigate the level of adherence to the WHO/Kenyan Pneumonia clinical guidelines in the management of children aged between 2 months to 5 years in the outpatient department of Kenyatta National Hospital in 2022.

2.1.4 Primary Objectives

1. To determine the proportion of patients with cough and or difficulty in breathing who are adequately assessed to allow for classification among children aged between 2 months to 5 years in the outpatient department of Kenyatta National Hospital in 2022.
2. To determine the proportion of patients with cough and or difficulty in breathing who are correctly classified consistent with the national guidelines among children aged between 2 months to 5 years in the outpatient department of Kenyatta National Hospital in 2022.
3. To determine the proportion of patients with cough and or difficulty in breathing who receive correct treatment in line with the national guidelines among children aged between 2 months to 5 years in the outpatient department of Kenyatta National Hospital in 2022.

2.1.5 Secondary Objective

To determine factors associated with uptake of the new national pneumonia case management guidelines.

CHAPTER 3: RESEARCH METHODOLOGY

3.1.Study Design

This quantitative data was collected through a hospital based Cross sectional survey of all eligible patients who presented to the outpatient department of Kenyatta National Hospital. We chose the cross-sectional survey because it is a valuable study to explain what was happening in that moment at the outpatient department, it was less costly and less time consuming.

Study Site

The study took place in the Pediatric Emergency Unit (PEU) of Kenyatta National Hospital a public, tertiary, teaching and referral facility located in Nairobi County. The unit filters and manages pediatric diseases and emergencies including all referrals as the first point of contact. Approximately 100 patients are seen in a day and of these, ten to thirty percent present with complaints of cough and/or difficulty in breathing. However, there was a notable decline in the number of patients visiting the unit due to the ongoing Covid-19 pandemic. Health care workers mainly involved in management of outpatient cases are non-physician clinicians and nurses the former forth referred to as clinical officers. A total of 20 clinical officers with higher diplomas in pediatrics are permanent employees of the hospital while five are employed on contract. There is a pediatric trainee doctor/senior house officer (resident/registrar) working on 12-hour shifts who mainly reviews and manages complex cases.

Four clinical officers work on six hours daytime shifts while three others work for 12 hours at night although this is not constant. Two nurses working at the triage station assign patients to be reviewed by health workers based on vital signs and triage guidelines. The clinical officers receive an in-service ETAT training on the current guidelines with yearly refresher courses. They also participate in continuous medical education sessions to improve their clinical skills on management of pediatric emergencies. Data on patients' history, examination findings, investigations and treatment plan are recorded on a general outpatient record; a green A4 card and a pediatric assessment form for patients who require admission. Each patient is assigned a unique outpatient department number for easy retrieval in subsequent visits. The records are later submitted to the records clerks in the clinic who store the forms on shelves for later computerization and coding in the health information department.

3.2.Study Population

3.2.1. Inclusion Criteria

- Patients presenting with cough and / or difficulty in breathing for less than two weeks.
- Aged between 2 to 59 months

3.2.2. Exclusion Criteria

- Refusal to give consent
- Comorbidities whose management guidelines are not consistent with the standard pneumonia guidelines. These include: meningitis, severe acute malnutrition typically identified as visible severe wasting or edema, HIV infected or exposed, asthma or wheeze, kidney disease, gastroenteritis (dehydration can tachypnea) and tuberculosis.
- Complex chronic cardiopulmonary conditions may be due to disease sequelae or congenital malformations involving multiple systems and thus may require complex investigations and management. They can also cause lower chest in-drawing and tachypnea.
- Cough for more than two weeks indicates chronic cough which requires further investigation for conditions such as tuberculosis, heart disease and asthma.

- Cough and or fast breathing with any of the aforementioned danger signs these indicate a diagnosis of severe pneumonia which requires in-patient management.

3.4 Case Definitions

No pneumonia or upper respiratory tract infection – History of cough or difficulty breathing without age-specific tachypnea, lower chest wall in-drawing and absence of any danger sign in a child aged 2-59 months (61)

Pneumonia- History of cough or difficulty breathing for less than 14 days with age specific tachypnea, and or lower chest wall in-drawing without any danger signs in a child aged 2-59 months (61) .

Severe pneumonia- Cough or difficulty breathing with fast breathing for age +/- chest in-drawing with presence of danger sign(s) in a child aged 2-59 months (61).

Persistent vomiting- Three or more repeated episodes of vomiting after oral amoxicillin administered within ½ hour of administration.(20)

Danger signs: The danger signs that will be used in this study are; cyanosis or spo2 <90%, inability to drink/breastfeed and AVPU<A/ not alert. This are signs to look out for while assessing a child for non-severe pneumonia. A classification of non-severe pneumonia requires that the clinician excludes these signs in the outpatient department as per the Kenyan IMNCI guidelines

3.5 Key outcomes of Interest

Primary outcome of interest: assessment and documentation of all clinical signs and symptoms, classification given and treatment for children aged between 2-59 months who presented with cough or difficulty breathing.

Secondary outcome of interests: Potential determinants of incorrect evaluation, diagnosis / classification and treatment of pneumonia to identify interventions that may further decrease under- fives mortalities.

Dependent variables; Number of patients aged between 2-59 months who presented with cough or difficulty breathing without any danger signs with complete assessment and full documentation of history taking and examination findings, number of correctly classified patients in line with assessment, number of patients with guidelines recommended treatment.

Independent variables: Age in months, weight, time of consultation, fever status, presence or absence of comorbidity and history of premedication with any antibiotic.

3.6 Sample Size Determination

The desired sample size calculation was done using the Fischer's formula:

$n=Z^2 p (1-p) /d^2$

$n=1.96^2 \times 0.566(1-0.566) /0.05^2$

Where;

n- Desired sample size

z- Statistical level of confidence

p- Proportion of patients who were correctly assessed, classified and treated as per the current recommended guidelines

d -Precision

Proportions were obtained from the literature review of a study on adherence of pneumonia guidelines for children aged between 2-59 months at Garissa county hospital. This was an inpatient study that used guidelines as the ones used in this study as the audit criteria. Proportions of patients, who had assessment and documentation of clinical signs and symptoms, those who were correctly classified and correctly treated were 42.9%, 56.6% and 27.7% respectively. The proportion giving the largest sample size (56.6%) was used at 95% confidence level with a 5% error of precision. Therefore, a sample size of 377 was used in this study.

3.7 Study Procedure;

3.7.1 Sampling Procedure

Consecutive sampling method was used where the principal investigator together with pre-trained research assistants enrolled eligible patients whose parents or guardians gave consent to participate until the sample size was achieved.

3.7.2 Recruitment of the research assistants and role

Two research assistants were recruited and trained to ensure that data collection process was accurate and valid information is obtained.

The research assistants were certified and licensed nursing officers with experience in pediatrics healthcare. They were tasked with enrolling patients and monitoring the application of the revised guidelines based on the aspects that were being investigated in this study. The principal investigator re-evaluated patients and also solved challenges that came up during the period of this project.

3.7.3 Pretest

A Pretest of the adapted questionnaires was conducted using 10% of the sample size at the Pediatric Emergency Unit prior to the actual data collection. This allowed for training of research assistants, familiarization of the study setting, data collection process as well as tests the research tool. This was done to maintain high levels of reliability of the data collection tool to achieve the relevant study outcomes. The questionnaire was also reviewed by supervisors of this study to assess its validity and efficacy in obtaining relevant data for analysis.

3.7.4 Validity and Reliability

Validity is postulated to be the extent to which the interpretations of the results of a test are warranted. Reliability on the other hand is a measure of how consistently an instrument can collect similar data when administered to different populations and/or at different times. A qualified statistician was employed to ensure quality data management, data collection as well as conducting data analysis. Internal validity of the study was achieved by reviewing collected information.

3.7.5 Participant Recruitment and Consenting Procedure

Four fifty children presenting with cough and or difficulty in breathing were screened for eligibility and enrolled through consecutive sampling at the triage desk until the desired sample size of 377 was attained.

Informed consent to participate in the study was sought from their caretakers but 10 of the guardians denied consent (Appendix 1 and 2). Demographic data were entered into coded checklists/ questionnaires (Appendix 3) adapted from WHO (62) for those who consented. Five of the participants' caretakers absconded before they were reviewed by a clinical officer. We screened the remaining 435 for eligibility and excluded 38.

Data abstracted from the patient sick card included recorded clinical signs and symptoms as well as the classification given. These were checked for completeness and correctness with the 2018 Kenyan IMNCI pneumonia guidelines as the audit criteria. Treatment prescribed was obtained from the treatment sheets. Correct IMNCI guidelines recommended treatment; dispersible amoxicillin tablets with the correct dosage for weight given 12 hrly for five days. Patients diagnosed as pneumonia with any other amoxicillin containing antibiotic prescribed had that assessed to check if it was given at 40-45mg/kg/dose, 12hrly for five days.

Table 1: Amoxicillin Dosing

Weight (kg)	Dosing (mg) 12 hourly
4 - <10	250
10 - < 14	500
14 - < 19	750

3.8 Data Collection Tools

Data abstracted from the patient outpatient sick card was collected by hand into a data collection form / checklist (appendix 3). This abstract tool was adapted from a WHO health facility survey tool of the year 2003(62). This was a tool used to evaluate the quality of care offered to sick children attending outpatient facilities.

The first part contained the patient's demographic details.

The second part contained the assessment module that checked for completeness of history taken as documented by a clinician during a consultation. These included:

Presence or absence of history of cough and or difficulty in breathing, ability or inability to drink or breastfeed.

The assessment module also included documentation of presence or absence of examination findings namely; axillary temperature recording, level of consciousness using AVPU scale, oxygen saturations (SpO_2) or cyanosis, respiratory rate per minute and chest wall in drawing. The third part was the classification module which required documentation of correct diagnosis and classification as either no pneumonia-- cough or difficulty in breathing in absence of tachypnea for age, lower chest wall in drawing or any danger sign(s).

Pneumonia--cough or difficulty in breathing plus fast breathing for age and or chest wall in drawing without any danger sign(s). Any other diagnosis given inclusive of comorbidities was to be documented. The fourth part was the treatment module which required documentation of treatment given that is, choice of medication or antibiotic given, dosage, route, frequency and duration of treatment.

Pneumonia should have been remedied with oral dispersible amoxicillin tablets at (4kg–<10kg: 250mg, 10kg–<14kg: 500mg, 14kg -<19kg: 750mg) twelve hourly daily for 5 days in tandem with the current MoH guidelines. If classified as no pneumonia, a safe remedy to sooth the throat should be recommended (encourage breastfeeeding for those patients who were exclusively breastfed and warm water plus lemon tea, honey for children aged > six months.

The final part is the communication module that required documentation of counseling given to the caretaker / parent in regards to when to return immediately in patients allowed for home care. Patients diagnosed as pneumonia were to be advised return after 48 hour. The level of guidelines adherence was determined at three levels using the aforementioned checklist (63). Documentation of all clinical signs and symptoms for all the patients presenting with cough and or difficulty in breathing was checked and each task documented earned the clinician a point. A point was also granted for correct recommended treatment based on the classification with the national MoH IMNCI guidelines as the benchmark.

3.9 Data Management and Statistical Analysis

Questionnaires were validated and checked for completeness during the data collection period. Coded data were entered into excel spreadsheet using excel form. Data were later imported into R version 4.1.2, recoded and cleaned using an inbuilt data error check and any range check error was checked to confirm if it was a data entry error or a true error. Data captured included documented patients' demographics, signs and symptoms, classification of pneumonia severity, treatment prescribed and counseling done as captured on the checklist. This was checked for completeness, accuracy and consistency with the 2018 MoH IMNCI pneumonia guidelines as the audit criteria.

Table 2: Performance Indicators

Task	Documented Indicator Presence/ Absence
Assessment	
History and Clinical Examination	Cough and or difficulty in breathing Ability to drink/breastfeed Respiratory rate Lower chest wall in-drawing Alert No cyanosis/ oxygen saturations ≥90% **Absence of any danger signs and symptoms**: Inability to drink or breastfeed Central cyanosis / SPO2 <90% Not alert.
Disease Classification	Pneumonia – cough and or difficulty in breathing and fast breathing for age +/- lower chest wall in-drawing. In absence of any danger sign(s). No pneumonia - Cough or difficulty breathing without age specific tachypnea+/LCI and no danger sign(s).

Treatment Prescribed	Pneumonia – oral dispersible tablets of amoxicillin dosages of (4kg–<10kg: 250mg, 10kg–<14kg: 500mg, 14kg -<19kg: 750mg) 12 hourly for a duration of 5 days. *Those given oral suspensions of any amoxicillin containing antibiotic had the dosage determined against their weight too. No Pneumonia-Supportive treatment: Encourage breastfeeding for patients on exclusive breastfeeding Warm water, lemon and honey for children aged more than six months.
Counseling done	A patient with a diagnosis of pneumonia allowed home on oral high dose dispersible amoxicillin tablets should: Return for follow up in 2 days Mother to return immediately she notices that the child becomes sicker, unable to drink or breastfeed develops fever. Patients with cough should be brought back if they develop fast breathing, or difficult breathing.

Table 2 above shows expected documentation of tasks with their performance indicators as reflected on the sick child card.

3.10 Ethical Considerations

Ethical approval was given by the Kenyatta National Hospital / University of Nairobi Ethics and Research Committee. Permission to collect data in the outpatient department was also given by the Kenyatta National Hospital Research Committee. Informed consent was sought from the legal guardians and parents of research participants and participation was on voluntary basis. Anonymity of participants and the healthcare practitioners working in the outpatient department was upheld. Collection and entry of data from the patients' medical records was strictly done within the hospital. Data collected on coded checklists was kept in a safe and locked area accessible only to research personnel. Soft copies were stored in a password protected computer.

3.10.1 Covid 19 Protection Measures

To protect participants and research assistants from Corona virus disease (COVID-19), the principal investigator ensured that social distance was maintained during the data collection period. Surgical masks were provided for research assistants. Sanitizers were also provided in plenty to ensure maximum hand hygiene.

3.11 Quality Assurance

1. The data collection tool was assessed by supervisors of this research who are experts in the field of Pediatrics to ensure that it addressed relevant aspects of this project.
2. Research assistants were trained to ensure that they fully understood the objectives of the study and better data retrieval methods.
3. A qualified statistician was also recruited.

3.12 Quality Control

Questionnaires were checked daily to ensure completeness**.** Reconciliation of ambiguous responses was done by rechecking the sick child card. During analysis, creation of data summaries and graphical exploration for all variables was done.

Rechecking for irrelevant and inconsistent data entries and making the necessary corrections was done to ensure quality control

CHAPTER 4: RESULTS

4.1 Recruitment of Study Participants

Four hundred and fifty patients aged between 2 to 59 months with cough and or difficulty in breathing were identified and screened for eligibility between February 2022 and April 2022. 10 of the caretakers denied consent and 5 absconded before consultations. 38 were excluded as they did not fit the pre-determined eligibility criteria. Enrollment through consecutive sampling was done until the desired sample size was obtained as shown on figure 3 below.

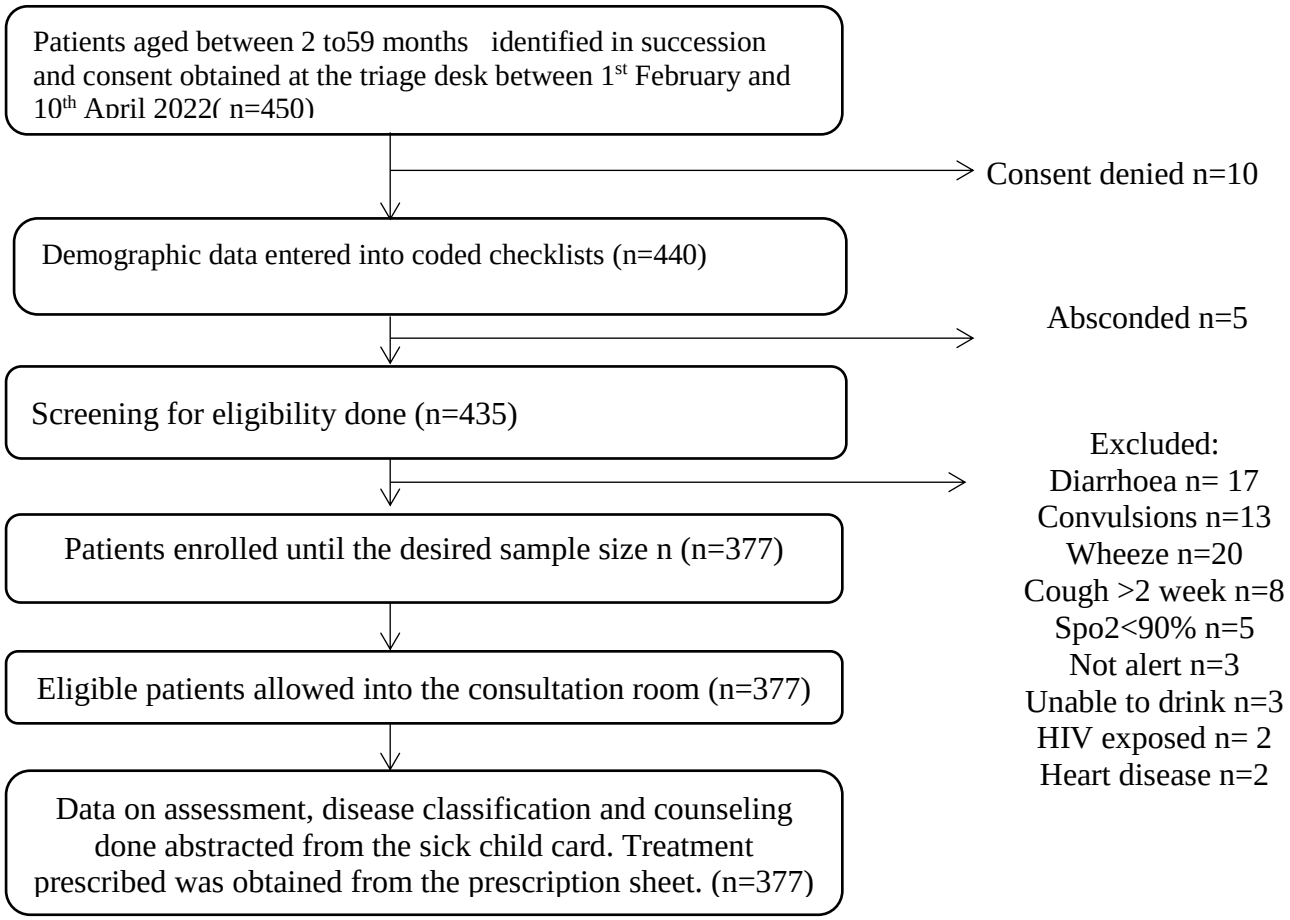

Figure 3: Flow Diagram Illustration of Participant Description

4.2 Demographic Characteristics

The youngest participant was two months while the oldest was 59 months. In terms of weight, the maximum weight was 33 kilograms while the lowest was 2.7 kilograms. Majority of the study participants weighed between 5-10 kilograms 37.9% (n=143). Most of the children were aged between 2 to 12 months 33.4% (n = 126) while the least were between 36-47 months 13.3% (n = 50). There were more males 57% (n=215) than females 43.2% (n=162).

The density of the curves of distribution for weight and age were right skewed so we used median and interquartile range for their summary statistics. The median age of the study participants was 20 months IQR (8-36)

The median weight was 11 IQR (8-15) as shown on table 3 below.

Table 3: Descriptive Statistics of Participants

Variable		Frequency N = 377 (%)
Age in months:		**Median (IQR) 20.4 (8-36)**
	2-12	126 (33.4)
	12-23	75 (19.9)
	24-35	60 (15.9)
	36-47	50 (13.3)
	48-59	62 (16.4)
	Not indicated	4 1.1)
Weight in kilograms		**Median (IQR) 11 (8,15)**
	<5	13 (3.4)
	5-10	143 (37.9)
	>10-15	126 (33.5)
	>15-20	68 (18.0)
	>20	6 (1.6)
	Not indicated	21 (5.6)
Gender:	Male	214 (56.7)
	Female	163 (43.2)

4.3 Clinical characteristics

Table 4: Other Presenting Illness among Study Participants

Feature	Frequency N = 377	Percentage (%)
Cough	356	94.4
Fever	268	71
No other symptoms	131	34.7
Nasal congestion	113	30.0
Difficulty in breathing	66	17.5
Poor appetite	37	9.8
Vomiting	33	8.8
Rash	12	3.2
Irritability	11	2.9
Sore throat	11	2.9
Abdominal pain	9	2.3
Constipation	6	1.5
Malaise	4	1.1
Running nose	3	0.8
Halitosis	2	0.5
Chest pain	1	0.3
Ear ache	1	0.3
Headache	1	0.3
Hoarseness of voice	1	0.3
Polyuria	1	0.3

Cough was more common compared to difficulty breathing 94.4% (n=356) and 17.5% (n=66). Majority of the participants 77% had fever (n = 268) followed by nasal congestion 30.0% (n=113). Patients with history of poor appetite were more compared to those with vomiting 9.8% (n= 37) and 8.8% (n=33) respectively. Patients with no other presenting complaint except cough or difficulty in breathing were 34.7% (n=131). Other presenting complaints such as rash, irritability, sore throat, abdominal pain, constipation , malaise, running nose, halitosis, chest pain, earache, headache, hoarseness voice and polyuria were negligible. Table 4 above

Fever Status among Study Participants

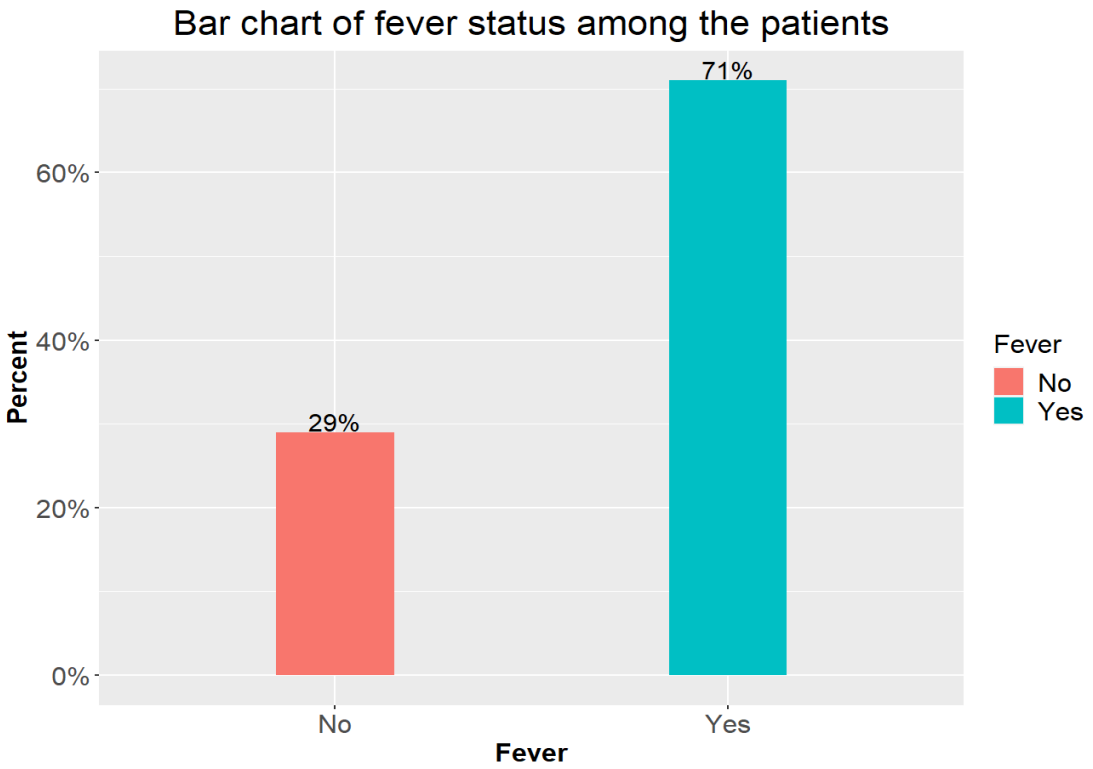

Figure 4: Fever Status among Study Participants

Fever status assessment and documentation was a 100% for all the study participants. Among these, 71% (n=268) had fever while 29% (109/377) were afebrile.

4.3 Adherence to the Current Kenyan Pneumonia Clinical Guidelines.

4.3.1 Documentation of Essential Signs and Symptoms

Table 5: Documented assessment of essential signs and symptoms

Indicator		Frequency N = 377	Percentage (%)
Assessed feeding status:	Yes	145	38.5
	No	234	62.1
Assessed alertness:	Yes	316	83.8
	No	61	16.2
Assessed for cyanosis:	Yes	314	83.2
	No	63	16.7
Assessed for respiratory rate	Yes	25	6.6
	No	352	93.3
Assessed for oxygen saturations	Yes	18	4.8
	No	359	95.2
Assessed for Lower	Yes	177	45.6
chest wall in-drawing	No	200	53.0

Among the patients who presented with cough or difficulty, 38.5% (n 145) had their feeding status assessed and documented. AVPU for alertness was the most assessed and documented clinical finding at 83.8% (n=316) followed by presence or absence of cyanosis 83.2% (n=314). The least assessed and documented clinical finding was oxygen saturation at 4.8% (n=18) followed by counting of the respiratory rate at 6.6% (n=25). Assessment and documentation of lower chest was in-drawing was done at 45.6% (n=177). Table 5 above.

4.3.2 Adherence to Clinical Guidelines during Assessment for Pneumonia

Table 6: Adherence to clinical guidelines during assessment of pneumonia

Domain of care	**Composite and individual indicators**	**Patients who achieved the indicator**
Assessment of patient	**Composite indicator**	**3/377 (0.8%)**
	Level of consciousness	316/377 (83.8%)
	Respiratory rate	25/377 (6.6%)
	Lower chest wall in-drawing	172/377 (45.6%)
	Ability to drink	145/377 (38.5%)
	Oxygen saturations	18/377 (4.8%)

The overall adherence to guidelines for recorded assessment tasks of pneumonia was 0.8%. Level of consciousness was the most recorded assessment task 83.8% (316/377) while oxygen saturations was the least documented assessment task 4.8% (18/377). Table 6 above

Table 7: Documented Clinical Findings during Assessment for Pneumonia

Clinical indicator	Frequency	Percentage (%)
Respiratory rate: Normal	15	60.0
Tachypnea	10	40.0
Patient alert: Yes	285	90.2
Undocumented	31	9.8
Oxygen saturations=/>90%: Yes	17	94.4
Undocumented	1	5.6
Lower chest wall in-drawing: Yes	102	59.3
No	70	40.7
Ability to drink: Yes	145	100

Majority of the patients with documented assessment respiratory rate had a normal age specific respiratory rate at 60% n= (15). The rest had a high respiratory rate for age at 40% (n=10). Most of the patients who had a documented assessment for level of consciousness were alert at 90.2% (n=285).

Among the patients whose oxygen saturations were assessed, 94.4% n=17 had normal oxygen saturations. Out of the 172 patients who were assessed for lower chest wall in-drawing 59.3% (n=102) had lower chest wall in drawing while the rest did not have in-drawing. Table 7 above

4.3.3 Adherence to Guidelines during Classification

Table 8: comparison between clinician classification and guideline classification

Clinician Classification	**Classification according to guidelines**		
	Pneumonia N = 164	No pneumonia N = 166	Indeterminate N = 47
Pneumonia	63 (38.4%)	4 (2.4%)	0 (0%)
No pneumonia	57 (34.8%)	118 (71.1%)	37 (78.7%)
Unclassified	44 (26.8%)	44 (26.5%)	10 (21.3%)
Correct classification 63 (38.4%) of 164 patients with pneumonia 118 (71.1%) of 166 patients no pneumonia 10 (21.3%) of 47 patients with indeterminate classification			Overall correct classification 181 (48.0%) of 377 patients were correctly classified.

* *Indeterminate are the patients who did not have enough clinical signs and symptoms to enable classification.

Table 8 above shows that of the 164 patients who were classified by the guidelines as having pneumonia, the clinician was able to classify 63 (38.4%) correctly.

The guidelines classified 166 patients as no pneumonia of which the clinicians were able to correctly classify 118 (71.1%) as no pneumonia.

The clinicians had failed to classify 26% (n=98) of the patients among whom, 26.8% (n=44) had pneumonia, 26.5% (n=44) had no pneumonia and 21.3% (n=10) were indeterminate table 8 above.

4.3.4 Adherence to Current Pneumonia Treatment Guidelines

Table 9: Treatment of patients correctly classified as pneumonia

First antibiotic treatment given	Patients with pneumonia n = 63
Augmentin syrup	29 (46.0%)
Cefaclor	20 (31.7%)
Amoxicillin syrup	5 (11.6%)
Azithromycin	3(7.0)%
Clarithromycin	3 (7.0%)
Cefuroxime	2 (8.7%)
Erythromycin	2 (4.7%)
Second antibiotic treatment given	
Crystapen penicillin STAT	8 (12.7%)

Table 9 shows that none of the patients diagnosed as pneumonia had a prescription of the recommended oral dispersible tablets of amoxicillin. Among those given an amoxicillin containing antibiotic they were given a low dosage ranging between 25-30mg/kg/dose. Majority of these patients were treated with augmentin syrup 29/63 (46.0%) followed by Cefaclor syrup 20/63 (31.7%). In addition to oral antibiotics, 8/63 (12.7%) of these patients received a STAT dosage of intramuscular crystapen penicillin.

Table 10: Antibiotic Prescription for Patients Classified as No Pneumonia

First antibiotic treatment	Patients with no pneumonia N=118
Cefaclor	30 (25.5%)
Augmentin syrup	27 (22.8%)
Amoxicillin syrup	15 (12.7%)
Erythromycin	12 (10. 2%)
Clarithromycin	11 (7.2%)
Cefuroxime	6 (3.9%)
Flucloxacillin	5 (4.2%)
No antibiotic	5 (3.3%)
Other antibiotic treatment given: intramuscular crystapen penicillin STAT	7(4.6%)

Majority of the patients who did not have pneumonia were also treated with antibiotics as shown on table 8 above. The most prescribed antibiotic was Augmentin syrup 27/118 (22.8%) followed by Cefaclor 30/1118(25.5%). Amoxicillin syrup was prescribed for 15/118 (12.7%) of the patients with no pneumonia. Other antibiotics prescribed were cefuroxime, clarithromycin, erythromycin and Flucloxacillin. In addition to the oral antibiotics, 7(4.6%) of the patients were given a STAT dose of intramuscular crystapen penicillin as shown on table 10.

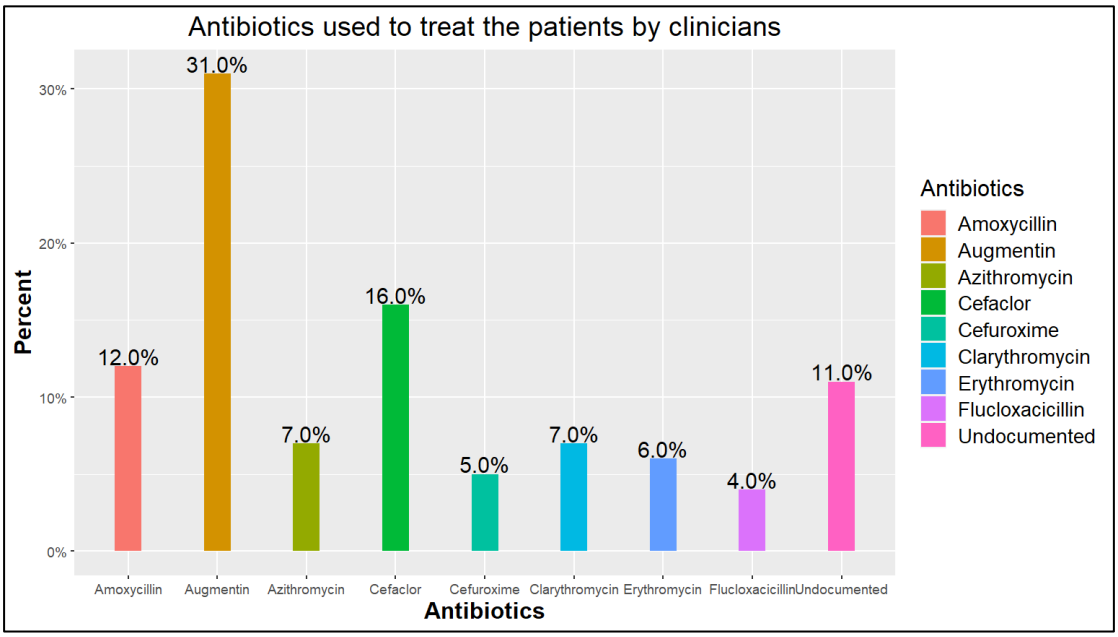

Figure 5: Overall Antibiotic Prescription

Augmentin syrup was the most prescribed antibiotic at 31% while the least prescribed was Flucloxacillin syrup at 4% as shown on figure 4.

Counselling Status of the Study Participants.

Table 11: Advice given to caretakers of the study participants.

Variable	Counselled	Frequency N = 377	Proportion
Unable to drink/breastfeed	Yes	71	18.8
	No	306	81.2
Becomes sicker/ weaker	Yes	72	19.1
	No	305	80.9
Develops fever	Yes	72	19.1
	No	305	80.9
Develops / fast breathing worsens	Yes	67	17.8
	No	310	82.2
Persistent/develops of difficulty breathing	Yes	66	17.5
	No	311	82.5
Return after 48 hour if diagnosis was pneumonia (n=63)	Yes	10	15.8
	No	53	84.1

Majority of caretakers were advised to return in the event that the study participants developed fever or became sicker 19.1% (n=72), followed by if the patient developed inability to drink/breastfeed at 18.8% (n=71). Among patients diagnosed with pneumonia, 15.8% (n=10) of the caretakers were advised to return after 48 hours while 84.1% (n=53) were not. Table 11 above

4.4 Factors Associated with Adherence of the New National Pneumonia Management Guidelines.

Bivariate analysis

Table 12 below shows a bivariate analysis of factors associated with incorrect assessment of pneumonia. The p-value of 0.03 at 5% significance level indicates that there was a significant statistical association between age and incorrect assessment for pneumonia. We used the number of patients correctly classified as our reference value to compute our binary logistic regression. Increasing the age of a child by 1 month increased the odds of incorrect assessment by 29% Crude Odds Ratio 1.29(95%CI 1.03-2.19).

Table 12: Bivariate Analysis of Factors Associated with Incorrect Assessment of Pneumonia

Variable	Assessment		Crude OR (95% CI)	p-value
	Correct **(ref)** N = 3	Incorrect N = 374		
Age in months	NA	NA	1.29 (1.03, 2.19)	0.03
Fever: No **(ref**)	1 (33.3%)	108 (28.9%)	1.0 **(ref)**	
Yes	2 (66.75)	266 (71.1%)	1.23 (0.11, 13.7)	1.00
Comorbidities: Absent**(ref)**	2 (66.7%)	152 (40.6%)	1.0 **(ref)**	
Present	1 (33.3%)	222 (59.4%)	2.92 (0.26, 32.5)	0.57
Time of consultation: Before mid-day(**ref)**	0 (0%)	209 (55.9%)		
Past mid-day	3 (100%)	163 (44.1%)	NA	0.09
Premedication: No**(ref)**	2 (66.7%)	298 (79.7%)		
Yes	1 (33.3%)	76 (20.3%)	0.51 (0.05, 5.70)	0.50

Table 13: Bivariate Analysis of Factors Associated with Incorrect Classification of Pneumonia

Variable	Classification of pneumonia		Crude OR (95% CI)	p-value
	Correct **(ref)** N = 181	Incorrect N = 196		
Age in months	NA	NA	1.004 (0.99, 1.02)	0.52
Fever: No **(ref**)	59 (32.6%)	50 (25.5%)	1.0	
Yes	122 (67.4%)	146 (74.5%)	1.41 (0.90, 2.21)	0.13
Comorbidities: Absent **(ref)**	79 (43.6%)	75 (38.3%)	1.0	
Present	102 (56.4%)	121 (61.7%)	1.25 (0.83, 1.89)	0.29
Time of consultation: Before mid-day **(ref)**	104 (57.5%)	105 (53.6%)	1.0	
Past mid-day	77 (42.5%)	89(45.4%)	1.14 (0.76, 1.72)	0.53
Night	0 (0.0%)	2 (1.0%)	NA	0.50
Premedication: No **(ref**)	138 (76.2%)	162 (82.7%)		
Yes	43 (23.8%)	34 (17.3%)	0.67 (0.41, 1.12)	0.12

Table 13 above shows a bivariate analysis of factors associated with incorrect classification of pneumonia. None of the factors was significantly associated with incorrect classification of pneumonia at 5% significance level.

The odds of being classified incorrectly given that the patients presented with fevers were 1.41 times the odds of those who presented without fevers OR 1.41 (95% CI 0.90, 2.21).

Patients who presented with comorbidities were 1.25 times likely to be incorrectly classified compared to those who did not present with comorbidities OR 1.25 (95% CI 0.83, 1.89).

Multivariable Analysis

Factors Associated with Assessment of Pneumonia

Model selection in the multivariable analysis was done using an information criterion that selects the best model. The best fitted model contains the least number of parameters and is based on the lowest information criteria value. The selected model contained variables that best explained the data. Based on this information criterion, only one variable was selected in relation to assessment of pneumonia. Therefore, a multivariable model could not be fitted. The factor is presented under the bivariate analysis (table 12).

Factors Associated with Incorrect Classification of Pneumonia

We used information Criteria for variable selection to best fit a binary logistic regression model to assess factors associated with classification of pneumonia. Three variables were selected and the results are displayed on table 16 below.

Table 14: Binary Logistic Regression of Factors Associated with Misclassification of Pneumonia

Variable		Classification of pneumonia		Crude OR (95% CI)	p-value
		Correct **(ref)**	Incorrect		
		N = 181	N = 196		
Fever: No **(ref)**		59 (32.6%)	50 (25.5%)	1.0	
Yes		122 (67.4%)	146 (74.5%)	1.46 (0.93, 2.29)	0.10
Premedication:	No **(ref)**	138 (76.2%)	162 (82.7%)		
	Yes	43 (23.8%)	34 (17.3%)	0.65 (0.39, 1.08)	0.09

None of the factors evaluated under multivariable analysis were significantly associated with incorrect classification of pneumonia at significance level 0.05. However, presence of fever increased the odds of a child being classified incorrectly i.e., the odds of incorrect classification for the children who presented with fever was 1.46 the odds of those who did not present with fevers OR 1.46 (95% CI 0.93, 2.29). Table 14 above

CHAPTER 5: DISCUSSION, CONCLUSION and RECOMMENDATIONS

5.1 DISCUSSION

The current pneumonia guidelines were adopted following local research with the aim of reducing disease burden in low resource nations. Correct uptake of guidelines is preceded by comprehensive history taking beyond what a caretaker reports and meticulous clinical examination during a consultation in a patient presenting with cough and or difficulty in breathing. This allows a health practitioner to think critically and make a decision on the appropriate treatment to prescribe for the best outcome.

This study sought to determine adherence of the current Kenyan pneumonia guidelines for patients presenting during the mild and early stages of this acute respiratory infection.

We used a strict definition of cough and or difficulty in breathing to identify participants with an acute respiratory tract infection. Cough was more common 94.4% (n=356) compared to difficult breathing 17.5% (n=66).

The overall comprehensive assessment of patients for non- severe pneumonia was low at 0.8%. This was similar to two studies done in two African countries among under-fives being evaluated for acute respiratory tract infections in the outpatient department (36,38). History taking beyond what a parent reports has been shown to be one of the most infrequently completed task in other studies(33,36,38). A cross sectional survey conducted by Ngozi et al 2015 in 11 outpatient clinics, demonstrated a slightly higher overall IMCI guidelines adherence assessment score at 7% (12/176) on history taking beyond what a caretaker had reported among 126 under- fives.

During clinical examination, the least performed and documented task was oxygen saturations at 4.8% (18/377), even with two functional portable pulse oximetry gadgets available at the triage desk. Respiratory rate assessment was also low at 6.6% (25/377). Assessing for level of consciousness was the most recorded during assessment for non-severe pneumonia at 83.8% (n=316). Adequate chest exposure to assess for chest in-drawing was performed during 45.6% (n=172) of the patient clinician encounters.

Hypoxemia still remains a critical sign identifying as a risk of death, hence a vital sign that should be routinely assessed in all outpatient settings. However, It is one of the least performed assessment task in most outpatient settings(52,53,64,65).

Even the most experienced health experts can only identify saturations below 80% without pulse oximetry. Our study participants were patients presenting during the early

and mild stages of an acute respiratory infection. Studies have demonstrated that patients are likely to get a pulse oximetry if they present with signs of severe illness such as an altered mentation, tachypnea and severe chest in-drawing (53,65). It is possible that clinicians working in such busy outpatient settings utilize an abductive form of logical thinking while evaluating less sick patients hence the low frequency of oxygen saturations assessment in this study.

Counting the respiratory rate is also one of most infrequently performed task despite being the starting point for disease classification in a patient presenting with history of cough and or difficulty in breathing(33,36,37,43). W.H.O recommends counting the respiratory rate for a fixed duration of 60 seconds often viewed as cumbersome in busy clinics(64) . The task might also be considered time consuming because factors such as noise and anxiety may influence its accuracy necessitating repetition perceived as unrealistic in settings with high patient workloads. In addition, majority of our study participants were infants who are more sensitive, hence easily agitated and less likely to rationalize surrounding contextual factors compared to older children.

It is not well understood why clinicians depict low performance when it comes to guideline implementation and adherence. Even after provision with essential equipment, supportive training and user guides, the quality of care in patients presenting with features of a respiratory infection is low(37,42). On the contrary, they often portray a good knowledge score on IMCI guidelines but the knowledge- practice gap remains a w (38,42,66). However, studies have also shown that regular training is more effective in improving guidelines adherence compared to one time training sessions(38,42).

The overall correct classification was 48% (181/377). This was higher compared to a study conducted in Malawi in 742 outpatient departments at 21% (25). Two studies although conducted in-patient settings of two Kenyan hospitals, demonstrated higher findings at 55% and 56% (5,67) compared to this study. Our study findings demonstrate a discrepancy between documented complete assessment and correct classification. This is expected as it is possible to make a diagnosis without complete assessments since most busy hospital settings use the most efficient route to diagnose and treat patients.

Clinical officers were able to correctly identify 38.4% (n=63) patients as pneumonia as opposed to 107 patients who actually had pneumonia according to the guidelines. The clinical officers had failed to classify 28.6% (n=44) of patients as pneumonia. These findings of pneumonia misclassification are almost similar to those found in a study conducted in Malawi at 26% (25). Use of vague terms by clinicians when unsure of a diagnosis was also a common practice due to suboptimal assessments during consultations and the inability to interpret those incomplete findings(25,42).

None of the patients correctly classified as pneumonia had the recommended high dose of amoxicillin dispersible tablets prescribed. This was similar to a study conducted in patients admitted with a diagnosis of pneumonia in KNH by Kemunto et al in 2017(67).

Dispersible amoxicillin tablets were available during majority of the data collection period except for the month of March when the Paediatric Emergency Department had a limited stock of only 500 tablets. Majority of the patients correctly classified as pneumonia were treated with Amoxicillin clavulanic acid syrup at sub-optimal dosages 46.0% (29/63). Thirteen percent (8/63) were given a STAT dose of intramuscular crystapen penicillin. Patients seeking a primary service in a tertiary institution will have sought services from a primary facility or self-medicated with an antibiotic bought from private pharmacies. As demonstrated in this study, majority of the study participants with a diagnosis of pneumonia had taken an antibiotic prior to consultation.

A mixed methods Study done by Chomba et al (68) demonstrated better adherence to treatment guidelines during 1497 pneumonia consultations conducted by ninety community health workers. Ninety two percent of 219 children diagnosed with fast breathing pneumonia received dispersible amoxicillin tablets in tally with their clinical findings. Seventy nine percent of patients diagnosed with pneumonia received the correct dosage of dispersible amoxicillin tablets. Two studies conducted in Africa also demonstrated better acceptability and compliance to dispersible amoxicillin tablets among patients and their caregivers respectively while treating ambulatory pneumonia(69,70). Our study findings revealed poor guidelines adherence and zero acceptability of high dose oral amoxicillin among clinicians for management of ambulatory pneumonia. It may be the case that, clinicians working in this department utilize metacognition, the process of monitoring one's own thinking while making clinical decisions. The complexity in healthcare today encourages health practitioners to have the desire to use checklists, protocols and algorithmic processing, leading to a false sense of predictability. While in reality the decisions made are majorly influenced by one's critical thinking on factors such as diagnostic and therapeutic uncertainties as well as patient preferences. Therefore, a qualitative study will give a better understanding as to why health care workers working in this busy study setting portray low acceptability of the guideline recommended treatment.

Dispersible amoxicillin tablets are better compared to other amoxicillin syrups because of their cost effectiveness. They are cheaper, less bulky in terms of weight and volume, no refrigeration is needed, easier to swallow and administer, and they offer greater dosage accuracy as opposed to the manually measured dry syrups. UNICEF demonstrated that shifting from the use of amoxicillin dry syrups has saved 8.4 million US dollars globally(71)..

This study also demonstrated unnecessary use of antibiotics in patients with no pneumonia at 96% (113/118) among whom five percent (n=4) received a stat dosage of intramuscular crystapen penicillin. Cefaclor was the most frequently prescribed antibiotics at 26%%. A study conducted in Thailand by Bounxou et al in 2019, demonstrated a similar practice of inappropriate antibiotics prescription at 96.4% among 576 under –fives with a diagnosis of no pneumonia. Contrary to our study findings, beta-lactams were the most frequently prescribed drugs at 87.7% (72).

Most respiratory tract infections are of viral origin, self-limiting and they do not require use of an antibiotic (28). However, they account for majority of antibiotic prescription in outpatient departments facilitating development of microbial resistance and increased healthcare costs(72). The challenge of limited resources in terms of diagnostic tests in developing countries has been reported to influence this unnecessary use of antibiotics. Complex interplay between viral and bacterial aetiology in pneumonia and other RTIs in children requires hospitals to prioritize provision of rapid diagnostic tests to curb unnecessary use of antibiotic(41).

We also looked at factors associated with poor adherence to guidelines in the paediatric emergency unit during assessment and classification of a child presenting with cough and or difficulty in breathing. We did not run an analysis for factors influencing correct treatment because none of the patients diagnosed with pneumonia had the correct guideline recommended prescription as this was our main point of focus.

We found that age was significantly associated with a correct or an incorrect assessment during a consultation p value 0.03.

Every increase in age by a month increased the odds of incomplete assessment by 1.3 times, OR 1.29 95% (CI 1.03-2.19). This is similar to findings of a study done in Malawi by Johansson et al where they found that the older a patient, the less likely they are to have a complete assessment OR 0.35 95% CI 0.16-0.75).

The worried parent is likely to report more symptoms in an infant compared to when a child is older than one year and this might prompt a clinician to ask more questions while taking history and during clinical examination(45).

5.2 Study Strengths

This was the first study to determine uptake of the new pneumonia guidelines in a tertiary facility. Clinicians working in the department were blinded to the ongoing survey as much as possible to avoid the Hawthorne effect. The study surveyed 20-25 clinical officers working in the department with similar levels of training. The clinicians had a comparable number of duties and therefore, we did not expect the results to be biased towards performance of one or a few workers.

5.3 Study Limitations

Some of the limitations of this study were the sampling method used reduced the power of the study. This would have been mitigated by randomization of the study participants during enrollment and data collection. The other limitation is that Kenyatta National Hospital is a tertiary institution and generalizability may be a problem. One way around this would have been to demonstrating the number of children who came to the facility as their primary site or were referred and even though costs lead to selection bias.

The other limitation was that data abstracted and analyzed was based on what was recorded with the assumption that what was not documented was not done whereas a clinician may have performed a task but not documented it. Thus making conclusions on this kind of biased analysis may not have been inferential in regards to guidelines knowledge and task performance among the clinical officers working in the pediatric emergency unit.

5.4 Conclusion

There is poor adherence to the revised Kenyan guidelines for the management of pneumonia among patients aged between two to fifty-nine months at the outpatient department of Kenyatta National Hospital. Adherence to the 2018 MoH IMNCI pneumonia guidelines was poor varying from zero during treatment, to extremely low at less than 1% during assessment, and 48% for classification. There was misuse of scarce and costly resources such as antibiotics in this department with a 96% prescription frequency of antibiotics among patients diagnosed as having no pneumonia. In addition, majority of the patients had prescriptions with sub-optimal antibiotics dosages and this poses a major threat to antimicrobial resistance in this facility as a result of partial treatment.

5.6 Recommendations

From the findings of this study, we make the following recommendations:

1. Assessment of all vital signs at the triage desk for all patients regardless of their clinical status and presenting complaints.
2. The ministry of health needs to form regulatory bodies and policies aimed at close monitoring of prescription practices in outpatient departments.
3. A qualitative study to determine the reasons why clinicians working in the pediatric emergency unit portray poor guideline adherence despite regular in-service trainings.
4. Look for ways of improving guidelines adherence such as provision of well-structured documents or job aids to act as guides during consultation.

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5.7 Dissemination of Results

A feedback report on study findings will be distributed to the UON/ KNH Ethics Research Committee, KNH Research Department, department of Pediatrics and Child Health and the outpatient department of KNH.

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APPENDICES

Appendix 1: Consent Form for Participation in The Study

Consent Form for Participation in This Study.

TITLE OF THE STUDY: The Uptake of Revised WHO/Kenyan Guidelines for the Management of Pneumonia Among Children Aged 2 To 59 Months at the Kenyatta National Hospital, Outpatient Department.

Principal investigator and institutional affiliation (student being supervised):

DR. MUNDATI VIRGINIA - KENYATTA NATIONAL HOSPITAL-UNIVERSITY of NAIROBI Department of Pediatrics and Child Health.

Supervisors and institutional affiliation:

PROFESSOR RUTH NDUATI -KENYATTA NATIONAL HOSPITAL - UNIVERSITY of NAIROBI, Department of Pediatrics and Child Health

DR. BONIFACE OSANO - KENYATTA NATIONAL HOSPITAL - UNIVERSITY of NAIROBI, Department of Pediatrics and Child Health.

Introduction: I would like to inform you about a study being conducted by the above named principal investigator after approval from the KNH-UON Ethics and Research Committee. This consent form serves to equip you with information necessary to help you decide whether or not to be a participant in the study. Feel free to inquire about the purpose of the study, what happens if you choose to participate, the possible risks and benefits, your rights as a volunteer or anything else about the researcher or in this form that is not clear. Should our answers be satisfactory, you may decide whether to be in the study or not. This process is called 'informed consent'. Once understandable and agreeable to you, I will request you to sign your name on this form that you agree to participate in this study. please note that : i) Your decision to participate is entirely voluntary ii) You have the right to withdraw from the study at any time without necessarily giving an explanation as to why iii) refusal to participate or withdrawal will not affect the services you are entitled to in this health facility or other facilities. You are entitled to a copy of this form for your records.

May I continue? YES/NO

This study has approval from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee **protocol NO…… (This will be after ethics approval.)**

WHAT IS THIS STUDY ABOUT

The researcher listed above is a clinician that takes care of pediatric patients on a daily basis. We are conducting brief interviews with caretakers of children presenting with complaints of cough and or difficulty in breathing with an aim of determining clinicians' outpatient uptake of the revised WHO guidelines in managing pneumonia. We shall ask you brief questions to assess the care your child received in line with the WHO and Ministry of Health guidelines. There will be an estimated 377 participants in this study. We would like to ask for your consent as a participant in this particular study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

Should you agree to participate in this study, the following steps will take place; You will be interviewed by trained research assistant(s) in a private area where you feel comfortable answering questions. This will last for 3-5 minutes after which you are free to leave at your own leisure. Please note that there will be no form of recording.

ARE THERE ANY RISKS, HARMS or DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Research in the medical field has the probability of causing psychological, social, emotional and physical risks. We shall put maximum efforts to minimize the risks. Potential risk of this study is loss of privacy but we will keep everything you tell us as confidential as possible. A code number will be used to identify your child in a password protected computer database and all our paper records will have no names written on them and they shall be kept in a locked file cabinet. Information collected about your child will also be within the hospital. You have the right to refuse to answer any questions asked during the process. Please note that all the interviewers

are trained professionals. There are no invasive procedures involved in this study that may cause direct physical harm

ARE THERE ANY BENEFITS IN THIS STUDY?

The information you provide will help us better understand the level of clinicians' adherence to the national guidelines while assessing your child for pneumonia. This information is a contribution to science and will help us form strategies tailored towards improving Kenyan clinicians' skills and knowledge for earlier identification and treatment of pneumonia in their clinical practice. In the event that a particular intervention is required in your child's management, we shall facilitate that you receive the necessary help. Please note that there will be no monetary compensation for participating in this study.

WILL THE STUDY COST YOU ANYTHING?

The study will not cost you any money but we shall take approximately 3-5 minutes of your time.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is entirely voluntary. Please note that you are free to decline participation in the study and that you can withdraw from the study at any time without injustice or loss of any benefits. You shall also continue to receive care as usual.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or heard the information read to me. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this study. I understand that all efforts will be made to keep information regarding my child's personal identity confidential.

By signing this form, I have not given up any of the legal rights that my child and I have as participants in a research study.

I agree to participate in this study:	**Yes**	**No**
I agree to have my responses preserved for later study	**Yes**	**No**

Participant printed name:

Participants Signature/ Thumb Stamp_____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his or her consent.

Researcher's Name _____ Date _____

Signature _____

Role in the study:_____ [study staff who explained informed consent form]

For more information contact any of the following:

Dr Boniface Osano (supervisor) consultant pediatric cardiologist, Department of Pediatrics and Child Health in Kenyatta National Teaching and Referral Hospital - University of Nairobi, P.O BOX 19676, Nairobi. Telephone +254 020 2726300 Email: drosanob@gmail.com.

Dr Virginia Njoki Mundati (post graduate student being supervised for this dissertation),

Resident Year 3 at the Department of Pediatrics and Child Health, Kenyatta National Teaching and Referral Hospital- University of Nairobi, P.O BOX 19676, Nairobi, Telephone: +254720418990, email: vmundati@gmail.ke.

KNH-UoN ERC Committee is the ethics review board which focuses on ensuring that ethics of research are maintained and incase of any queries relating to this research can be addressed to the secretary.

Secretary/Chairperson, Kenyatta National Hospital –University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext.44102 email UoN/ KNH erc@uonbi.ac.ke

Witness Printed Name (If witness necessary, (A witness is a person mutually acceptable to both the researcher and participant)

Name _____ Contact Information _____

Signature/Thump Stamp:_____ Date: _____

Appendix 2: Idhini ya Kushirikishwa Katika Utafiti Huu

ANWANI YA UTAFITI: Uchukuzi wa Maelekezo Mapya ya W.H.O Na Wizara ya Afya kwa Matibabu ya Nimonia Katika Watoto Wenye Umri Kati ya Miezi Miwili na Miaka Mitano Kwenye Idara ya Wagonjwa wa Nje Katika Hospitali ya Taifa ya Kenyatta.

Mpelelezi Mkuu na Shirika Husiano (Mwanafunzi Anayesimamiwa)

Dr. Mundati Virginia – Hospitali Kuu ya Taifa ya Kenyatta, Chuo Kikuu cha Nairobi, Idara ya Watoto.

Wasimamizi na Shirika Husiano

Professor Ruth Nduati - Hospitali Kuu ya Taifa ya Kenyatta, Chuo Kikuu cha Nairobi, Idara ya Watoto.

Dr Boniface Osano -Hospitali Kuu ya Taifa ya Kenyatta, Chuo Kikuu cha Nairobi, Idara ya Watoto.

Dibaji /utangulizi

Ningependa kukufahamisha kuhusu utafiti unaofanywa na mpelelezaji mkuu aliyetajwa hapo awali. Fomu hii ya idhini inakupa ujumbe muhimu kukusaidia kuamua kushiriki au kutoshiriki. Jisikie huru kuuliza kususdi la utafiti, kitakachotokea ikiwa utashiriki, hatari na faida zinazowezekana na haki yako,au ujumbe wowote juu ya mtafiti au kwa fomu hii. Majibu yote yakikuridhisha, unaweza amua kushiriki au kutoshiriki. Mchakato huu unaitwa ridhaa ya habari. Ukielewa na kukubali, nitakuomba utie sahihi, jina lako kwenye fomu hii kuwa unakubali kushiriki katika utafiti huu. Tafadhali fahamu kuwa; (i) uwamuzi wa kushiriki ni wa hiari kabisa (ii) unahaki ya kujiondoa wakati wowote bila kutoa ufafanuzi wowote (iii) kukataa kushiriki au kujiondoa hakutaadhiri huduma unazostahiki katika kituo hiki cha afya au vituo vingine. (iv) unahaki ya nakala ya fomu hii kwa kumbukumbu zako.

Naomba niendelee **Ndio** **Apana**

UTAFITI HUU UNAHUSU NINI?

Mtafiti aliyeorodheshwa hapo juu ni anahudumia watoto kila siku

Tunafanya mahojiano mafupi na watunzaji / wazazi wa watoto wanaowasilisha malalamiko ya kikohozi na au shida ya kupumua kwa lengo ya kukutathmini

uchukuzi wa miongozo ya wizara ya afya kwa wagonjwa wa idara ya nje katika matibabu ya homa ya mapafu

Tutakuuliza maswali mafupi kutathmini matunzo ambayo motto wako amepata kulinganana na miongozo ya wizara ya afya hapa Kenya.

NINI KITATOKEA UKIAMUA KUSHIRIKI KATIKA UTAFITI HUU?

Ikiwa utakubali kushiriki, hatua zifuatazo zitafanyika; utahojiwa na mpelelezi mkuu katika eneo la kibinafsi ambapo unahisi huru kujibu maswali. Hii itadumu dakika tatu hadi tano. Baada ya hapo uko huru kuondoka. Tafadhali fahamu kuwa hakutakuwa na aina yeyote ya kurekodi.

KUNA HATARI YEYOTE, MADHARA AU USUMBUFU UNAOHUSISHWA NA UTAFITI HUU?

Utafiti katika uwanja wa matibabu una uwezekano wakusababisha hatari za kisaikolojia, kijamii, kihemko na kiafya; tutatia juhudi ili kupunguza hatari. Kunauwezekano wa utafiti huu kupoteza faragha , lakini tutaweka kila ujumbe unaotuambia kama siri iwezekanavyo. Tutatumia nambari kumtambua motto wako katika hifadhidata ya tarakilishiiliyolindwa. Habari iliyokusanywa juu ya motto wako itakuwa ndani ya hospitali. Unahaki kukataa kujibu swali lolote. Kumbuka kuwa anayekuhoji ni mtaalamu aliyefunzwa. Hakuna taratibu ya uvamizi zinazoweza kusababisha madhara ya mwili.

KUNA FAIDA YOYOTE KATIKA UTAFITI HUU?

Habari utakayotoa itatusaidia kuelewa vizuri kiwango cha madaktari kufuata mwongozo wa wizara ya afya hapa Kenya wakanapotaathmini mtoto kwa homa ya mapafu. utafiti huu utachangia kwa sayansi na itatusaidia kuunda mikakati iliyokusudiwa kuboresha ustadi na maarifa ya wahudumu wa afya wakenya kwa utambuzi wa mapema na matibabu ya nimonia katika uhudu wao. Tafadhali fahamu kuwa hakutakuwa na faida ya pesa kwa kushiriki katika utafiti huu.

UTAFITI HUU UTANiGHARIMU?

Hakutakuwa gharama ya kifedha lakini tutachukua takribani dakika tatu hadi tano za wakati wako.

UCHAGUZI WAKO NI NINI?

Uamuzi wako wa kushiriki katika utafiti huu ni wakujitolea. Uko huru kijiondoa au kukataa kushiriki katika utafiti huu wakati wowote bila udhalimu au upotezaji wa faida yoyote. Utaendelea pia kupata huduma kama kawaida.

kauli ya Idhini

Kauli ya mshiriki

Nimesoma au kusomewa fomu hii ya idhini. Nimejibiwa maswali yangu kwa lugha ambayo ninaelewa. Hatari na faida nimeelezwa pia na kuelewa. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Nakubali kwa huru kushiriki katika utafiti huu. Ninaelewa kuwa juhudi zote zitafanywa kutunza ujumbe wa kutambulisha mtoto wangu.

Kwa kutia sahihi kwenye fomu hii, sitatoa haki yoyote ya kisheria ambayo mimimna mtoto wangu tunayo kama washiriki katika utafiti.

Ninakubali kushiriki katika utafiti huu; **Ndio** **Apana**

Ninakubali majibu yangu yahifadhiwe katika utafiti wa baadaye **Ndio**

ApanaJina la mshiriki yaliyochapishwa

Saini ya mshiriki/ stempu ya kidole gumba _____ **Tarehe** _____

Kauli ya Mtafiti

Mimi niliyesahihisha idhini hii nimemueleza mshiriki barabara maelezo muhimu kuhusu utafiti huu na ninaamini kuwa ameelewa na kukubali kushirikishwa kwenye utafiti huu

Jina La Mtafiti _____ **Tarehe** _____

Sahihi _____

Kwa ujumbe zaidi wasiliana na waliorodheshwa hapa chini:

Professor Ruth Nduati(Msimamizi), Mtaalamu wa Magonjwa ya Kuambukiza , Hospitali ya Kitaifa, Kufundisha na Rufaa ya Kenyatta, Idara ya Watoto, Chuo Kikuu cha Nairobi.

Sanduku la Posta 19676, Nairobi. Nambari ya Simu, +254 020 2726300. Barua Pepe, ruth-nduati2000@yahoo.Com

Dr. Boniface Osano (Msimamizi), Mtaalamu wa Moyo, Hospitali ya Kitaifa, Kufundisha na Rufaa ya Kenyatta, Idara ya Watoto, Chuo Kikuu cha Nairobi.

Sanduku la Posta 19676, Nairobi. Nambari ya Simu, +254 020 2726300. Barua ya Pepe, drosanob@gmail.com.

Dr Mundati Virginia Njoki N.

Mwanafunzi wa Shahada ya Uzamili Anayesimamiwa kwa Tasnifu, Chuo Kikuu cha Nairobi,Nambari ya Simu +254720418990. Barua Pepe Vmundati@Gmail.Com.

Katibu / Mwenyekiti, Hospitali ya Kenyatta ya Taifa- Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi . Nambari ya Simu 2726300 Ext.44102. Barua ya Pepe. Uonknh Erc@Uonbi.Ac.Ke

Jina la Shahidi

Jina _____ Maelezo ya Mawasiliano _____

Saini / Stempu ya Kidole Gumba _____ Date _____

Appendix 3: Data Collection Tool / Check-List

Questionnaire No. ……

Observation Checklist Audit criteria; 2016 Kenyan/ WHO Pneumonia

Guidelines for children aged between 2 Months to 5 Years

Date: … / …/ … **Time seen……..AM / PM**

Health worker Type: (1) Clinical Officer (2) clinical officer intern
(3) Other……..
Child: ID …… Sex: (1) M (2) F Age: ……
Residence …….

ASSESSMENT MODULE

Record what is documented.

A3. Does the health worker, or another staff, weigh and record the weight of the child today?
(1) Yes (2) No (8) doesn't know

A2. Does the health worker, or another staff, check the temperature of the child?
(1) Yes (2) No Temperature recorded……..

A3. What reasons does the caretaker give for bringing the child to the health facility? Circle all signs mentioned.

a. Fever/malaria (1) mentioned (2) not mentioned

b. Fast/difficult breathing 1) mentioned (2) not mentioned

c. cough/pneumonia (1) mentioned (2) not mentioned

d. Others, Specify …….

A4. Does health worker ask for cough or difficult breathing if not reported?
(1) Yes (2) No

A5. Does health worker ask if the child is able to feed drink or breastfeed?
(1)Yes **(**2) No

A6. Does health worker ask whether the child vomits everything?
(1) Yes (2) No

A7. Does health worker ask whether the child has convulsions?
(1) Yes (2) No

A8. Has the health worker asked for and indicated presence or absence of disturbance in level of consciousness? (Drowsy, lethargy, unconscious, playful)

(1) Yes (2) No

A9. Does the health worker feel for fever (or refer to temperature if taken previously)?
(1) Yes (2) No Indicate Temp……

A10. Has the health worker counted and indicated the respiratory rate per minute?
(1) Yes (2) No Indicate rate

A11. Has the health worker checked for and indicated the presence or absence of lower chest wall in drawing
(1)Yes (2) No

A12. Has the health worker listened to the chest using a stethoscope and indicted auscultatory findings

(1) Yes (2) No

A13. Has the health worker checked and indicated presence or absence of any of the following danger signs?
Cyanosis (1) Yes (2) No AVPU (1) Yes (No) Indicate scale given.....

Grunting (1) Yes (2) No SPO_2 (1) Yes (No) SPO_2 Indicated……

CLASSIFICATION MODULE

C1. Has the health worker given a pneumonia classification for the child?
(1) Yes (2) No

If yes tick classification given
(1) Pneumonia (2) No Pneumonia / URTI (3) Other; specify……

TREATMENT MODULE

T1. Has the health worker recommended home management for pneumonia?
(1) Yes (2) No

T2. Has the health worker recommended ward management for pneumonia?

(1) Yes (2) No

If yes specify reason……

T3. Has the health worker administered or prescribed oral treatment?
(1) Yes (2) No ➞ Skip to Communication Module, question # CM4.

If yes, record all medications given:

a)	Metronidazole tablets/syrup	(1) Yes	(2) No
b)	Cough syrup	(1) Yes	(2) No
c)	Other antimalarial tablet/syrup	(1) Yes	(2) No
d)	Paracetamol/brufen	(1) Yes	(2) No
e)	Recommended antibiotic tablets/syrup	(1) Yes	(2) No
f)	Other antibiotic tablets/syrup	(1) Yes	(2) No
g)	Multi-vitamins	(1) Yes	(2) No
h)	Other vitamins	(1) Yes	(2) No
i)	Antimalarial	(1) Yes	(2) No
j)	Antibiotic, specify ……	(1) Yes	(2) No
k)	Other, specify ……	(1) Yes	(2) No
l)	Antihistamine, specify ……	(1) Yes	(2) No

T4. If the oral treatment includes an antibiotic, record what health worker prescribes:

First antibiotic: Name: …… Second antibiotic: Name……...
Formulation: ……. Formulation.....
Dosage and Amount …….. Dosage and Amount ….
Number of times per day ……. # Times per Day …….
Total Days: ……. Total Days ……

COMMUNICATION MODULE

In some settings, tasks are shared and the dispenser counsels the caretaker on the treatment given and also administers the first dose. The child should then be followed to the dispenser to complete the observation.

CM1. Does the health worker explain how to administer oral treatment?
Antibiotic (1) Yes (2) No (8) N/A

CM2. Does the health worker ask an open-ended question to verify the caretakers' comprehension of how to administer the oral treatment i.e compliance?
(1) Yes (2) No

CM3. Does the health worker give or ask the mother to give the first dose of the antibiotic at the facility? (1) Yes (2) No (8) NA

CM4. Does the health worker tell the caretaker to bring the child back immediately for the following signs after 48 hours? Tick all that apply.

a. Child is unable to drink feed or breastfeed	(1) Yes	(2) No
b. Child becomes sicker/weaker	(1) Yes	(2) No
c. Child develops fever or if fever persists	(1) Yes	(2) No
d. Fast breathing persists, worsens or develops	(1) Yes	(2) No
e. Persistence or development of difficult breathing	(1) Yes	(2) No
f. Child develops bluish discoloration of lips/limbs	(1) Yes	(2) No

g. Other, specify ……

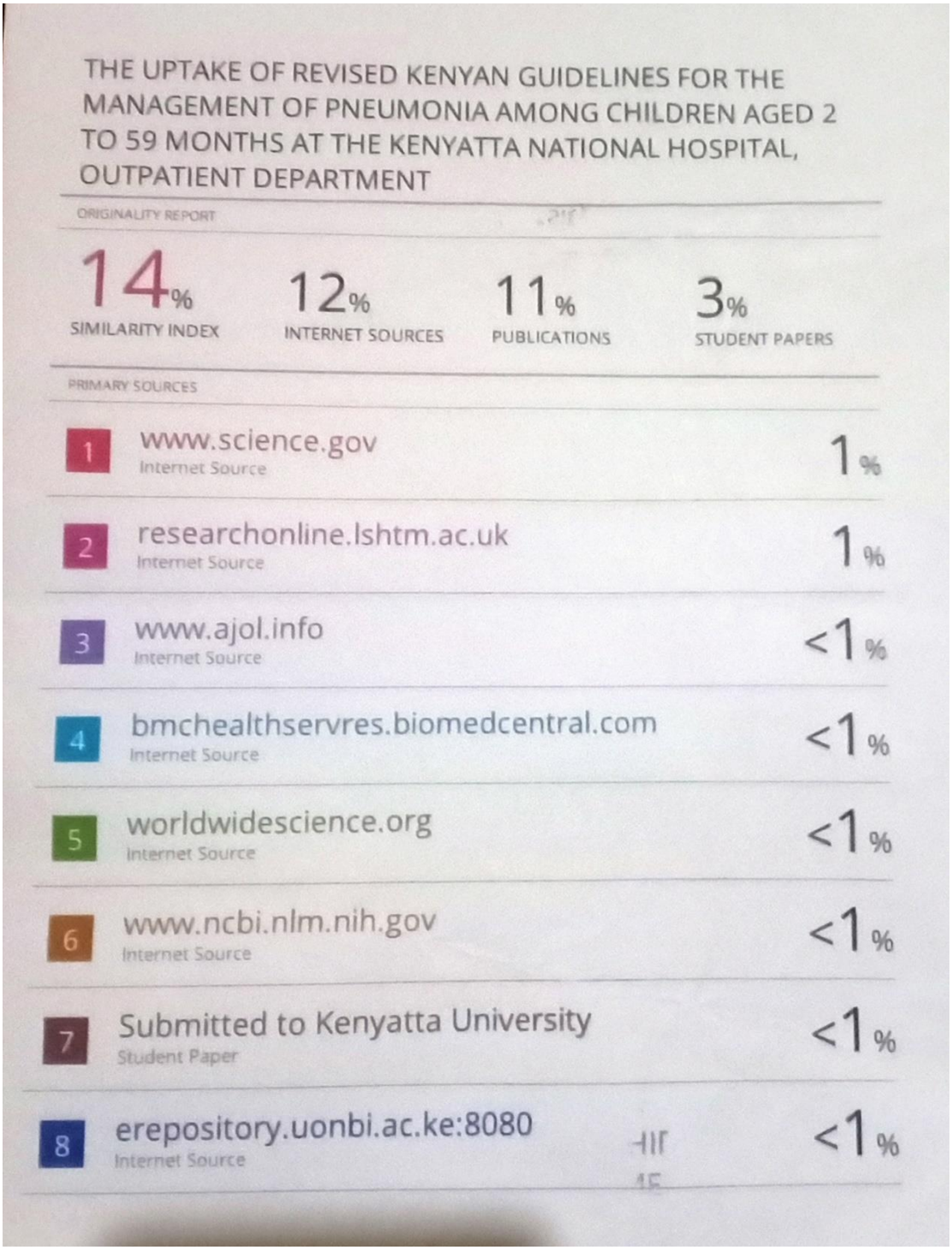
Appendix 4: Study Budget

Personnel	Unit	Amount (KES)
Principal investigator Dr Mundati.	1	Nil
Statistician	1	40,000
Research assistants	2	80,000
ERC fee	1	2000
Stationery and printer supp.	1	10,000
Photocopying	1	12,000
Telephone airtime		6000
Publication/ dissemination		30,000
Miscellaneous		12,000
Total		192,000.

Appendix 5: Study Timelines

Activity	Jan 2021- Aug 2021	Aug – Dec 2021	Jan – Feb 2022	March 2022	April 2022
Proposal preparation	X				
Ethics board review		X			
Data collection			X		
Data analysis				X	
Presentation of results					X

Appendix 6: Plagiarism Check Certificate



THE UPTAKE OF REVISED KENYAN GUIDELINES FOR THE MANAGEMENT OF PNEUMONIA AMONG CHILDREN AGED 2 TO 59 MONTHS AT THE KENYATTA NATIONAL HOSPITAL, OUTPATIENT DEPARTMENT

ORIGINALITY REPORT

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Appendix 7: Ethics Approval Letter

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/482

17th December 2021

Dr. Virginia Njoki Mundati
Reg. No. H58/11422/2018
Dept. of Paediatrics and Child Health
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 17 DEC 2021 KNH/UON-ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Mundati,

RESEARCH PROPOSAL: THE UPTAKE OF REVISED KENYAN GUIDELINES FOR THE MANAGEMENT OF PNEUMONIA AMONG CHILDREN AGED 2 TO 59 MONTHS AT THE KENYATTA NATIONAL HOSPITAL OUTPATIENT DEPARTMENT (P711/08/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P711/08/2021.** The approval period is 17th December 2021 – 16th December 2022.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Dean-Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Paediatrics and Child Health, UoN
Supervisors: Prof. Ruth Nduati, Dept. of Paediatrics and Child Health, UoN
Dr. Boniface Osano, Dept. of Paediatrics and Child Health, UoN