EFFECT OF INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS PNEUMONIA GUIDELINE TRAINING ON HEALTH WORKERS UPTAKE OF ORAL AMOXICILLIN AMONG CHILDREN AGED 2-59 MONTHS AT THREE HEALTH FACILITIES IN NAIROBI COUNTY.

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DECLARATION

I declare that this research proposal is my original work and that it has not been submitted forthe award of a degree in any other academic institution.

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This research proposal has been submitted with the full approval of my supervisors.

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List of abbreviations

AVPU	It is a simple scale used to assess the level of consciousness. A- Alert, V- response to Voice, P- response to Pain, U- Unconscious.
BD	Twice a day
CAP	Community-Acquired Pneumonia
CI	Confidence Interval
EMR	Electronic Medical Record
EHC	Eastleigh Health Centre
HIV	Human Immunodeficiency Virus
HLHC	Huruma Lions Health Centre
HRIOs	Health Records Information Officers
IMCI	Integrated Management of Childhood Illnesses
IMNCI	Integrated Management of Newborn and Childhood Illnesses
ITS	Interrupted Time Series
KNH	Kenyatta National Hospital
MoH	Ministry of Health
MUAC	Mid Upper Arm Circumference
NAR	Newborn Admission Record
ORS	Oral Rehydrate Solution
PAR	Pediatric Admission Form
RR	Respiratory Rate
SAM	Severe Acute Malnutrition
SCMF	Sick Child Management Form
PTB	Pulmonary Tuberculosis
UNICEF	United Nations International Children's Emergency Fund

WHC Westlands Health Centre

WHO World Health Organization

OPERATIONAL DEFINITIONS

Case definition of pneumonia- A child aged 2-59 months, with a history of difficulty breathing or cough for less than 14 days with age-specific tachypnea and or lower chest wall indrawing, without a danger sign(s).

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

Danger sign(s)- Refers to a sick child with any of the following clinical signs: not alert, refusal to drink/breastfeed, central cyanosis- referred in this research as cyanosis, oxygen saturation <90%. These danger signs are adapted from the 2014 revised WHO IMCI pneumonia guidelines.

New IMCI pneumonia guidelines- Refers to 2014 WHO IMCI guidelines for outpatient management of pneumonia in children.

Syndromic classification of pneumonia before 2014 WHO revised IMCI guidelines-

Classification of pneumonia severity using clinical signs :

i) **Very severe pneumonia–** History of difficulty breathing or cough with a danger sign(s).

ii) **Severe pneumonia–** History of difficulty breathing or cough, age-specific tachypnea, lower chest wall indrawing, and without danger sign(s). Also referred to in this research as lower chest wall indrawing pneumonia.

iii) **Pneumonia**– History of difficulty breathing or cough, age-specific tachypnea (also referred in this research as fast breathing pneumonia), without lower chest wall indrawing, and without danger sign(s).

iv) **No pneumonia–** History of difficulty breathing or cough, without age-specific tachypnea, without lower chest wall indrawing, and without danger sign(s).

Syndromic classification of Pneumonia after 2014 WHO revised IMCI guidelines-

Classification of pneumonia severity using clinical signs :

i) **Severe pneumonia** – History of difficulty breathing or cough with age-specific tachypnea and or lower chest wall indrawing and danger sign(s).

ii) **Pneumonia**- History of difficulty breathing or cough with age-specific tachypnea and or lower chest wall indrawing and without danger sign(s). Also referred to in this research as ‘non-severe pneumonia'.

iii) **No pneumonia–** History of difficulty breathing or cough without lower chest wall indrawing or age-specific tachypnea and without danger sign(s).

Childhood pneumonia- Syndromic pneumonia of any severity among children younger than five years of age.

Community-acquired pneumonia- A child presenting with symptoms and signs of pneumonia without a history of hospital admission 30 days prior.

Health workers uptake of oral amoxicillin- This is a composite indicator of health workers documented correct assessment, correct classification, and correct treatment of pneumonia (non-severe pneumonia).

Adequate assessment- Health workers documentation of all the symptoms (history of difficulty breathing and or cough) and signs (age-specific tachypnea and or lower chest wall indrawing, no cyanosis /oxygen saturation ≥90%, able to drink/breastfeed, and alert) that enable classification of pneumonia (non-severe pneumonia).

Correct classification- Health workers documentation of the correct classification of pneumonia (non-severe pneumonia) as per all the documented symptoms (history of difficulty in breathing and or cough) and signs (age-specific tachypnea and or lower chest wall indrawing, no cyanosis/oxygen saturation ≥90%, able to drink/breastfeed, alert) that enable classification of pneumonia (non-severe pneumonia).

Correct treatment- 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 frequency and correct duration of 5 days.

Correct prescription of high-dose oral amoxicillin dispersible tablets- This is a composite indicator comprising of correct dose (4kg – <10kg:250mg, 10kg – <14kg:500mg, 14kg – <19kg:750mg), correct 12 hourly frequency and duration of 5 days.

Level change-The immediate change of health workers uptake of IMCI pneumonia guidelines after intervention.

Trend-The gradual change of health workers uptake of IMCI pneumonia guidelines after intervention.

ABSTRACT

Background In 2014, WHO re-classified childhood pneumonia syndromes. The new classification included; severe pneumonia, pneumonia, and no pneumonia(1). The class of pneumonia (non-severe) involved both age-specific tachypnea and or lower chest wall indrawing and no danger sign(s). Further, WHO recommended using oral high-dose amoxicillin for outpatient management of pneumonia. In 2018 Kenya MoH updated national IMNCI pneumonia guidelines and introduced oral high-dose amoxicillin for outpatient management of pneumonia (2). The broad objective was to determine the effect of IMCI pneumonia guidelines training and introduction of Sick Child Management Form on health workers uptake of high-dose amoxicillin among children aged 2-59 months. The effect of training and introduction of Sick Child Management Form on health workers adequacy of assessment and classification of pneumonia (non-severe pneumonia) were assessed as secondary outcomes.

Methodology We conducted, in Eastleigh Health Centre, Westlands Health Centre and Huruma Lions Health Centre in Nairobi County, a before and after intervention study. We utilized an interrupted time series approach in analysis with an attempt to evaluate the effect of IMCI pneumonia guidelines training and the introduction of SCMF on health workers uptake of correct assessment, correct classification and correct treatment of non-severe pneumonia among children aged 2-59 months with cough and or difficulty in breathing reviewed between May 1, 2020 to February, 2022. We compared the trend of change overtime using health workers performance indicators for correct assessment, correct classification and correct treatment of non-severe pneumonia.

Results During pre-intervention 1, the clinical adherence to IMCI pneumonia guidelines was poor with none of the children reviewed had a correct assessment, correct classification and correct treatment for non-severe pneumonia. After the training (1st intervention) there was no change of the same poor trend. After the introduction of the SCMF (2nd intervention) there was a noted immediate improvement with correct assessment by a factor of 19.4, P-value of 0.9, correct classification by a factor of 19.05, P-value of 0.9 and correct treatment by a factor of 17.3, P-value of 0.9. However, overtime there was a decline in the improvement effect. The correct assessment declined overtime by a factor of -0.009, P-value of 1, correct classification by a factor of -0.06, P-value of 1 and correct treatment by a factor of -0.1, P-value of 0.9.

Conclusion Training health care workers alone may not improve and sustain uptake of IMCI pneumonia guidelines. The introduction of SCMF will improve uptake of IMCI pneumonia

guidelines, however, better implementation strategies are needed to sustain the improvement overtime.

1.0 INTRODUCTION

The World health organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) in 1995 developed IMCI to provide a holistic approach to improving sick children's management. IMCI comprises a community component (Community–IMCI) and a facility component (Facility-IMCI). The facility component of IMCI helps in health system strengthening as well as improving health workers skills and is the main focus of this study (3).

Worldwide, pneumonia is the main cause of mortality among children younger than five years of age, accounting for estimated 802,000 mortalities in 2018. In the region (eastern and southern Africa) in 2015, childhood pneumonia caused 138,000 deaths which were 15% of the global deaths(4).

In 2014, WHO recommended using oral high-dose amoxicillin for outpatient treatment of pneumonia. The outpatient treatment of pneumonia with oral high-dose amoxicillin excluded children with cough > 2 weeks, fevers > 2 weeks, HIV exposed/infected, severe acute malnutrition, positive history of contact with a known PTB patient, known cardiac and kidney disease, inpatient care <1 month (1). This WHO recommendation was not adopted in Kenya until after a local study was done in 2015 and showed noninferiority of high-dose amoxicillin to benzylpenicillin in treatment failure outcomes for non-severe pneumonia at 48 hours (5). Previously, severe pneumonia (previous pneumonia classification) was treated with crystalline penicillin until the local study(5) showed that high dose amoxicillin can be used. The Kenya MoH IMNCI guidelines on the use of high-dose oral amoxicillin for outpatient management of pneumonia (current classification) were updated in 2018(2).

Benefits of the revised 2014 WHO IMCI pneumonia guidelines include; reduced cost benefits, decreased hospitalization, reduced risk of hospital-acquired infections, reduced antimicrobial resistance, reduced need for referrals, simplified pneumonia classification, and management (1).

Training health care workers on IMCI provides a significant improvement in recognition of danger signs and adequate prescription of antibiotics(6). Failure of trained health workers' to follow IMCI guidelines is due to a lack of training, job aides, among other factors(7). A previous study done in 2019 on health workers uptake of new pneumonia guidelines in a tertiary hospital in Kenya showed poor adherence though it was focused on inpatients(8). Since 2018 when Kenya MoH IMNCI pneumonia guidelines(2) were updated until now, adherence of health workers to IMCI pneumonia guidelines in outpatient setting remains unknown. This study focused and addressed this knowledge gap.

2.0 LITERATURE REVIEW

This chapter reviews the literature on clinical classification of pneumonia, previous pneumonia classification, previous pneumonia management, evidence that led to the revision of IMCI childhood pneumonia guidelines. It also reviews literature on health workers adherence to IMCI pneumonia guidelines, effect of IMCI pneumonia guideline training on implementation of the new IMCI pneumonia guidelines, health workers challenges in implementation of IMCI pneumonia guidelines, effect of user friendly review forms on health workers performance, effect of knowledge decay on health workers performance after training and role of interrupted time series study design in evaluation of immediate and sustained change of health care workers performance after training.

2.1 Clinical classification of pneumonia.

In the 1980′s, WHO developed simple signs for the classification of childhood pneumonia. The simple signs included; age-specific tachypnea and lower chest wall indrawing in a child with lower chest wall indrawing or difficulty breathing. A more severe form of pneumonia was shown by the presence of danger signs such as; central cyanosis or measured oxygen saturations <90%, not alert, and inability to drink or inability to breastfeed(1).

2.2 Previous pneumonia classification and management.

Before 2014, WHO classified the severity of pneumonia for children aged between 2-59 months into four classifications namely: no pneumonia, pneumonia, severe pneumonia, very severe pneumonia as demonstrated in figure 1.

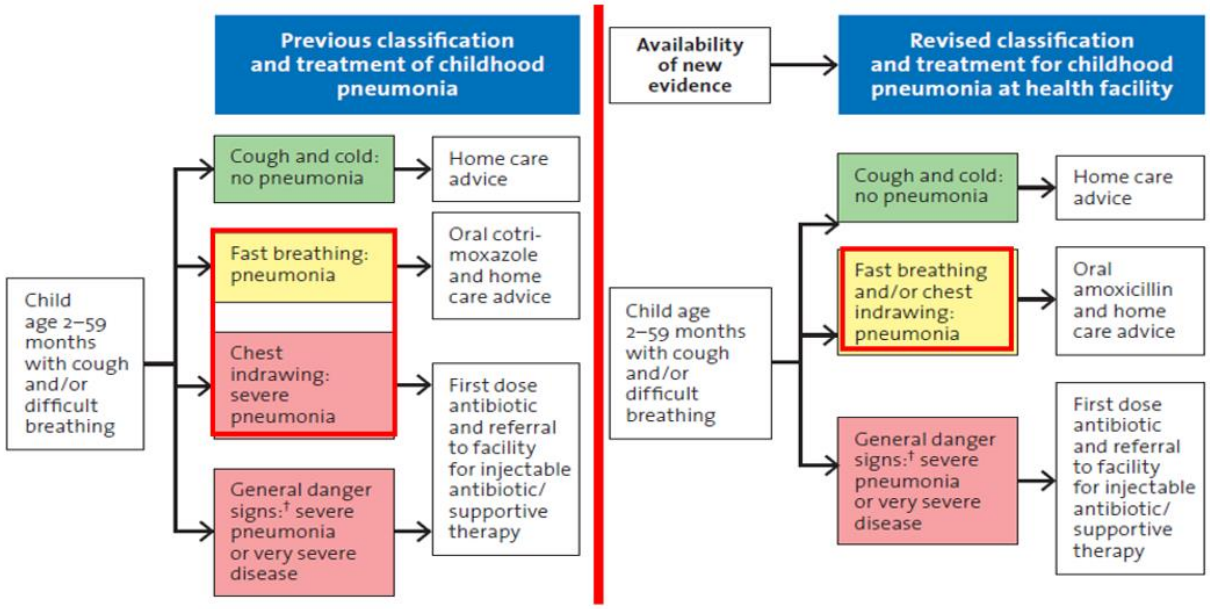

Figure 1: Old and current classification and treatment of childhood pneumonia at health facility(1).

2.2 Literature with the evidence that brought a change in the IMCI guidelines.

In 2014, WHO revised IMCI pneumonia guidelines by re-classifying pneumonia with indrawing and no danger sign(s) to be treated as outpatient and thus managed as fast breathing pneumonia and no danger sign(s) with oral high-dose amoxicillin (1).

2.21 Evidence that informed choice of amoxicillin for treatment of pneumonia

Addo-yobo *et al* in 2004, conducted a two-arm multicenter randomized open-label equivalency study, comparing the efficacy of amoxicillin and injectable penicillin in treating severe pneumonia (previous classification). The participants were 1702 children ages 3-59 months. One group got oral amoxicillin 50.3% (n=857) and another group got parenteral penicillin 49.7% (n=845). The study was conducted at 9 tertiary facilities in 8 developing countries in Africa, Asia, and South America. At 48 hours, there were treatment failure rates of 19% in both arms of the study, 161/845, 19.05% children on benzyl penicillin; 167/857, 19.4% children on amoxicillin; risk difference -0.4%; 95% CI-4.2 to 3.3. The study revealed that in controlled settings, benzyl penicillin and oral amoxicillin had similar efficacy for the treatment of lower chest wall indrawing pneumonia. Oral amoxicillin treatment was more advantageous over parental penicillin due to low risk of infections, less cost, and reduced need for admission or referral(9).

Hazir *et al* in 2008, conducted a randomized equivalency trial on oral high-dose amoxicillin for lower chest wall indrawing pneumonia management at seven sites in Pakistan. The study enrolled 2037 children between 3-59 months of age. The participants were allocated randomly to either home-based care with high-dose oral amoxicillin at 80-90 mg/kg/day in two divided doses for 5 days 49.6%(n=1012) or admitted and given injectable ampicillin 100mg/kg/day in four divided doses for 48 hours then followed by high dose oral amoxicillin at 80-90mg/kg/day in two divided doses for 3 days 50.1%(n=1022). On day 6, treatment failure among the hospitalized participants was 8.6%, and among the home-based treatment was 7.5%, group risk difference was 1.1% 95% CI-1.3 to 3.5. Home treatment with oral amoxicillinwas comparable to admission treatment with injectable ampicillin. The study recommended that pneumonia with chest wall indrawing without underlying complications be managed at home with oral high-dose amoxicillin and not inpatient care with injectable ampicillin(10).

In 2007, Thomson *et al* in England conducted a multicenter pragmatic randomized non blinded study and compared efficacy of oral amoxicillin and injectable benzylpenicillin for management of childhood community-acquired pneumonia. The study recruited 246 children with a history of fever, respiratory signs, radiologically established pneumonia, and required admission. The participants were randomly selected to receive either oral amoxicillin for 7 days (n=126) or injectable penicillin (n=120). Children receiving injectable penicillin after a median of 6 injectable doses were changed to oral amoxicillin. The primary objective was the time taken for the temperature to be <38 ℃. Both groups had a median time of 1.3 days for the temperature to normalize. The median time to resolution of illness in both groups was 9 days. In the intravenous group, 7children were changed to different injectable antibiotics, while 3 children in the oral amoxicillin group were switched to injectable antibiotics. The study found oral amoxicillin and injectable benzylpenicillin to have similar efficacy in the management of children admitted with pneumonia except those with more severe disease(11).

2.22 Evidence on dose and frequency of oral amoxicillin for treatment of pneumonia

Fonseca *et al* compared pharmacokinetics of amoxicillin given 12 hourly or eight hourly among children older than 3 months with pneumonia. The study was conducted in 1995/1996 at a tertiary level health facility in Brazil. Participants were 66 children with pneumonia aged between 3-59 months. There were two groups in the study. One group received amoxicillin 25mg/kg/dose every 12 hours, and the other group amoxicillin 15mg/kg/dose every 8 hours. Liquid high-performance chromatography was used to determine amoxicillin concentrations on day 1 and day 3 after the first dose. After the first dose on day 1, the mean area under the concentration-time curve for 25mg/kg dose amoxicillin was 54.7 μg·h/ml versus 24.9 μg·h/ml after the 15mg/kg dose. On day 3 after the first dose of amoxicillin 25mg/kg/dose, the mean area under the concentration-time curve was 44.1 μg·h/ml versus 24.9 μg·h/ml after the first dose of 15mg/kg/dose. Amoxicillin given 12 hourly was found a feasible alternative to giving amoxicillin every 8 hours. The study recommended an increase of amoxicillin dosage from 25mg/kg/dose to 30-40 mg/kg/dose every 12 hours to increase the time above the minimum inhibitory concentration levels(12).

Vilas-Boas *et al* in 2014, conducted at a center in Brazil a randomized controlled trial comparing oral amoxicillin(50mg/kg/day) given 8 hourly or 12 hourly every day to children between 2-59 months with non-severe pneumonia. The study enrolled 820 participants diagnosed with non-severe pneumonia by trained pediatricians based on symptoms and chest x ray findings. One group 50.2% (n=412) received amoxicillin every 8 hours, and the other group 49.7%(n=408) every 12 hours. Among participants diagnosed with pneumonia radiologically, treatment failure in the thrice daily amoxicillin dose was registered in 18.8% (25/133) and among those with twice-daily amoxicillin dose 18.8% (27/144) (risk difference -0.05%; 95%CI: -9.3%- 9.2%). Oral amoxicillin (50mg/kg/day) given 12 hourly daily was as efficacious as giving 8 hourly(13).

Table 1: High-dose amoxicillin for outpatient treatment of pneumonia.[1]

PNEUMONIA CLASSIFICATION	AGE/ WEIGHT	AMOXICILLIN DISPERSIBLE TABLET (S)(250mg)/DURATION.
Pneumonia (non-severe)	2m- 12m (4—<10 kg)	1 tablet twice a day for 5days (10 tablets)
	12m- 3yrs. (10–<14 kg)	2 tablets twice a day for 5days (20 tables)
	3yrs- 5yrs. (14–19 kg)	3 tabs twice a day for 5 days (30 tablets)

[1] Revised 2014 WHO classification and treatment of childhood pneumonia at the health facility. WHO evidence summaries of childhood pneumonia.

2.23 Evidence on reduced cost of pneumonia treatment with high-dose amoxicillin.

In 2005–2006, Chola *et al* did a study in Zambia that estimated the average inpatient and outpatient costs of managing a child with pneumonia. Cost per bed/day for inpatient management of pneumonia was US$215 compared to outpatient treatment of US$48(14).

Hussain *et al* in 2008 did cost-analysis of pneumonia among children in northern Pakistan. Every child admitted with pneumonia costs the health system US$ 71, and outpatient costs averaged US$13. when household costs were added together with the provider costs for outpatient treatment of pneumonia, the total cost in average per episode was US$ 142.90 for chest indrawing pneumonia and US$ 22.62 for fast breathing pneumonia(15).

In 2010, Lorgelly *et al* in England estimated and compared the cost of managing children presenting with symptoms and signs of non-severe pneumonia when using oral amoxicillin and injectable penicillin. The study randomized 232 children with non-severe pneumonia to a controlled non-blinded equivalence study and a cost-minimization analysis. Oral amoxicillin and injectable penicillin had similar efficacy. However, there was extended hospital stay for children treated with injectable penicillin (3.12 vs. 1.93 days $p<0.01$), and treatment with injectable penicillin was more expensive than oral amoxicillin treatment. Treatment with oral amoxicillin would save the England health system 473£ to 518£ per child admitted with non-severe pneumonia. This study revealed that using oral amoxicillin was less costly than using injectable penicillin to treat children with lower chest wall indrawing pneumonia (16).

2.3 Revised 2014 WHO IMCI pneumonia guidelines at the health facility.

Children aged 2-59 months presenting at the health facility with a history of difficulty breathing and or cough without age-specific tachypnea or lower chest wall indrawing and without danger sign(s) were classified as no pneumonia and required home care advice. Children aged 2-59 months with difficulty breathing and or cough with age-specific tachypnea and or lower chest wall indrawing and no danger sign(s) were classified as pneumonia and required home treatment with oral high-dose amoxicillin(1).(Figure1)

2.4 The process of development of Kenya IMCI pneumonia guidelines

In 1995, WHO and UNICEF launched IMCI guidelines for the classification and outpatient management of childhood pneumonia(3). Kenya has faced several challenges in the implementation of the IMCI guidelines since its initial adoption in 1999. These challenges include low training coverage, failure of health care workers to follow guidelines, and barriers for the community to access IMCI services among others(7).

In 2014, WHO revised the IMCI pneumonia guidelines and recommended using oral high-dose amoxicillin in the outpatient management of pneumonia(1). A team of experts in the Kenya MoH recommended a local study to confirm the effectiveness of oral high-dose amoxicillin in the outpatient management of pneumonia. In 2015, Agweyu *etal* did a study among 527 Kenyan children aged 3-59 months with lower chest wall indrawing at 6 Kenyan hospitals. The patients were randomly given oral high-dose amoxicillin or benzylpenicillin and followed up at 48 hours for treatment failure. Treatment failure was 7.7% among children on high-dose amoxicillin and 8.0% among children on benzylpenicillin. The study revealed non-inferiority of oral high-dose amoxicillin to benzylpenicillin (5). In 2018, Kenya MoH updated IMNCI pneumonia guidelines (2).

2.5 Health workers uptake of clinical practice guidelines.

Guidelines for clinical practice are developed under given systematic ways and they help the practitioner and patients choose the best health care for the different diseases (17). Grimshaw *et al* did a systematic review on the influence of clinical guidelines on clinical practice. The study reviewed 59 evaluations of clinical practice guidelines. There was a significant improvement in clinical practice from among 55 of the clinical guidelines(18). Clinical practice guidelines improve the quality of clinical decisions made by health care workers and provide an accepted point of reference for clinical audits(19).

2.6 Challenges of clinical practice guidelines.

Clinical practice guidelines provide inadequate room for clinicians to consider patients individualized circumstances, conditions, preferences and may have been inaccurate in their development, leading to flawed recommendations(19).

2.7 Evidence on health workers adherence to current IMCI pneumonia guidelines.

Kruger *et al* in 2017, conducted in Namibia, Kenya, Tanzania, and Uganda a cross-sectional study on health workers adherence to the IMCI pneumonia guidelines. The study involved 7304 sick child assessments(Namibia:21.6%(1578),Kenya:28%(2049),Tanzania:35.1%(2565), Uganda:21.6%(1578). Physical examination rates for pneumonia (respiration rate/auscultation) were 24% in Kenya. Health workers IMCI adherence rates were lower among children ≥24 months and among health workers who had no recent training in the IMCI guidelines(20).

Izudi *et al* in 2017, conducted in South Sudan a cross-sectional study on health workers adherence to IMCI guidelines in managing children with difficulty breathing or cough. The participants were 232 health workers from 36 health facilities. Among all the respondents 9.9%(23/232)(95%CI:6.4-14.5) of the respondents adhered to all the steps of the IMCI pneumonia guidelines(21).

Uwemedimo *et al* in 2018, conducted a study in Malawi on the use of the IMCI guidelines to diagnose pneumonia. The study involved 3136 children aged 2-59 months. On average, health workers completed 30% of IMCI guidelines on assessment and management of these children, and only 118/573 (21%) of children were correctly diagnosed with pneumonia(22).

Kemunto *et al* in 2019, did a study in Kenya at the KNH on health workers uptake of new pneumonia guidelines among children admitted with childhood pneumonia. It was a cross-sectional retrospective study involving 390 children admitted with pneumonia. Only 17%(43/246) of the children classified as severe pneumonia received the correct treatment as per the revised 2014 WHO pneumonia guidelines. None of the 21.2% (83/390) children who were diagnosed with pneumonia (non-severe pneumonia) received the 2018 Kenya MoH IMNCI pneumonia guideline-recommended oral high-dose amoxicillin(8).

2.8 Knowledge decay after training health care workers

Ching-Wei Yang *etal* in 2012 conducted a systematic review of knowledge and skills retention of advanced life support among health care providers after completion of advanced life support course. 11 articles were included and showed that advance life support knowledge and skills decay by six months to one year after advanced life support training course(23).

Phillip ayieko *etal* in 2019 conducted a randomized controlled trial among 12 hospitals in Kenya. The trial had two arms; one arm with 6 hospitals that were assigned enhanced feedback and the other arm with 6 hospitals that were assigned standard feedback. At the beginning of the trial, health workers in all the hospitals were trained on the new pneumonia guidelines. The randomized controlled trial included two thousand two hundred and ninety-nine childhood pneumonia admissions, 47.2% (1087/2299) were grouped to receive enhanced feedback, 52.7% (1212/2299) were grouped to receive standard feedback. During the 9month period in the first 24 hours 38.2% (393/1030) children were correctly classified and treated in the the enhanced feedback group and 38.4% (410 /1068) children were correctly classified and treated in the standard feedback group (odds ratio 1.11; 95% confidence interval [CI] 0.37–3.34; P = 0.855). During the 9-month trial time was noted to have an effect on adoption of the new policy (24).

Shabina Arif *etal* in 2021 conducted in two provinces of Pakistan a quasi-experimental study to assess the effect of a bridged 7-day IMNCI course compared to a 11-day standard course. The study involved 104 healthcare workers. Health workers knowledge and clinical skills were assessed pre-intervention, immediately post-intervention and 6months after intervention. After the intervention there were an immediate improvement in mean knowledge scores of the 7-day and 11-day training groups of 31.6 (95% CI 24.3, 38.8) and 29.4 (95% CI 23.9, 34.9) respectively, however non-significant p=0.630. After the intervention, there were an immediate improvement of clinical skills scores of the 11-day and 7-day groups 23.0 (95% CI 18.9, 27.0) and 23.8 (95% CI: 19.3, 28.2) respectively, however a non-significant p=0.784. Six months after the intervention there were a decline in mean knowledge scores of − 6.4 (95% CI − 10.5, − 2.3) and− 12.4 (95% CI − 18.5, − 6.4) in the 11-day and 7-day groups respectively, non-significant p=0.094. Six months after the intervention there were a mean decline in clinical skills of − 9.1 (95% CI − 11.5, − 6.6) in the 11-day group − 6.3 (95% CI − 11.3, − 1.3) in the 7-day group, non-significant p=0.308(25).

2.9 Role of Interrupted time series design on knowledge decay after training.

Before and after study designs are used to assess the effect of health interventions at population level. Before and after study divide time into pre-intervention and post-intervention periods. However, the collective combination of time is prone to bias as they don’t account for existing short- and long-term trends before and after the interventions. An Interrupted time series analysis is stronger, and does control

and evaluate for short and long-term trends before and after the intervention (26). A collective combination of time of pre-intervention and post-intervention ignores the effect of time on performance of health workers after the IMCI training. The ability of interrupted time series to observe the trends overtime enables data obtained to be more accurate and actionable.

2.91 Challenges of health workers in implementation of the IMCI guidelines

Renosa *etal* in 2019, conducted a review on the main challenges facing health care workers during implementation of an IMCI program. The review involved 24 studies and among these studies 65% were conducted in African region. The challenges of health care workers included; poor governance, inadequate resources, Lack of training, lack of supervision and mentorship, high staff turnover, demotivation and burn out(7).

Kiplagat *etal* in 2014, conducted a cross-sectional study to evaluate in Mwanza, Tanzania the factors influencing implementation of IMCI guidelines among 95 health care workers. The challenges of health care workers identified included; low initial training coverage, drug stock outs, lack of mentorship, lack of regular supportive supervision, lack of refresher courses(27).

Idindili *etal* in 2018, conducted a cross-sectional study to evaluate in southern Tanzania, the factors influencing implementation of IMCI. The challenges of health care workers included; understaffing, shortage of essential medicines, shortage of IMCI trained heath care workers(28).

Renosa *etal* in 2021, conducted a qualitative study on "the staff are not motivated anymore", a health workers perspective of IMCI program in the Philippines. The challenges of health care workers in implementation of IMCI program included; inadequate training, poor governance, inadequate resources and professional hierarchies that challenged fidelity of the guidelines(29).

2.92 Effect of IMCI guideline training on performance of health workers.

Mayhew *etal* in 2015, conducted a cross-sectional cohort to compare pre-intervention knowledge and performance with post-intervention knowledge and performance after long and short IMCI training courses in Afghanistan. The study involved 2 similar cohorts with 30 health workers trained for 7-days and 31 health workers trained for 11-days. At eight months post training there was a mean improvement of knowledge scores of 29 among the 7-days course trainees, while among the 11-day course trainees

there was a mean improvement of knowledge scores of 23. At eight months the health workers assessment of sick children was 95% among the 7-days training cohort and 96% among the 11-days training cohort. Health workers performance in classification of sick children was 95% among the short 7-days trainees and 96% among the longer 11-day trainees. Health workers performance in treatment of sick children was 95% among the 7-day training cohort and 97% among the 11-day course training cohort (30).

Tawfiq *etal* in 2018 conducted in Afghanistan a cross-sectional after interventional study to evaluate the effects of training health workers on under five quality of care in health facilities. It were a two arm study comparing healthcare workers who had received IMCI training in the previous 12 months and health care workers who had never received IMCI training. Data was obtained from 733 primary health care facilities with 5818 patients over a period of 3 years (2015-2017). In 2016 there were improvement of 8.7% in physical examination index. There was an increase of 5.7% in history taking index and 17.2% in physical examination index in 2017(31).

Sarma *et al* in 2016, conducted a mixed-method study to improve adherence on the use of oral amoxicillin dispersible tablets in the management of childhood pneumonia. The study was on two sub-districts of Bangladesh. The interventions in one sub-district included; training, job aids, and provision of amoxicillin dispersible tablets. In the control sub-district, training was not conducted, but there was a provision of user-friendly instructions manual and amoxicillin dispersible tablets. Participants included community health care providers, health service providers (in both public and private Hospitals), and caregivers. In the intervention sub-district, 96.4% of children were given amoxicillin at the appropriate dose twice per day, and 65.8% of children in the comparison group were given amoxicillin at an appropriate dose twice per day. The training and provision of job aids with amoxicillin dispersible tablets positively affected health workers adherence to IMCI pneumonia guidelines(32).

2.93 The effect of a user-friendly structured review form on health workers performance.

David Gathara *etal* in 2011 conducted a 2-year descriptive study to evaluate quality of care for sick newborns and severely malnourished children among 8 rural district hospitals in Kenya. The study showed poor documentation with often missing records. The introduction of NAR was associated with improvement of assessment score to 25/28 from 2/28 and also improvement in correct prescription of penicillin (33).

Sekela Mwakyusa *etal* in 2006 conducted a study to evaluate implementation of a structured PAR among district hospitals in Kenya. The PAR was developed from IMCI diagnostic algorithm. The PAR form was introduced with 3-hour physical training. Before introduction of the PAR, data was collected from consecutive records (n=163) and after the introduction of the PAR form data was collected randomly(n=705) to assess the quality of care. The period after introduction of the PAR form was divided into four 2-month blocks. During the first 2-months after introduction of the PAR form, the use of the PAR form among health care workers improved to 50%. During the final 2 months after introduction of the PAR form, the use of the PAR form improved to 83%. The quality of documentation improved overtime with documentation of skin turgor in diarrhoea cases improve from 2% before introduction of the PAR form to 83% in the final 2 months after the introduction of the PAR form. Documentation of immunization status improved from 1% before introduction of the PAR form to 21% in the final 2-months after the introduction of the PAR form(34).

Table 2: Challenges of health care workers in implementation of IMCI guidelines.

Study title/author/year	Type of study/study population	Findings
Key challenges of health care workers in implementing the IMCI program. Renosa *etal* in 2019	Scoping review that involved 24 studies and among these studies 65% were conducted in African region.	The challenges included; poor leadership and governance, lack of resources, lack of training, lack of supervision and mentorship, poor quality of care, high staff turnover, demotivation and burn out.
Factors influencing the implementation of IMCI guidelines among healthcare workers in Mwanza, Tanzania. Kiplagat *etal* in 2014.	-Cross sectional study -95 health care workers	The challenges included; low initial training coverage, lack of essential drugs, lack of mentorship, lack of regular supportive supervision, lack of refresher courses.
Factors influencing implementation of IMCI in Lindi region, southern Tanzania. Idindili *etal* in 2018,	-Cross sectional study	The challenges of health included; lack of adequate number of health care workers, shortage of essential medicines, shortage of IMCI trained heath care workers.
"The staff are not motivated anymore", a health workers perspective of IMCI program in the Philippines. Renosa *etal* in 2021	A qualitative study	The challenges in implementation of IMCI program included; inadequate training, poor leadership and governance, lack of adequate financial resources and professional hierarchies that challenged fidelity of the guidelines.

Table 3: Health workers adherence to IMCI pneumonia guidelines.

Study title / author/year	**Type of study/study population**	**Findings**
Adherence to the IMCI guidelines in Namibia, Kenya, Tanzania, and Uganda. Kruger *et al* 2017	-Cross-sectional study. 7304 sick child assessments. Namibia:21.6% (1578), Kenya:28% (2049), Tanzania:35.1% (2565), Uganda:21.6% (1578)	- <33%of the health workers assessed all the 3 IMCI danger signs. In Kenya:11% of health workers assessed all the 3 IMCI danger signs -<60% of health workers conducted an assessment of all 3 main IMCI symptoms. Kenya: 34% of health workers assessed all the 3 main IMCI symptoms.
Distribution and determinants of pneumonia diagnosis using IMCI guidelines: a nationally representative study in Malawi. Uwemedimo *et al* 2018	-Observational study. - 3136 children aged 2-59months	-Health workers completed an average of 30% of IMCI guidelines in every review. -118/573 (21%) of children were correctly diagnosed with pneumonia.
Adherence to IMCI guidelines in treating South Sudanese children with cough or difficulty in breathing. Izudi *et al* 2017	-Cross-sectional Study. -232 health workers from 36 health facilities.	- 193/232(83.2%) participants asked about the ability to breastfeed or drink. - 28/232(18.7%) participants counted and recorded RR. - 186/232(80.2%) participants gave the correct antibiotic.

Uptake of new guidelines for treating pneumonia in children aged 2-59 months admitted at KNH. Kemunto *etal* 2019	-Cross-sectional retrospective study. -390 children were admitted with pneumonia	-21.2% (83/390) of the patients were classified as non-severe pneumonia, and none got the recommended oral high-dose amoxicillin.

Table 4: Effect of IMCI training on performance of health workers.

Study title/author/year	Type of study/study population	Findings
Long and short IMCI training courses in Afghanistan: comparison of post-course knowledge and performance. Mayhew *etal* 2015	-Cross-sectional study -30 Health workers trained for 7 days and 31 health workers trained for 11 days.	Mean increase of knowledge scores of 29 among the 7-days course trainees and mean increase knowledge scores of 23 among the 11-day course trainees. Health workers performance in treatment of sick children was 95% among the 7-day course trainees and 97% among the 11-day course.
Effects of training health workers in integrated management of childhood illnesses on quality of care for under 5 children in primary health care facilities in Afghanistan. Tawfiq *etal* 2018	-Cross-sectional Post-interventional study	-In 2016 there was increase of 8.7% in physical examination index. There was an increase of 5.7% in history taking index and 17.2% in physical examination index in 2017.
Evaluating the use of job aids and user instructions to improve adherence for the treatment of childhood pneumonia using amoxicillin dispersible tablets in a low-income setting. Sarma *et al* 2016	-Mixed method study. -Interventions-training, job aides,user-friendly instructions. Participants: -community health care providers.	- 96.4% of children in the intervention sub-district were given amoxicillin at an appropriate dose 12hourly. - In the comparison group, 65.8% of children were given amoxicillin at an appropriate dose 12hourly.

Table 5: The use of a user-friendly structured review form on health workers performance.

Study title/author/year	Type of study/study population	Findings
Quality of hospital care for sick newborns and severely malnourished children. David Gathara *etal* in 2011	A 2-year descriptive study in 8 rural Hospitals in Kenya	-showed poor documentation of for neonatal and malnutrition admission with often missing records. -Introducing NAR form led to improvement of assessment score to 25/28 from 2/28 and also improvement in correct prescription of penicillin.
Implementation of a structured Pediatric Admission Record among district hospitals in Kenya. Sekela Mwakyusa *etal* in 2006	Before and after intervention study.	-There were improvement in the use of the PAR form among health care workers from 50% in the first 2-months post - intervention period to 83% final 2-months post-intervention period. -Improvement in documentation of skin turgor in diarrhoea cases from 2% pre-intervention to 83% in the final 2 months. -Documentation of immunization status improved from 1% before use of PAR form to 21% in the final 2-months after use of PAR form.

2.94 Study Justification and utility

Worldwide childhood pneumonia is the leading cause of mortality among children under 5 years of age(4). These mortalities could be prevented by prompt diagnosis and correct pneumonia treatment. Since 2018 when Kenya MoH IMNCI pneumonia guidelines were updated until now, health workers adherence to the 2018 Kenya MoH IMNCI guidelines in outpatient management of pneumonia remains unknown. The Kenya MoH launched high-dose amoxicillin dispersible tablets for treatment of pneumonia in 2017. The amoxycillin dispersible tablets have been available in the health facilities in Nairobi County since 2018.

A previous study done in 2019 on health workers uptake of new pneumonia guidelines in a tertiary hospital in Kenya showed poor adherence though it was focused on inpatients(8). This scientific research is embedded in a large quality of care initiative and sought to focus on addressing this knowledge gap and the study results will help develop policies to improve health workers adherence to the 2018 Kenya national MoH IMNCI pneumonia guidelines.

2.95 Research question

What is the effect of IMCI pneumonia guidelines training on health workers uptake of oral high-dose amoxicillin in the treatment of pneumonia among children aged 2-59months at three health facilities in Nairobi County?

2.96 Research objectives.

2.961 Broad objective.

To determine the effects of IMCI pneumonia guidelines training and the introduction of Sick Child Management Form on health workers correct prescription of oral high-dose amoxicillin dispersible tablets in the outpatient treatment of pneumonia among children aged 2-59 months

at three health facilities in Nairobi County**.**

2.962 Specific objectives.

- To determine the effects of IMCI pneumonia guidelines training on health workers adequacy of assessment of pneumonia (non-severe pneumonia) and illness classification among children aged 2-59 months presenting with difficulty breathing and or cough at three health facilities in Nairobi County.
- To determine effects of introduction of Sick Child Management Form on health workers adequacy of assessment of pneumonia (non-severe pneumonia) and illness classification among children aged 2-59 months presenting with difficulty breathing and or cough at three health facilities in Nairobi County.

3.0 METHODOLOGY.

3.1 Study design

We used interrupted time series intervention study design to determine the effects of the IMCI pneumonia guideline training (1st intervention) and the introduction of the Sick Child Management Form (2nd intervention) on health workers adherence to the 2018 Kenya MoH IMNCI pneumonia guidelines(2). We chose the interrupted time series study design because it's a valuable study design to evaluate the effectiveness of population level interventions that have been undertaken at clearly defined time points (35) .

3.2 Study sites

This study is part of an ongoing project to improve quality of care of management of childhood pneumonia in twenty health centers within Nairobi County. As part of intervention in this project over 90% of health workers were trained in pneumonia case management in September 2020 (Intervention 1). Data for evaluation of this project were initially on 204A register. As part of health system strengthening, the project developed a structured patient record form, named as Sick Child Management Form (Appendix 9.3). This was piloted and introduced in three of the facilities implementing the pneumonia project. A tool for data collection in the three facilities using the SCMF was developed in RedCap. The introduction of the SCMF is referred to in this dissertation as Intervention 2. Three sites were chosen for testing the implementation of the SCMF. These sites included Westlands Health Centre, Eastleigh Health Centre, and Huruma Lions Health Centre in Nairobi County. These sites were chosen because they were the top most busy health centers in the facilities implementing the pneumonia project, additionally they do not have electronic medical records.

Westlands Health Centre is a Nairobi County health facility in Westlands Sub-County, along Waiyaki way near Safaricom customer care offices. It delivers health care services to people mostly from Westlands Constituency. It opens Monday-Friday 8am-5pm and Saturday 8am-12pm. **Eastleigh Health Centre** is a Nairobi County health facility located in Eastleigh section 7 in Kamukunji Constituency. It provides only outpatient services and opens Monday-Friday 8am-5pm and Saturday 8am-12pm. **Huruma Lions Health Centre** is a Nairobi County health facility located in Starehe Constituency, Huruma location, Kia Maiko Sub-location. It provides only outpatient services and opens Monday-Friday 8am-6pm.

In the three facilities, on average about 5-10 children under 5 years of age with cough or difficulty breathing are reviewed daily. Patients are first triaged upon arrival at the facility and a registration clerk captures the biodata of the patient. The child is weighed, and MUAC measured. A clinical officer documents in a structured form the history and examination findings of the patient, including the history of difficulty breathing and or cough, duration of cough or difficulty in breathing, HIV status, lower chest wall indrawing, oxygen saturations, cyanosis, inability to drink/ breastfeed and level of consciousness. The clinician classifies the condition and issues an antibiotic prescription. The antibiotic prescription is received in the pharmacy, and medication is dispensed to the patient-caregiver (Fig 2).

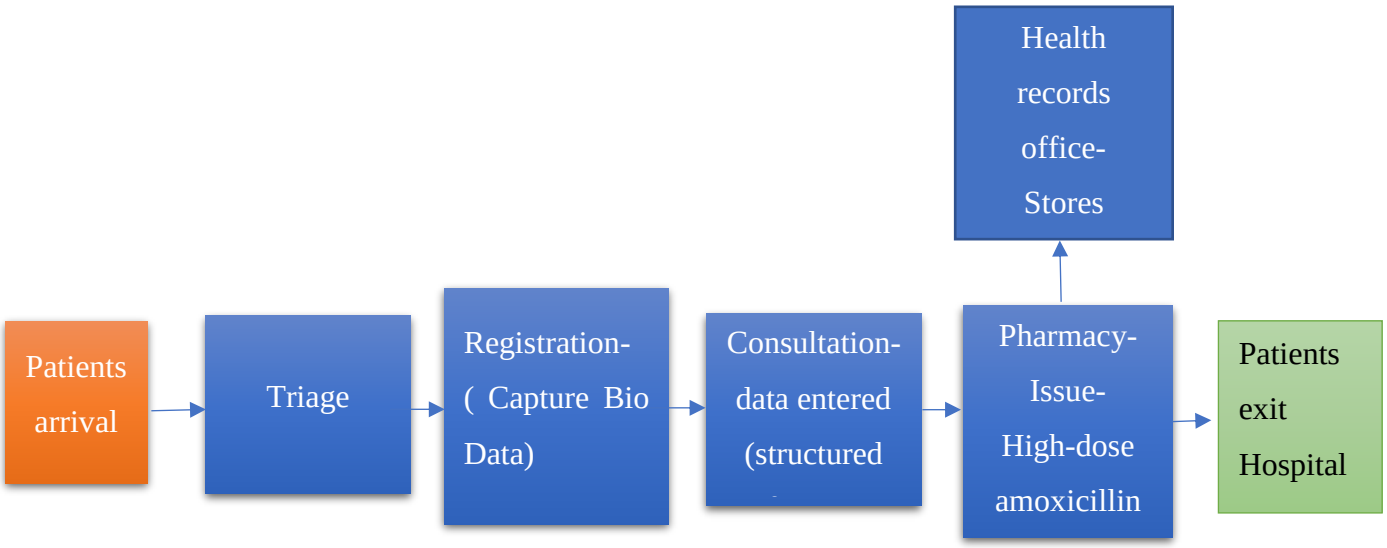

Figure 2: Flow of patients at Eastleigh Health Centre, Westlands Health Centre and Huruma Lions Health Centre.

3.3 Study population

Children aged 2-59 months with difficulty breathing and or cough <14 days, and who attend Eastleigh Health Centre, Westlands Health Centre and Huruma Lions Health Centre during the study period.

3.4 Participant selection

3.41 Inclusion criteria

A child aged 2-59 months with a history of difficulty breathing and or cough ≤ 14 days.

3.42 Exclusion criteria

a. Children documented HIV positive/exposed(1).
b. Children documented to have severe acute malnutrition(1).
c. Children documented to have heart disease.
d. Children documented to have kidney disease.
e. Children documented to have been discharged from inpatient care in the previous 1 month.
f. Children documented to have fever > 14 days.
g. Contact with known PTB patient .
h. Children documented to have a wheeze.

3.5 Key study variable.

3.51 Evaluation of oral amoxicillin uptake.

The effect of the IMCI pneumonia guideline training and the introduction of SCMF on health workers uptake of high-dose oralamoxicillin will be evaluated by the following performance indicators [22]. Oral amoxycillin prescription was considered correct if it was consistent with the MoH IMNCI in dosage per weight category, frequency and duration.

a. Correctly documented dosage of amoxicillin dispersible tablet(s).

   (4kg – <10kg: 250mg, 10kg –<14kg: 500mg, 14kg – <19kg: 750mg).

b. Correctly documented timing (12hourly or BD) of amoxicillin dispersible tablet(s).

c. Correctly documented duration (5 days) of amoxicillin dispersible tablet(s).

3.6 Sample size determination

We determined the sample size through the simulation-based methods (80% power,1000 simulation data sets). The R studio statistical software simulation method was used with a regression model of the following equation (36):

$$Y_i = \beta_0 + \beta_1 * time_i + \beta_2 * intervention_i + \beta_3 * time\ after\ intervention_i + e_i$$

Where:

Y_i – refers to the average event rate.

$time_i$ −the time points from the pre- to post-intervention periods (16-time points).

$time\ after\ intervention$ −refers to the number of time points after the training is implemented (8-time points).

The pre-probability of 0.6 and post-probability of 0.9 used in the simulation method to get the sample size was obtained from the study done by Sarma *etal* in Bangladesh. In the intervention sub-district, 96.4% of children were given amoxicillin at the appropriate dose, twice per day, and 65.8% of children in the non-intervention group were given amoxicillin at an appropriate dose, twice per day, effect size of 30.6%(32).

After the simulations, we obtained a minimum sample size of 35 eligible records every two weeks in the first pre-intervention period with a total of eight data collection points and a minimum of 35 eligible records every two weeks in the first post-intervention period with a total of eight data collection points. A minimum sample size of 35 eligible records every two weeks in the second pre-intervention period with a total of eight data collection points. A minimum sample size of 35 eligible records every two weeks in the second post-intervention period with a total of eight data collection points as demonstrated in figure 3.

Interrupted Time Series study design requires a minimum of eight time points in the pre-intervention and a minimum of eight time points in the post-intervention period to adequately estimate immediate and gradual change after intervention (35). The two weekly unit time intervals that were used in the data collection depended on the transition period of two weeks between intervention and the hypothesized effect.

3.7 Sampling method

We **retrospectively retrieved patient and clinical data** from MoH 204 A register for the pre-intervention 1 and post-intervention 1. **We also retrospectively retrieved patient and clinical data** for post-intervention 2 from the Redcap Server. The records were obtained every two weeks for all patients aged 2-59 months who were reviewed with difficulty breathing and or cough. From these records, we identified the eligible records and obtained a **minimum** of 35 clinical records every two weeks during the study period.

3.8 Study procedure

3.81 Interventions for the pneumonia project

1. Training health care workers

In September 2020, nurses, clinical officers, and pharmaceutical technologists working at Westlands Health Centre, Eastleigh Health Centre and Huruma Lions Health Centre among other facilities within Nairobi County were trained on Kenya's 2018 MoH national IMNCI pneumonia guidelines. The training was virtual and conducted for 3 hours by the Nairobi County pneumonia trainers. The Kenya MoH and other key stakeholders validated the training materials and training methods in August 2020. The Nairobi County pneumonia trainers have done childhood pneumonia instructors course and are IMCI facilitators. Job aides inform of A3 posters near the clinicians, nurses, and pharmacy desk were also provided (appendix 5.4). The health care workers and health record officers were trained on data entry in the 204 A register.

2. Introduction of Sick Child Management form.

In September 2022 the Sick Child Management Form, a structured outpatient record form for children aged 2-59 months was introduced at the 3 health facilities (Appendix 9.3). The SCMF was derived from the IMCI booklet and made into a structured form that is user friendly. On 31st August 2020 the Sick Child Management form was validated by stake holders including; Kenya MoH, Academia, Kemri/Welcome Trust, County Governments and Non-Governmental Organizations.

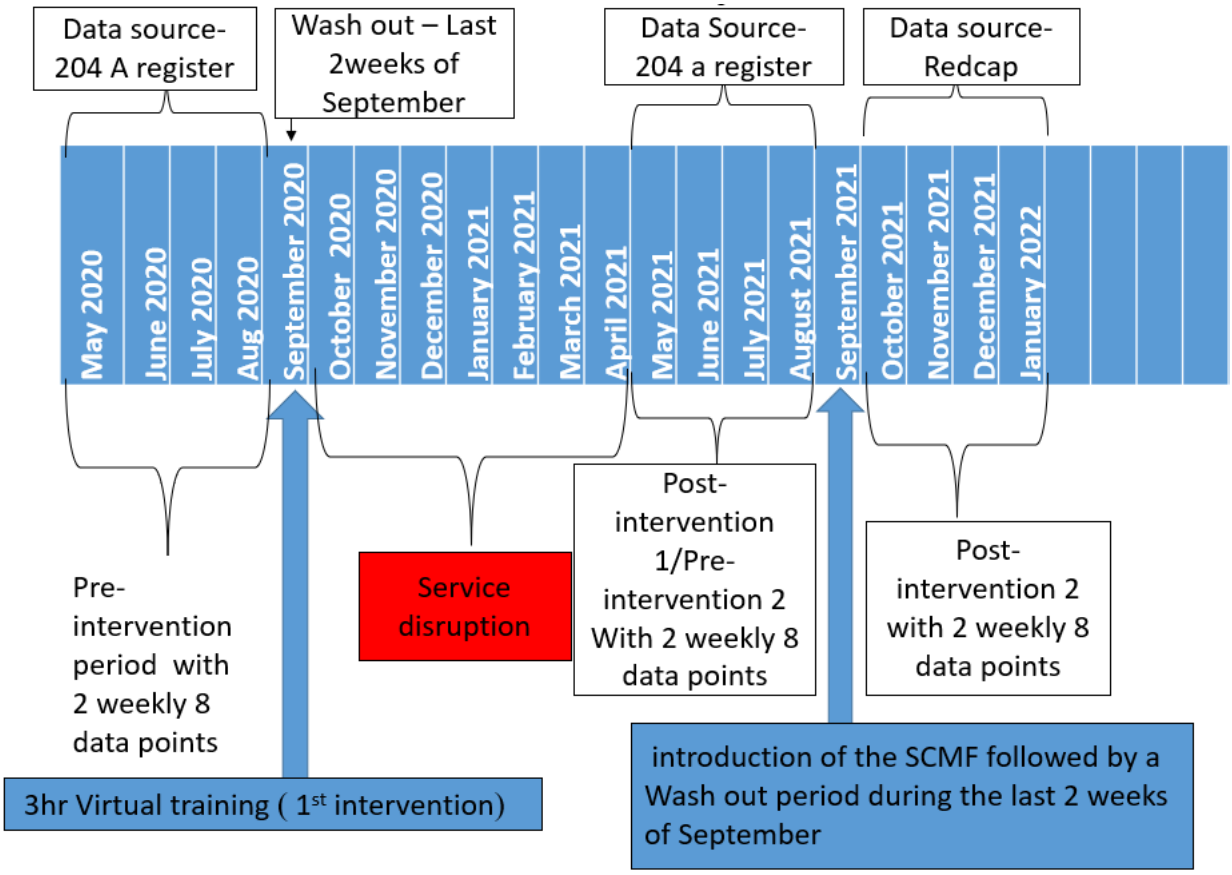

Figure 3: Study time period, two interventions and data source.

3.82 Data tools.

Data were collected from the MoH 204 A register through the use of a structured questionnaire (appendices 5.4). The Sick Child Management Form was translated to an electronic data collection tool in Redcap. In October 2021 health records and information officers from Eastleigh Health Centre, Westlands Health Centre and Huruma Lions Health Centre among other facilities within Nairobi County had a whole day training on the use of the Redcap data collection tool at hotel within Nairobi County. The principal investigator also attended and helped in piloting the Redcap data collection tool, in training the HRIOs for data collection as well revising the data collection tool to make it user friendly.

During the study period the data collection tool was similar across pre-intervention1, post-intervention 1, post-intervention 2. Thus, data for the pre-intervention1, post-intervention 1 were extracted from the 204A register while that for post-intervention 2 were extracted from the Redcap.

3.83 Data collection

The principal investigator with the help of health records and information officers collected data from the MoH 204 A register for under five for the period before and after the IMCI pneumonia guideline training. Data for the period before the introduction of the SCMF was obtained from the MoH 204 A register for under five. Data for the period after the introduction of the SCMF was collected from Redcap server using a redcap data collection tool. Data collection tool was similar for the whole study period.

3.91 Ethical considerations

3.911 Authorization to conduct the study

Authorization to conduct the study was obtained from the Kenyatta National Hospital–University of Nairobi Ethics and Research Committee (KNH–UON ERC) (Appendix 9.6, Reference number: KNH/ERC/mode &SAE/403). We also sought verbal consent from individual facilities.

3.912 Request for waiver of informed consent.

Consent was not obtained from individual participants since the study is an interrupted time series design of anonymized patients records and as per practice of such studies individual informed consent is not required. Request for waiver of informed consent was filled and approved by the Kenyatta National Hospital–University of Nairobi Ethics and Research Committee (KNH–UON ERC). Although case records from which data were abstracted had names, data collected were de-identified and unique study patient identifiers created.

4.0 DATA MANAGEMENT AND ANALYSIS

For the purpose of data management, after validating questionnaires we entered the data in excel then imported into R studio program for analysis. Data was stored in a password secured computer and used only for intended purpose.

4.1 Data analysis.

We used interrupted time series model to determine the effect of IMCI pneumonia guideline training and the introduction of Sick Child Management Form on the proportion of health workers correct assessment, correct classification, and correct treatment of pneumonia. The proportions were modeled using segmental beta regression during the study period.

To examine the effect of the two interventions, we fitted a segmented regression model with the parameters specified below:

$$Y = \beta_0 + \beta_1 time + \beta_2 intervention_1 + \beta_3 time\ after\ intervention_1 + \beta_4 intervention_2 + \beta_5 time\ after\ intervention_2 + \varepsilon_t$$

Where:

Y = average correctness in assessment, classification and treatment of non-severe pneumonia

$\beta_0 = average\ correct\ assessment, classification, treatment, without\ influencing\ factor$

$\beta_1 = the\ effect\ of\ time\ on\ prescription\ treatment$

$\beta_2 = the\ effect\ of\ intervention\ one\ on\ correct(assessment, classification\ and\ treatment)$

$\beta_3 = effect\ of\ time\ after\ intervention_1 on\ correct\ assessment, classification, treatment$

$\beta_4 = effect\ of\ intervention_2\ on\ correct\ assessment, classification\ and\ treatment$

$\beta_5 = effect\ of\ time\ after\ intervention_2\ on\ correct\ assessment, classification, treatment$

$\epsilon_t = the\ error\ term$

4.2 Outcomes of interest

Table 6: performance indicators

Task (conducted by health worker)	Expected action (performed by health worker)
Correct assessment; History Clinical examination	**All the following must be documented**. • History of difficulty breathing and or cough • Respiratory rate • Lower chest wall indrawing • Alert • Able to breastfeed or drink • No cyanosis/ oxygen saturations ≥90%
Correct disease classification Pneumonia (non-severe pneumonia)	All the dangers signs must be documented as absent. • Not Alert • Unable to breastfeed or drink • Either cyanosis/ oxygen saturations <90% Either age specific fast breathing or lower chest will must be documented as present.

Correct treatment:	**All the following must be documented**
a) The correct choice of antibiotic	a) High-dose oral amoxicillin dispersible tablet(s)
b) Correct dosage of high dose amoxicillindispersible tablet(s)	b) 4kg–<10kg: 250mg, 10kg–<14kg: 500mg, 14kg -<19kg: 750mg.
c) Correct frequency of the amoxicillin dispersible tablet(s)	c) 12hourly or BD
d) Correct duration of the amoxicillin dispersible tablet(s)	d) Duration of 5 days

5.0 STUDY RESULTS

5.1 Records screening and enrolment.

Clinical records identified during the study period for children who presented with cough and or difficulty in breathing at the three facilities were 3,115. We identified 1,123 clinical records from West Lands Health Centre, 674 clinical records from Eastleigh Health Centre and 1,318 clinical records from Huruma Lions Health Centre during the study. Among these clinical records, those excluded from the study included; 6 (0.001%) had documented severe malnutrition, 8 (0.002%) had documented HIV positive/exposed, 12 (0.003%) had a documented wheeze. Clinical records included in the whole study period were 3,089. Pre-intervention period 1 had 432 clinical records, post-intervention 1 had 800 clinical records, post-intervention 2 had 1,857 clinical records. All the included records in the study were analysed.

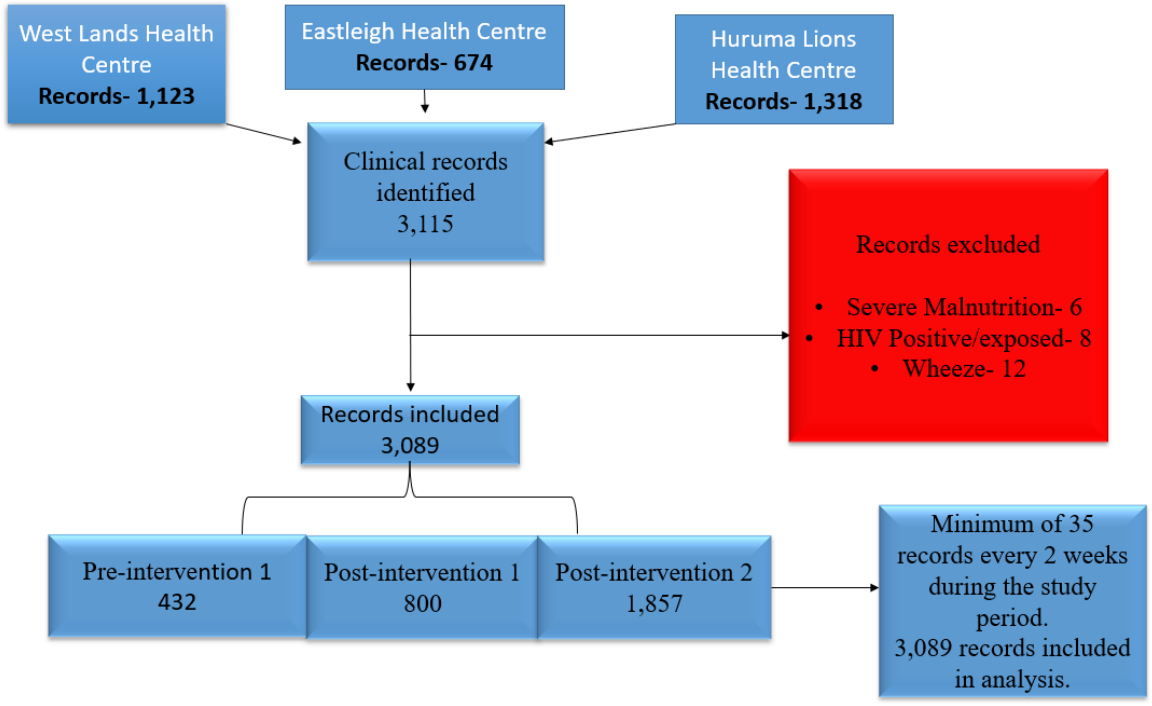

Figure 4: Flow diagram of clinical records identified, clinical records excluded and clinical records included for analysis in the study.

5.2 Study population characteristics

Patients characteristics. During pre-intervention 1 period; median age was 12.0 months and majority of children included in the study were males 55.3% (n=239). Majority of patients had a weight of 5-10 kgs 10.9% (n=47) and 81.9% (n=354) had a missing documented weight.

In the post-intervention 1 period; median age was 14.0 months and majority of the patients were males 52.0% (n = 416). Majority of patients had a weight of 5-10 kgs 11.6%(n=93) and 74% (n=591) had a missing documented weight.

In the post-intervention 2 period; median age was 17.0 months, majority of patients were males 48%(n=892), 4.3%(n=79) had no documented gender. Majority of patients had a weight 5-10kgs 51.4% (n=954). All the patients had a documented weight.

The majority of the children in all the study periods were age less than 12 months 46.5% (n = 201), 39.0% (n = 312) and 35.8% (n = 664) for the pre-intervention, post-intervention 1 and post-intervention 2 respectively (Table 7).

Table 7: Patients Characteristics and the comparison between pre-intervention 1, post-intervention 1 and post-intervention 2

Variable		Pre-intervention N = 432		Post-intervention1 N = 800		Post-intervention2 N = 1857	
		Freq (n)	Percent (%)	Freq (n)	Percent (%)	Freq (n)	Percent (%)
Age in months		(Median = 12.0, IQR = 18 months)		(Median = 14.0, IQR = 18.8months)		(Median = 17.00, IQR = 23.0 months)	
Weight in Kgs:		(Median =8.9, IQR = 5.1)		(Median =11.0, IQR= 4.4)		(Median =10.0, IQR =5.0)	
weight categories	<5 kgs	1	0.2	1	0.13	32	1.7
	5-10kgs	47	10.9	93	11.6	954	51.4
	>10-15 kg	25	5.8	80	10	641	34.5
	>15-20 k	5	1.2	30	3.8	203	10.9
	>20 kgs	0	0	5	0.6	27	1.5
	Not indicated	354	81.9	591	74.0		
Gender:	Male	239	55.3	416	52.0	892	48.0
	Female	192	44.4	383	47.9	886	47.7
	Not indicated	1	0.3	1	0.1	79	4.3
Age Categories	2- <12 months	201	46.5	312	39.0	664	35.8
	12-23 months	127	29.4	270	33.8	586	31.6
	24-35 months	30	6.9	64	8.0	214	11.5
	36-47 months	42	9.7	95	11.9	230	12.4
	48-59 months	32	7.4	59	7.3	163	8.8

5.3 Effect of IMCI pneumonia guideline training and introduction of SCMF on health workers correct prescription of high-dose amoxicillin dispersible tablet(s) for non-severe pneumonia.

The immediate and sustained effect of IMCI pneumonia guideline training and the introduction of the SCMF on correct prescription of high-dose amoxicillin dispersible tablet(s) among health care workers was evaluated during the study period.

Table 8: Effect of the two interventions on correct prescription of high-dose amoxicillin dispersible tablet(s) for non-severe pneumonia.

Factor	Estimate	Standard error	Z value	p-value
Intercept	-17.5	346.2	-0.005	0.9
Time	0.00	464.1	0.000	1.0
Intervention1	0.00	984.3	0.000	1.0
Time after intervention 1	0.00	486.3	0.000	1.0
Intervention2	17.35	489.3	0.035	0.9
Time after intervention 2	-0.119	148.7	-0.001	0.9

Training showed no sustained effect on correct prescription of high-dose amoxicillin dispersible tablets for non-severe pneumonia as demonstrated in figure 5. The immediate effect of the training was not assessed due to service disruptions from county and national health workers strikes as demonstrated in figure 3.

After introduction of Sick Child Management Form, there was an immediate improvement in the correct prescription of high-dose amoxicillin dispersible tablet(s) by a factor of **17.35**, with a P-value of 0.9 while over time (sustained effect) the correct treatment of non-severe pneumonia decreased by a factor of -0.1 with a P-value of 0.9.

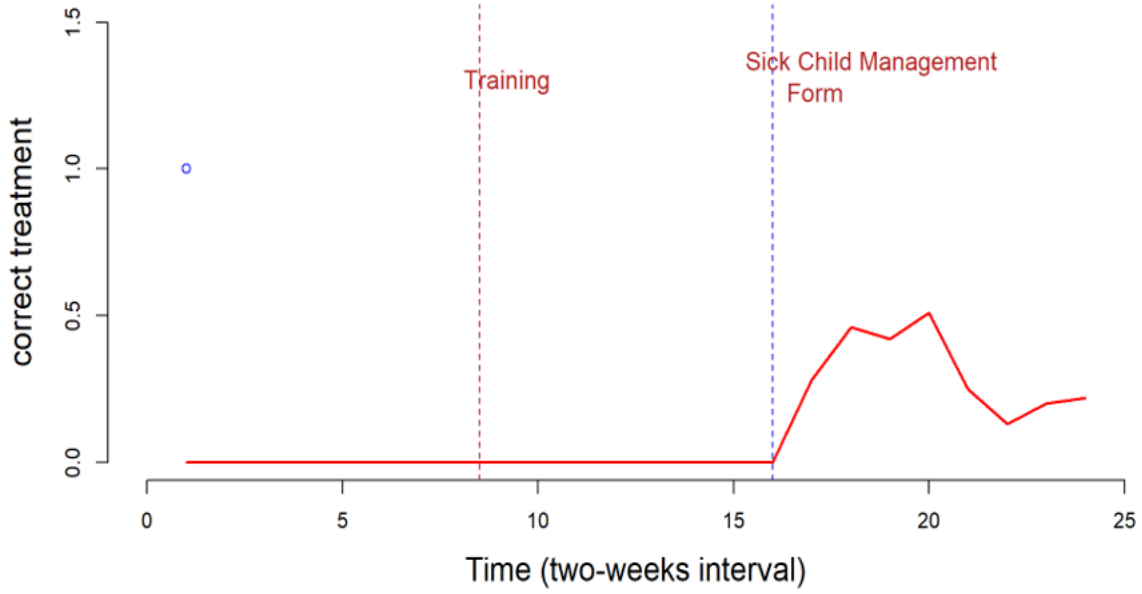

Figure 5: Graph showing effect of IMCI pneumonia guidelines training and introduction of SCMF on health workers correct prescription of high-dose amoxycillin dispersible tablet(s) for treatment of non-severe pneumonia.

Training did not have an improvement on health workers uptake of high dose amoxycillin dispersible tablet(s) for management of non-severe pneumonia. After the introduction of the Sick Child Management Form, there was an immediate rise in correct prescription of high-dose amoxycillin dispersible tablet(s) for treatment of non-severe pneumonia by a factor of 17.35, however overtime there was a decline on the sustained effect of SCMF on correct treatment of non-severe pneumonia (figure 5).

5.4 Effect of IMCI pneumonia guideline training and the introduction of SCMF on health workers correct assessment of non-severe pneumonia.

Table 9: Effect of the two interventions on correct assessment of non-severe pneumonia

Factor	Estimate	Standard error	Z value	p-value
Intercept	-19.57	1176	-0.017	0.9
Time	0.00	217.9	0.000	1.0
Intervention1	0.00	115.7	0.000	1.0
Time after intervention 1	0.00	292	0.026	1.0
Intervention2	**19.45**	735	0.026	0.9
Time after intervention 2	**-0.01**	174.4	-0.001	1.0

Training showed no sustained effect on correct assessment of non- severe pneumonia by a factor of 0, and a p value of 1. The immediate effect of training could not be assessed due to service disruptions by county and national health workers strikes.

The introduction of Sick Child Management Form increased correct assessment by a factor of 19.45 (immediate effect) with a P-value of 0.97. Overtime there was a noted decline of correct assessment of non-severe pneumonia by a factor of -0.01 with a P-value of 1.

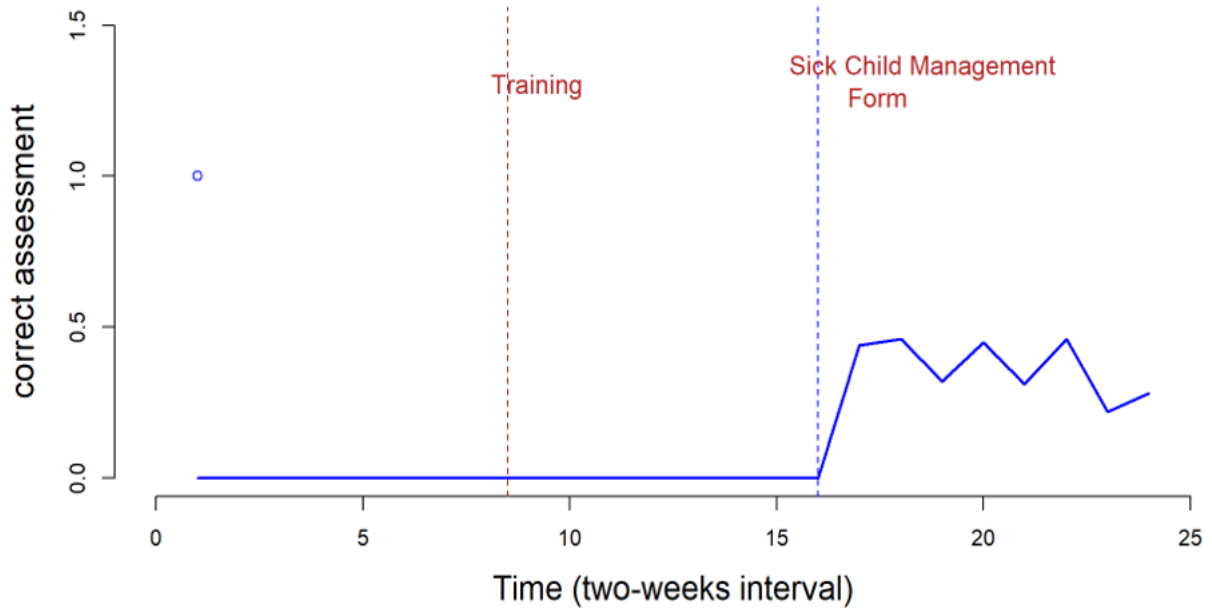

Figure 6: Graph showing effect of IMCI pneumonia guideline and introduction of SCMF on health workers correct assessment of non-severe pneumonia

After the training there was no sustained effect of health care workers uptake of correct assessment of non-severe pneumonia. The immediate effect of training on the uptake of health workers correct assessment of non-severe pneumonia was not assessed due to disruption of service delivery by county and national health workers strikes.

After the introduction of the Sick Child Management Form, there was a noted immediate improvement on correct assessment of non-severe pneumonia, however overtime there was an observed decline on the sustained effect of SCMF on correct assessment of non-severe pneumonia (figure 6).

5.5 Effect of IMCI pneumonia guideline training and the introduction of SCMF on health workers correct classification of non-severe pneumonia.

Table 10: Effect of the two interventions on correct classification of non-severe pneumonia

Factor	Estimate	Standard error	Z value	p-value
Intercept	-19.57	1176	-0.017	0.9
Time	0.00	217.9	0.000	1.0
Intervention1	0.00	1157	0.000	1.0
Time after intervention 1	0.00	292	0.000	1.0
Intervention2	19.05	735	0.026	0.9
Time after intervention 2	-0.060	174.4	0.000	1.0

Training showed no sustained effect on correct classification of non- severe pneumonia with a factor 0 and a P-value 1 as demonstrated in figure 7. The immediate effect of training could not be assessed due to service disruptions by county and national health workers strikes as demonstrated in figure 3. Introduction of the SCMF increased correct classification of non-severe pneumonia by a factor of 19.05 (immediate effect) with a P-value of 0.9 while with time (sustained effect) the correct classification decreased by a factor of -0.06 with a P-value of 1.

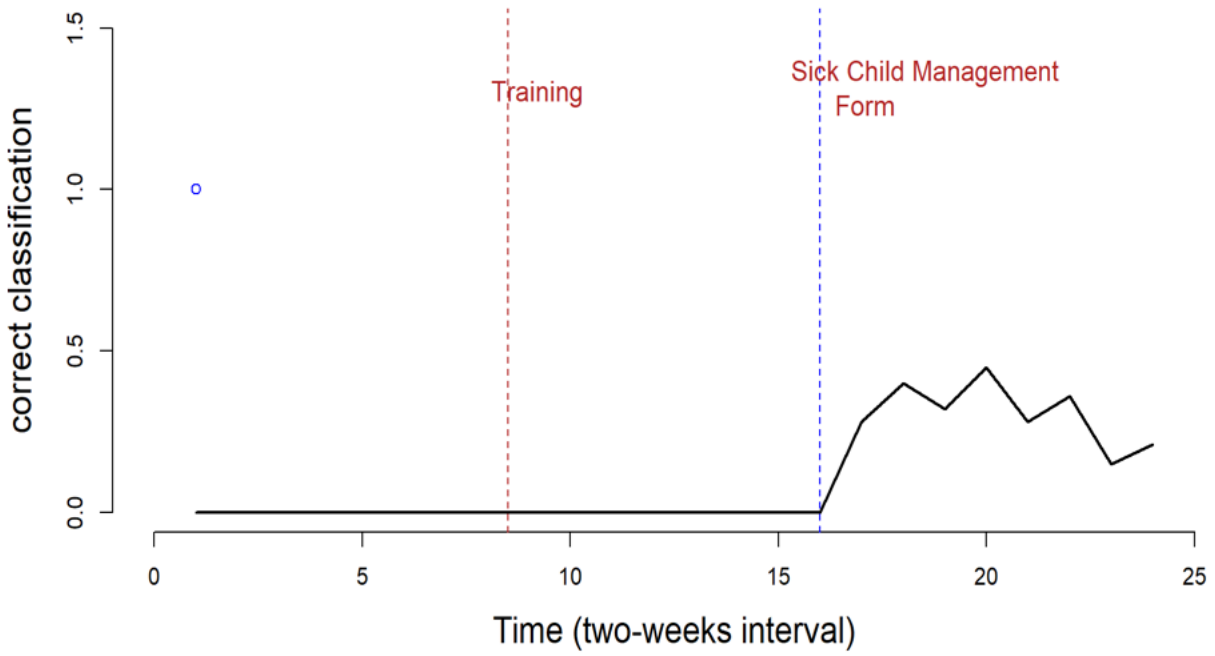

Figure 7: Graph showing effect of IMCI pneumonia guidelines training and SCMF on health workers correct classification of non-severe pneumonia

Training did not have a sustained effect on health workers uptake of correct classification of non-severe pneumonia. The immediate effect of training on the uptake of health workers correct classification of non-severe pneumonia was not assessed due to disruption of service delivery by county and national health workers strikes.

After the introduction of the sick child management form, there was an immediate rise in the correct classification of non-severe pneumonia, however overtime there was a decline on the sustained effect of SCMF on correct classification of non-severe pneumonia as demonstrated in figure 7.

6.0 DISCUSSION

We sought to determine the effect of IMCI pneumonia guideline training (First intervention) and introduction of Sick Child Management Form (Second intervention) on health workers uptake of correct assessment, correct classification and correct treatment of children aged 2-59 months with non-severe pneumonia at 3 health facilities in Nairobi County.

Effect of training and introduction of SCMF on health workers correct treatment of pneumonia was evaluated during the study period. During the pre-intervention 1 period, none of the children with cough and or difficulty in breathing had a documented correct treatment for non-severe pneumonia. This is consistent with earlier findings of a study in 2019 by Kemunto *etal* in KNH which showed out of 83 patients classified as non-severe pneumonia none of them got the guideline recommended treatment of high-dose amoxicillin. However, this study focused on inpatient setting in a tertiary facility (8). Documented health workers correct treatment included 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 frequency and correct duration of 5 days. During the pre-intervention period 84% of the children included in the study didn't have a recorded weight which was necessary to enable a clinician determine the correct high dose amoxycillin dispersible tablet. This poor documentation is consistent with earlier studies done in the district hospitals in Kenya(33) and Kenyatta National Hospital(37) that showed poor documentation practices among health care workers.

After the training the same poor trend continued and none of the children with cough and or difficulty in breathing had a correct treatment of non-severe pneumonia. This poor correct treatment was largely contributed by lack of weight documentation of 74% among children included in the study in the post-intervention 1 period. There was a gap of seven months between the training and the post-intervention 1 period due to health workers service disruption from national and county health workers strikes. Seven months after the training there was no change in trends of health workers correct treatment of non-severe pneumonia by a factor of 0 and a non-significant P-value of 1. This is different from the study by Shabina Arif *etal* done in Pakistan that showed health workers mean knowledge score reduction six months after the training by a factor of –12.4 for 7-day course training group and by a factor of -6.4 for 11-day course training with a statistically non-significant P-value of 0.09. It also showed health workers mean clinical skills reduction six months after training by a factor of -6.3 in 7-day training group and -9.1 in 11-day training group with a statistically non-significant P-value of 0.3. However, in this Pakistan study the IMCI trainings were physical and for longer duration compared to our study that had a virtual 3-hour training.

The introduction of SCMF had an immediate improvement in the correct treatment of non-severe pneumonia by a factor of 17.3 times with a P-value of 0.9 that was statistically not significant. This is similar to the effect of Pediatric Admission Form that improved documentation of immunization status of a child from 1% to 21% though it was used for children requiring admission(34). This is also consistent with the introduction of Newborn Admission Form that led to considerable improvements in correct prescription of penicillin(33). During the post-intervention 2 period, 100% of children included in the study had a documented weight and we speculate probably this improved documentation of weight and the use of a structured SCMF enabled health workers to improve on the correct treatment of high-dose amoxicillin dispersible tablet(s) among those the clinician had classified as non-severe pneumonia. This improvement in documentation is consistent to the study of Sekela Mwakyusa *etal* on the use of Pediatric Admission Form leading to improved documentation among health care workers(34) and the study by David Gathara *etal* on use of Newborn Admission Form leading to improvement of documentation among health workers in Kenyan hospitals(33).

Overtime the sustained effect of SCMF on health workers correct treatment of non-severe pneumonia with high-dose amoxycillin dispersible tablets started declining by a factor of -0.1 with a statistically non-significant P-value of 0.9. This declining health workers performance overtime is consistent with study by Phillip ayieko *etal,* in 2019 conducted among 12 hospitals in Kenya that showed a decline overtime of health workers performance in hospitals receiving standard feedback(24). This is consistent with the possibility that health care workers were slowly reverting to prior behavior(23). The decline in health workers performance overtime could also be due to staff rotations that occur commonly in Kenyan health facilities. Some of the front-line health care workers who review patients in the health facilities are intern clinicians in their first year of training and rotate every 3 months. Clinicians in the health facilities also get transfers to other facilities within Nairobi County. The decline in performance may therefore have resulted from clinician rotations and transfers thus having clinicians that had no specific IMCI pneumonia guideline training and not familiar with the use of the SCMF. We were unable to collect data on the initial health workers trained in September 2020 and those that were introduced to SCMF in September 2021 and those that could have dropped or joined during the study.

Effects of IMCI pneumonia guideline training and introduction of the SCMF on health workers correct assessment for non-severe pneumonia were evaluated during the study. Correct assessment included health workers documentation of all the symptoms (history of difficulty breathing and or cough) and signs (age-specific tachypnea and or lower chest wall indrawing, no central cyanosis /oxygen saturation ≥90%, able to drink/breastfeed, and alert) that enable classification of pneumonia (non-severe pneumonia). Correct assessment was the composite indicator that was made up of all documented individual indicators. None of the clinical records obtained during the pre-intervention 1 had all individual indicators documented to enable correct assessment of non-severe pneumonia. During the pre-intervention 1 period, no child with cough and or difficulty in breathing had a correctly documented assessment for non-severe pneumonia. We speculate the lack of correct assessment of pneumonia was largely contributed by poor documentation on the 204 A register. This poor documentation is consistent with study done by David Gathara *etal* that showed poor documentation of health care workers among district hospitals in Kenya(33). After the training there was no change of trend on poor documented correct assessment of non-severe pneumonia with a factor of 0 and a non-significant P-value of 1. However, there was a gap of 7 months between the training and the beginning of post-intervention 1 period due to health workers service disruption from national and county health workers strikes. Due to service disruption, it was not attainable to assess the immediate effect of the training on correct assessment for non-severe pneumonia.

Introduction of the Sick Child Management Form (2^{nd} intervention) had immediate improvement in the correct assessment for non-severe pneumonia. The immediate effect of the introduction of SCMF led to improvement of correct assessment of non-severe pneumonia by a factor of 19.4 times compared to pre-intervention period and a P-value of 0.9 that was statistically not significant. This is similar to the effect of introducing Newborn Admission Form that showed an improvement in median assessment score to 25/28 from 2/28 (33). However, overtime the sustained effect of introduction of Sick Child Management Form on correct assessment of non-severe pneumonia started declining by a factor of -0.001 with a P value of 1 that was statistically not significant. This could probably have been due to knowledge decay as is consistent with Ching-Wei Yang *etal* systematic review in 2012 that showed clinical skills and knowledge decay after six months to 1 year(23).

The effects of IMCI pneumonia guideline training and the introduction of the SCMF on health

workers correct classification for pneumonia (non-severe pneumonia) were analyzed during the study. Correct classification of non-severe pneumonia was the composite indicator that included documentation of either age specific fast breathing or lower chest wall indrawing, absent dangers signs (not alert, unable to breastfeed or drink, either central cyanosis/ oxygen saturations <90%) in a child aged 2-59 months with cough and or difficulty in breathing. During the pre-intervention 1 period, none of the children with cough and or difficulty in breathing had correct documented classification for non-severe pneumonia. The was no improvement on health workers correct classification of non-severe pneumonia by a factor of 0 and a P-value of 1. However, there was a gap of 7 months between the training and post-intervention1 period due to health workers service disruption from national and county health workers strikes. Due to health workers service disruption, it was not possible to assess the immediate effect of the training on correct classification for non-severe pneumonia.

The introduction of SCMF had an immediate improvement in the correct classification of non- severe pneumonia by a factor of 19.05 times with a P-value of 0.9 that was statistically not significant. However, the sustained effect of the SCMF on health workers correct classification of non-severe pneumonia overtime started declining by a factor of -0.06 with a P value of 1 that was statistically not significant.

We speculate that the subconscious mind could have a role in influencing health workers behavior towards uptake of the new guidelines after the training and introduction of SCMF. The subconscious mind tends to hinder one from attempting a new behavior. The subconscious mind goes against changing any of ones already learned behaviors (38). This role of subconscious mind among other factors could have affected the impact of the training and also the introduction of SCMF on health care workers change of behavior towards uptake of new IMCI guidelines.

Further, the demonstrated health workers documented improvements from the use of the Sick Child Management form shows how multiple domains of care where improved during the single patient visit. Our observations reveal that the correct use of the SCMF involves team work and team work is built on professional and organizational norms which can be affected by poor leadership, inadequate supervision, erosion of professional values, transfers of trained health workers, absenteeism, among other factors(27).

Earlier studies done in the district hospitals in Kenya (33) and Kenyatta National Hospital(37) showed poor documentation practices among health care workers. The use of a structured pediatric admission form has demonstrated great improvement in documentation of signs and symptoms necessary for classification of common illnesses in children. This is comparable to the SCMF which has shown

improvement in health workers documentation of symptoms and signs that enable correct assessment, correct classification and even correct treatment of non-severe pneumonia.

We speculate that despite a clinician making a correct assessment, classification and treatment of non-severe pneumonia with high dose amoxicillin dispersible tablet(s), drug stock outs of the high dose amoxicillin dispersible tablets could influence the clinician to give the available antibiotic at the facility against IMCI pneumonia guidelines.

5.1 Strengths

1. This study seeks to serve as implementation research on adherence to IMCI clinical guidelines of non-severe pneumonia.
2. The ability of interrupted time series to observe the trends of health workers performance before and after each of the two interventions enables data obtained to be more accurate and actionable. ITS can identify changes that are immediate, intermediate and delayed.
3. ITS design controls for the effect of secular trend (a consistent pattern over a given period).
4. Sufficient number of 8 time periods before and after each of the interventions as per Interrupted Time Series study design model requirement.
5. ITS provides graphical results that are clear and easy to interpret.

5.2 Limitations

1. This analysis is subject to health workers documentation error and missing data.
2. Assumption that written records reflect actual practice
3. The intervention assumed that the IMCI pneumonia guidelines are uncontested and the two interventions would increase health workers adherence.
4. This model ignores the hidden factors that influence practitioner and organizational behaviors.
5. The study was done in one County making it a challenge to generalize similar performance of the SCMF in other Counties in Kenya.
6. Improving documentation has its value as a source of information but may not have a direct effect on quality of care.
7. The standardized approach in the SCMF may hinder a wider evaluation of a sick child.
8. The SCMF requires a cost of about 5-10 Kenya shillings to print and may hinder its sustainability.

6.0 CONCLUSIONS

There are few published studies evaluating effect of the current IMCI pneumonia guideline training on health workers uptake of correct assessment, correct classification and correct treatment of non-severe pneumonia.

Our results complement a consistent pattern of poor adherence to these guidelines before the training and no change of trend after the training though there was a 7-month gap due to service disruption from health workers national and county strikes. This implies that training health care workers alone may not sustain good clinical practice(39).

Our results reveal that the use of the Sick Child Management Form can result in considerable improvement of health workers correct assessment, correct classification, and correct treatment of non-severe pneumonia impacting positively on the quality of outpatient care.

Our results show a noted decline on the sustained effect of the SCMF on health workers correct assessment, correct classification, and correct treatment of non-severe pneumonia and this suggests that better implementation strategies are needed to sustain the effect of the SCMF overtime(40).

7.0 RECOMMENDATIONS

From the foregoing study we are able to make recommendations as follows:

1. Use of Sick Child Management Form to help dissemination of IMCI pneumonia guidelines.
2. Need for better organizational implementation strategies since correct management of children with non-severe pneumonia requires team-based quality of care.
3. More studies to assess factors associated with poor uptake of IMCI pneumonia guidelines among health care workers despite having knowledge from trainings.
4. More studies to assess hindrances to sustained improvement on health workers performance after introduction of SCMF.

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9.0 APPENDICES

9.1 Time frame.

Numbers	Activity	Duration
1	Concept presentation Proposal development	Jan to April 2021
2	Proposal submission to the ethics committee	May 2021
4	Data collection	November, December 2021- February 2022
5	Data analysis	March 2022
6	Thesis write-up and defense.	April 2022

9.2 Study budget.

Category	Remarks	Units	Unit Cost (KShs)	Total (KShs)
Development of proposal	New laptop	1	58,000	58,000
	Proposal copies	5	500	2,500
Data collection	Stationery Packs (pencils, paper, etc.)	10	100	1000
	Research assistants	2	20,000	40,000
	External hard drive	1	10,000	10,000
Data analysis	Statistician fee	1	30,000	30,000
Thesis write up	Printing thesis	10 copies	500	5,000
Contingency Funds				40,000
Total				186,500

9.3 Sick Child Management Form.

SICK CHILD MANAGEMENT FORM FOR AGES 2 - 59 MONTHS

S

☐ ☐

Name ☐		OP/No.	Date	Age mo	Sex M F
Revisit Y ☐ N		Caregiver Tel: ☐ ☐		Residence:	☐ ☐
Weight = Kg	Height= cm	MUAC G Y R	Temp = ^{0}C	HIV status known	Y N

Ask: What are the child'sproblems?.....

TRIAGE	General Danger signs	Lethargic or unconscious Y N	No Danger sign	
		Not able to drink/Breast feed Y N		
		Vomiting everything Y N	A danger sign present	Requires emergency assessment and treatment – take to TREATMENT ROOM –see chart booklet
		History of convulsions during this illness Y N		
		Convulsing Now Y N		
		Ask/Look/Listen/Feel	**Classify Illness**	**Treatment**
Cough OR difficulty breathing	No			
	Yes	Duration_____days	Severe pneumonia or very severe disease	Pre referral treatment andrefer
		SpO_2_____% RR =		
		Hypoxemia Y N		
		Central Cyanosis Y N		
		Stridor in a calm child Y N	Pneumonia (Non-severe pneumonia)	Amoxycillin DT for 5 days
		Grunting Y N		☐ 4-<10kg: 250mg 12hrly
		Lethargic or unconscious (not alert) Y N		☐ 10-<14kg : 500mg 12hrly
				☐ 14-19kg 750mg 12hrly
		unable to drink/BF Y N	No pneumonia	Refer to IMNCI Chart Booklet
		Chest indrawing Y N	Wheezing	☐ Ventolin inhaler 2 puffsX3/day
		Fast breathing Y N		☐ Spacer ☐ Mask
		Wheeze Y N		
			Chronic cough (more than 14days)	Pre referral treatment andrefer or investigate
Diarrhoea	No			
☐ ☐	Yes	Duration_____ days	Shock	Refer to IMNCI Chart Booklet
		Blood in stool Y N	Severe dehydration	Plan C – refer to IMNCI ChartBooklet
		Weak/absent pulse Y N	Some dehydration	Plan B: ORS over 4hrs
		Lethargy/unconscious (not alert) Y N		☐ <6kg – 200-450ml
		Cold hands & temp gradient Y N		☐ 6-<10kg = 450-800ml
		Capillary refill more than 3sec Y N		☐ 10-<12Kg = 800-960ml
		Drinking poorly/unable to drink Y N		☐ 12-19kg – 960-1600ml
		Sunken eyes Y N	No dehydration	Plan A: ORS after every loosemotion
		Skin pinch goes back very slowly Y N		

		Skin pinch goes back slowly **Y N** **Restless/irritable** **Y N** **Drinking eagerly** **Y N**		**☐ up to 2yrs = 50-100ml** **☐ over 2 years = 100-200mls**
			Dysentery	**Ciprofloxacin tab (250mg strength)for 3 days** **☐ Less than 6mo – ½ tab BD** **☐ Equal/> 6months =1tab BD**
			Severe Persistent diarrhoea	**Plan C – refer to IMNCI ChartBooklet**
			Persistentdiarrhoea	**Treat dehydration as above** **Multivitamin/mineral supplements -see Chart Booklet**
			All cases give Zinc	**Give for 10 days** **☐ 2mo-6mo =1/2 tab OD** **☐ >6mo =1 tab OD**
			Vitamin A- **See Chart Booklet**	**Vit A** **☐ 6mo-11mo = 100,000 units** **☐ over 1 year = 200,000 units**
History of fever or temp≥ 37.5^{0}C	**No**			
	Yes	**Duration_____days** **Running nose** **Y N** **Stiff Neck** **Y N** **BS/RDT Positive** **Y N** **Other causes of fever** **Y N** **Rash** **Y N** **Red eyes** **Y N**	**Very severe febrile illness or severe malaria**	**Pre-referral treatment andrefer**
			BS /RDT **positive Uncomplicated malaria**	**AL for 3 days (Day 1 @0hr, @8hrs then 12hrly for 2 days)** **☐ 5 to ≤ 14kg = 1 tab** **☐ 14 to ≤ 19kg = 2 tabs**
			BS /RDT **Negative: Fever, no malaria**	**Investigate/assess for othercauses of fever**
			Treat fever	**Paracetamol_____mg 6hourly**
			Measles	**See Chart Booklet**

Ear Pain or Ear discharge	☐ No									
	☐ Yes	**Ear discharge duration_____days**					**Mastoiditis**		**Prereferral treatment and refer**	
		Pus draining from the ear Y N					**Acute**		**Amoxycillin DT for 5 days**	
		Tender swelling behind the ear Y N							☐ **4-<10kg: 250mg 12hrly**	
									☐ **10-<14kg : 500mg 12hrly**	
									☐ **14-19kg 750mg 12hrly**	
									Paracetamol_____mg/6hourly	
							Chronic		**Dry ear by wicking at least X3 per day**	
Anaemia /Palmarpallor		☐ **Severe palmar pallor**					**Severe anaemia**		**Refer to IMNCI Chart Booklet**	
		☐ **Some palmar pallor**					**Anaemia**		**Refer to IMNCI Chart booklet**	
		☐ **No palmar pallor**								
Assess for acute malnutrition		**MUAC (for 6months and older)** ☐ **Green** ☐ **Yellow** ☐ **Red**					**SAM with complications**		**Prereferral treatment and refer**	
		WHZ score (for age less than 6months)					**SAM without complications**		**Treat above conditions and refer to nutritional clinic**	
		☐ **Less than-3 z-score**					**Moderate acute malnutrition**		**Treat above conditions and refer to nutritional clinic**	
		☐ **Between -3 to -2 z-score**					**No acute malnutrition**		**See chart Booklet**	
		☐**-2 z score or more**								
		All ages oedema of both feet Y N								
HIV Status	**Negative**						**Negative**			
	Positive/ exposed	**Assess for any other illnesses as above**					**Confirmed HIV infection**		**Link to Comprehensive Care Clinicafter treating any illness**	
							Exposed			
Contact with adult/adoles cent with confirmed or presumptive TB within the last 2 years	☐ **No**									
	☐ **Yes**	**Cough Y N**					**Presumed TB**		**Treat any acuteconditions and referto TB clinic or investigate for TB**	
		Fever and/or night sweats Y N								
		Lethargy/reduced playfulness Y N								
		Poor weight gain or weight loss Y N								
Immunization	**BCG**	**OPV 1**	**OPV 2**	**OPV 3**			**MR 1**	**MR 2**	**Other vaccines**	
		Penta V 1	**Penta V 2**	**Penta V 3**						
		PCV 10-1	**PCV 10-2**	**PCV 10-3**						
		Rota V	**Rota V**	**IPV 1**						
Vitamin A	**6mo**	**12mo**	**18mo**	**24mo**			**30mo**	**36mo**	**42mo**	**48mo**	**54mo**

Albendazole		**12mo (200mg)**	**18mo (200mg)**	**24mo (400mg)**	**30mo (400mg)**	**36mo (400mg)**	**42mo (400mg)**	**48mo (400mg)**	**54mo (400mg)**	**60mo (400mg)**
Assess for other problems						**Ask mother about her health**				
Other treatments										
HOME CARE MESSAGES GIVEN : ☐ Yes ☐ No FOLLOW UP ☐ Yes ☐ No **REFERRED TO ☐ CU, ☐ OTHER H/F ☐ CLINIC ☐ N/A** **Date : Clinician/nurse name_____sign_____**										

Version 1

9.4 Data collection tool.

Demographic data

Unique Code …….

Date of review …….

Age …….

Sex

a. Male
b. Female

Presenting complaint

History of difficulty breathing and or cough.

a. Yes b. No

Duration of difficulty in breathing and or cough…….

Duration of fever ……

History of presenting complaint

History of inability to drink/breast feed.

a. Yes, b. No

History of heart disease.

a. Yes, b. No

History of kidney disease.

a. Yes b. No

HIV status.

a. Sero-exposed

b. Negative

c. positive

History of admission in the previous 4 weeks.

a. Yes b. No

History of contact with known PTB patient.

a. Yes b. No

General examination

Central Cyanosis.

a. Yes b. No

Oxygen saturation <90%.

a. Yes b. No

Alert

a. Yes b. No

Respiratory rate ……

Age-specific respiratory rate.

a. normal
b. tachypnea

Weight ……

Systemic examination

MUAC …….

W/H Z score……

Oedema of both feet

a. Yes b. No

Respiratory system.

Lower chest wall indrawing.

a. Yes b. No

Wheeze

a) Yes b. No

Diagnosis

Classification of pneumonia

a) No pneumonia
b) Pneumonia (non-severe pneumonia)
c) Severe pneumonia

Treatment

1. High-dose oral amoxicillin dispersible tablet(s).
   a) 4kg–<10kg: 250mg,
   b) 10kg–<14kg: 500mg,
   c) 14kg -<19kg: 750mg.

2. 12 Hourly frequency of oral amoxicillin dispersible tablet(s).
   Yes b. No

3. 5 day duration of oral amoxicillin dispersible tablet(s).
   a. Yes b. No

9.5 IMCI pneumonia guideline poster2

[2] Management of a child aged 2-59 months with cough or difficulty breathing (no wheeze). Kenya national MoH 2018 IMNCI guidelines.

Management of a child aged 2-59months with cough or difficulty breathing (no wheeze)

Signs and Symptoms	Classification	Counsel Care Giver	Treatment Plans
• Danger signs – convulsions during this illness, vomiting everything or stridor in a calm child • Age less than 2 months or more than 59months • Fever more than 14 days • Cough or difficulty breathing more than 14 days • Positive history of contact with a patient with PTB • Discharged from inpatient care within one month • For age 6-59months MUAC less than 11.5 cm • For age 2-6months weight/length Z score less than -3SD • Oedema of both feet • Known to have heart or kidney problem	Not eligible for management with these protocols	Counsel care giver on: • Possible causes of the illness • Prevention of hypoglycaemia • Prevention of abnormal temperature	Use specific disease guidelines or Refer if indicated
Assess for signs of severe pneumonia - • Not Alert • Unable to drink • SpO_2 less than 90% • Grunting Lower chest wall indrawing AND HIV positive	SEVERE PNEUMONIA	Counsel care giver on: • Possible causes of the disease and treatment plans • Explain why referral • Prevention of hypoglycaemia • Prevention of abnormal temperature	Referral for inpatient management Give pre-referral treatment • Crystalline penicillin 50,000 IU/kg stat • Gentamycin 7.5mg/kg stat • Give oxygen 2L/min by nasal prongs if SpO_2 less than 90% • Give bronchodilators if wheezing • Prevent and treat hypoglycaemia • Prevent and treat abnormal body temperature if indicated
Assess for non-severe pneumonia • Lower chest wall indrawing and HIV negative • Fast breathing • 2-11months - Respiratory rate equal to or greater than 50/min • 12-59months - Respiratory rate equal to or greater than 40/min	PNEUMONIA (NON – SEVERE PNEUMONIA)	Counsel care giver on: • Possible causes of the disease and treatment plans • Prevention of hypoglycaemia • Prevention of abnormal temperature • Expected outcomes and why patient should be reviewed at 48hrs or earlier if condition worsens. • Home care messages	Treat for non-severe pneumonia • High dose oral amoxycillin dispersible Tablet (DT) *4 - <10kg : 250mg 12hrly X 5 days* *10 -<14kg : 500mg 12hrly X 5 days* *14 -19kg : 750mg 12hrly X 5 days* • Give bronchodilators if wheezing • Prevent and treat hypoglycaemia • Prevent and treat abnormal body temperature if indicated • Counselling on feeding • Give Vitamin A • Follow-up in two days
Cough or difficulty breathing • Not vomiting everything • Not convulsing during this illness episode • No stridor in calm child • SpO_2 90% and above • Able to drink • Alert • Not grunting • No lower chest wall indrawing • No fast breathing	NO PNEUMONIA (COUGH OR COLD)	Counsel care giver on: • Possible causes of the disease and treatment plans • Prevention of hypoglycaemia • Prevention of abnormal temperature • Expected outcomes and why patient should be reviewed at 5 days or earlier if condition worsens • Home care messages	Treat for no pneumonia/cough or cold • Safe cough remedy • Prevent and treat hypoglycaemia • Prevent and treat abnormal body temperature if indicated • Counselling on feeding • Check immunization, deworming & Vitamin A

KENYA PAEDIATRIC ASSOCIATION

University of Nairobi [3]10

9.6 Ethical approval.

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Ref. No.KNH/ERC/Mod&SAE/403

15th December 2021

Dr. Mutisya Nick Kioko
Reg. No. H58/34941/2019
Dept. of Paediatrics and Child Health
Faculty of Health Sciences
University of Nairobi

Dear Dr. Kioko,

Re: Approval of Modifications – study titled, "Effect of integrated management of childhood illness pneumonia guideline training on health workers uptake of oral amoxicillin among children aged 2-59 months at three health facilities in Nairobi County" (P357/05/2021)

Your communication dated 21st November, 2021 refers.

Upon review, the KNH-UoN ERC has **approved** the following requested modifications to the study:

1. Change of study sites from Mbagathi Hospital and Mama Lucy Hospital to ***Eastleigh Health Centre***, ***Westlands Health Centre*** and ***Huruma Lions Health Centre***.
2. Change in study procedure- Introduction of a second intervention i.e. second training for health workers that was conducted in September 2021 with subsequent introduction of the Sick Child Management Form.
3. Change of study period; study will now be from May 2020 to January 2022.
4. Change of study objectives to include assessment of effect of IMCI pneumonia guideline training and introduction of the Sick Child Management Form on health workers adequacy, classification and treatment of pneumonia (Specific Objectives 3 & 4).
5. Subsequent change of study title from '*Effect of integrated management of childhood illness pneumonia guideline training of health workers uptake of oral amoxicillin among children aged 2-59 months at two level 4 hospitals in Nairobi County*', to "***Effect of integrated management of childhood illness pneumonia guideline training on health workers uptake of oral amoxicillin among children aged 2-59 months at three health facilities in Nairobi County***".

Protect to discover

The suggested modifications are well justified and the proposed new sites are approved to facilitate implementation of the study. The updated research proposal and study instruments are hereby endorsed and approved for use.

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 Chair, Dept. of Paediatrics and Child Health, UoN
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