THE UPTAKE OF NEW GUIDELINES FOR THE TREATMENT OF PNEUMONIA IN CHILDREN AGED 2-59 MONTHS ADMITTED AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

This dissertation is my original work and has not been presented for the award of a degree in any other university.

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LIST OF ABBREVIATIONS

AVPU	-	A Simple scale to assess the level of consciousness. **Alert**, responding to **Voice**, response to **Pain, U**nconscious
CAP	-	Community Acquired pneumonia
CXR	-	Chest radiograph
ETAT +	-	Emergency Triage, Assessment and Treatment plus admission care
GRADE	-	Grading of Recommendations, Assessment, Development and Evaluations
KDHS	-	Kenya Demographic Health Survey
KNH	-	Kenyatta National Hospital
MDG	-	Millennium Development Goals
MoH	-	Ministry of Health
PAR	-	Paediatric admission record
SDGs	-	Sustainable Development Goals
WHO	-	World Health Organization

CASE DEFINITIONS AND OPERATIONAL TERMS

Severe pneumonia - History of cough or difficulty in breathing with any one of the danger signs (grunting, cyanosis with oxygen saturation less than 90%, inability to drink, or altered consciousness) with or without lower chest wall in drawing or age specific fast breathing.

Non-severe pneumonia - History of cough or difficulty in breathing with lower chest wall in drawing and/or age specific fast breathing with NO danger signs (grunting, cyanosis of oxygen saturation less than 90%, inability to drink, or altered consciousness).

Age specific fast breathing- Respiratory rate of ≥50 breaths per minute age (2- 11months), ≥40 breaths per minute age 12-59 months.

Danger signs- Occurrence of at least one of the following clinical signs in a sick child: Oxygen saturation <90%, cyanosis, and inability to drink or breastfeed, AVPU= 'V' 'P' or 'U' or grunting.

Admitting clinician – a qualified clinician, usually the paediatric resident at the paediatric emergency unit, qualified clinical officers with higher diploma training in paediatrics and medical officer intern who writes the wards admission notes. Medical students' medical notes unless countersigned by a qualified clinician will be disregarded. If patient is reviewed, in a span less than 6 hours by another clinician the notes of the reviewer overrules what will be previously recorded by the admitting clinician.

New pneumonia guidelines: "These are the February 2016 Kenya National guidelines for childhood pneumonia treatment adopted from the 2013 revised World Health Organisation (WHO) guidelines for the management of childhood pneumonia. These guidelines were adopted after the generation of evidence from studies conducted in Kenya."

ABSTRACT

Background Management of childhood pneumonia in Kenya is based on WHO case management guidelines. These guidelines were updated in 2013 by the WHO, adopted by the Kenyan Ministry of Health and disseminated in February 2016. Cases previously classified as severe pneumonia and treated with intravenous benzyl penicillin are now categorized as pneumonia and treated with an oral antibiotic. We aimed to establish the level of adherence to these guidelines at KNH.

The primary objective was to determine the proportion of children whose antibiotic treatment prescribed by the admitting clinician is consistent with the national pneumonia guidelines. The adequacy of clinical assessment (documented in admission notes) and consistency of severity classification with national guidelines were assessed as secondary outcomes.

The adoption of the revised WHO guidelines would result in reclassification of children with pneumonia and the clinical sign of lower chest wall indrawing as pneumonia and not severe pneumonia therefore decreasing the number of admissions and the cost of treatment per child.

Methodology We carried out a retrospective cross-sectional study of patients between the ages of two and fifty nine months admitted to KNH with pneumonia between April 1, 2017 and November 30, 2017. Patients with pneumonia and co-morbid diagnoses for which there are additional guideline recommended treatments were excluded. These conditions include dehydration, meningitis, diabetic ketoacidosis, pulmonary tuberculosis and patients with a wheeze.

Data were summarized using means, interquartile ranges and proportions. Adherence to four main domains (assessment, classification, antibiotic and supportive treatment was assessed using the MOH national pneumonia guidelines as the audit criteria. Cross tabulation were used to calculate consistency between clinician practice and guideline recommendations.

Results We assessed 390 clinical records of patients admitted to the hospital in the course of the period of study. The level of adherence to the clinical pneumonia guidelines was assessed at three levels: assessment of all five essential clinical signs was 17.7%(95% CI 14.0 - 21.85%), classification of pneumonia severity consistent with the guidelines was 44.87%(95% CI 39.86 - 49.96%) while the prescription of appropriate antibiotic and dosage was at 18.06%(95% CI 13.39 to 23.55%) .Oxygen was prescribed at admission for 160/390 (50.16%, 95% CI 36.1 to 46.09%) children with severe pneumonia who had a danger sign present but no record of oxygen saturation >90% .Of the 96 patients with severe pneumonia who had either a reduced level of consciousness or inability to feed, 86.45% were prescribed enteral feeds /intravenous fluids at admission .

Conclusion There was poor adherence to the clinical practice guidelines. Only 18.06% of the patients were properly classified and received the correct treatment according to the guidelines.

1.0 BACKGROUND AND LITERATURE REVIEW

1.1 Background

Pneumonia is an acute disease that is marked by inflammation of the lung tissue. Infectious agents like viruses, bacteria, fungi or parasites frequently, but not always cause it.

Despite having effective pneumonia protective and preventive strategies, pneumonia remains the leading cause of death among children aged five years and below worldwide and accounts for 19% of deaths in this age group. About two thirds of these deaths occur in sub-Saharan Africa and south East Asia.

Pneumonia case management guidelines have existed for the last three decades. The World Health Organization (WHO) case management, for resource limited settings, relies on syndromic diagnosis of the illness and prescription of treatment depending on severity of the pneumonia illness that is also assessed using simple clinical signs. The WHO pneumonia treatment guidelines were updated in 2013. Pneumonia, previously classified into three categories based on severity, in the new guidelines is classified into two categories. While the old guidelines recommended parenteral treatment for a patient with the clinical sign of lower chest wall in drawing and lacked danger signs that would signify a more severe form of disease, the new guidelines recommend outpatient treatment with oral antibiotics for this category of patients (3).

The Ministry of Health Kenya adopted the new WHO pneumonia treatment policy and revised the national pneumonia guidelines contained in the Basic Paediatric Protocols 4th Edition February 2016 (4). The training programme dubbed as ETAT+ (Emergency Triage Assessment and Treatment plus Admission care) for dissemination of the protocols was also revised accordingly. Kenyatta National Hospital, a national teaching and referral hospital, is among the training centres for ETAT+ and the hospital embraces the use of the protocols. We describe a study to evaluate the uptake of these guidelines at Kenyatta National Hospital.

1.2 Literature Review

In this section, we will define the syndromic classification of pneumonia and its benefits in low resource settings; review the old pneumonia classification, treatment and the evidence

that necessitated the change. We will also discuss the value evidence of locally conducted research that led to the revision of the national pneumonia guidelines.

1.2.1 Magnitude of Pneumonia

Globally – in 2016, pneumonia was responsible for about 16% of the 5.6 million under 5 deaths worldwide. That is about 2500 children per day (1).

Regionally - In 2015, Eastern and Southern Africa was responsible for 15% out of the 920,000 deaths globally due to pneumonia. That is 138,000 deaths(5).

Locally - in 2015, acute respiratory tract infection was the leading cause of mortality in children under the age of five. There were 10,507 deaths attributed to acute respiratory tract infection in these children contributing to 14% of all under five deaths in the country (1).

1.2.2 Diagnosis of Pneumonia

Pneumonia is described as infection of the lung tissue caused by microbes. The available methods that can be used to identify the specific etiological agent include cultures of the blood, lung biopsy, nasopharyngeal aspirates and immunological tests of urine and blood (6). Lung biopsies are rarely done because of the invasiveness of the procedure and the associated morbidity. Blood cultures have very low yields 5-15% hence cannot be relied upon (7). Rapid and highly sensitive laboratory tests performed on samples from the upper respiratory tract or induced sputum can detect nucleic material from pathogens in a majority of children with pneumonia. It is however not possible to differentiate between the organisms causing pneumonia and those colonizing the upper respiratory tract of such children. Nasopharyngeal aspirates are inconclusive since isolation of bacteria from the nasopharynx is not diagnostic of lower respiratory tract infection because normal flora colonizing the nasopharynx as well as pathogenic bacteria can cause pneumonia(8). There is no single test that reliably differentiates between bacterial and nonbacterial causes of pneumonia.

The clinical and radiological signs are usually nonspecific and diagnostic tests have limitations. The gold standard diagnostic test for pneumonia is a radiograph of the chest. However, obtaining a chest radiograph for every suspected pneumonia case does not make economic sense as it usually does not affect the outcome and it is neither sensitive nor

specific enough to identify the etiological microbe as bacterial or viral. Etiological diagnosis as well as radiological diagnosis is not feasible for routine use in limited resource settings. Therefore, the diagnosis of pneumonia is based on a clinical criterion that is syndromic diagnosis and classification of the severity of the illness. In addition, all patients diagnosed as having pneumonia should receive as antibiotics since viral and bacterial pneumonia cannot reliably differentiated (9).

1.2.3 Syndromic Classification of Pneumonia

The WHO in the early 1980's developed a control strategy for pneumonia appropriate for resource limited countries. This was necessitated by the high mortality caused by childhood pneumonia. In this strategy, simple signs were identified and they were used to classify pneumonia into various severities. The classes then determined the management of the cases. These management guidelines were based upon research findings produced in the 1970's and early 80's. The case management studies relied on the ability of simple clinical signs such as the rate of respiration and lower chest wall in drawing being able to distinguish pneumonia from other respiratory system diseases. Presence of any danger signs that include measured oxygen saturation levels lower than 90%, cyanosis, inability to drink or breastfeed, altered level of consciousness or grunting implied a more serious form of pneumonia disease(10). To avoid antimicrobial resistance, children with cough and no other signs of pneumonia should not be treated with antibiotics(9).

1.2.4 Previous Pneumonia Classification

In the Ministry of Health Kenya guidelines for year 2013 shown in figure 1, a child aged 2-59 months with cough and/or difficulty breathing of less than 14 days was classified into any of the three pneumonia severity categories based on whether or not the patient had more clinical signs. Any child with one of the danger signs like oxygen saturation lower than 90%, was not able to drink or breastfeed, ,cyanosis, AVPU<A and grunting was classified as very severe pneumonia and treated with a combination of parenteral antibiotics; an aminoglycoside and penicillin. Those with lower chest wall indrawing and no danger sign were classified as severe pneumonia, injectable penicillin monotherapy was the treatment of choice for these category of patients. Patients with fast breathing but no danger signs or lower

chest wall in drawing were classified as pneumonia and given received either cotrimoxazole or amoxicillin to take at home. Children with cough and no other signs or symptoms of pneumonia were classified as no pneumonia and no antibiotic treatment was given.

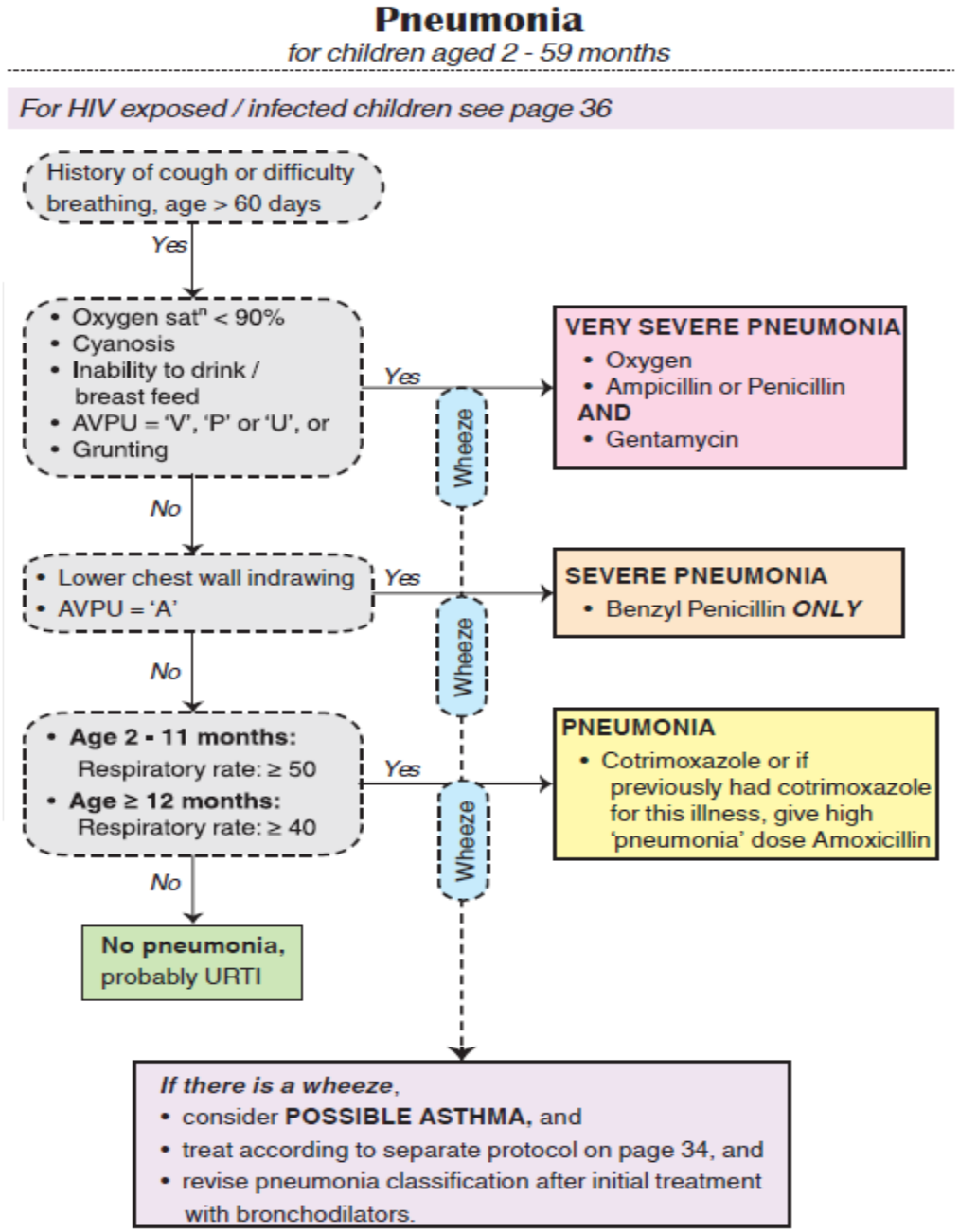

Figure 1: Ministry of Health Kenya, November 2013 guidelines for the management of pneumonia for children aged 2-59 months.

1.2.5 Development of Pneumonia Guidelines in Kenya

In 2006, Ministry of Health, Kenya adapted the WHO pneumonia guidelines for inpatient care (11). The guidelines were developed from the WHO pocket book of hospital care for children(12). They were developed in algorithm format (Fig 2), a linked paediatric admission record form was also developed(13) and a training Programme for their dissemination dubbed as ETAT+ (Emergency Triage Assessment and Treatment plus Admission)(14). In 2013, WHO revised the pneumonia guidelines, that necessitated change of the MoH pneumonia policy (3).

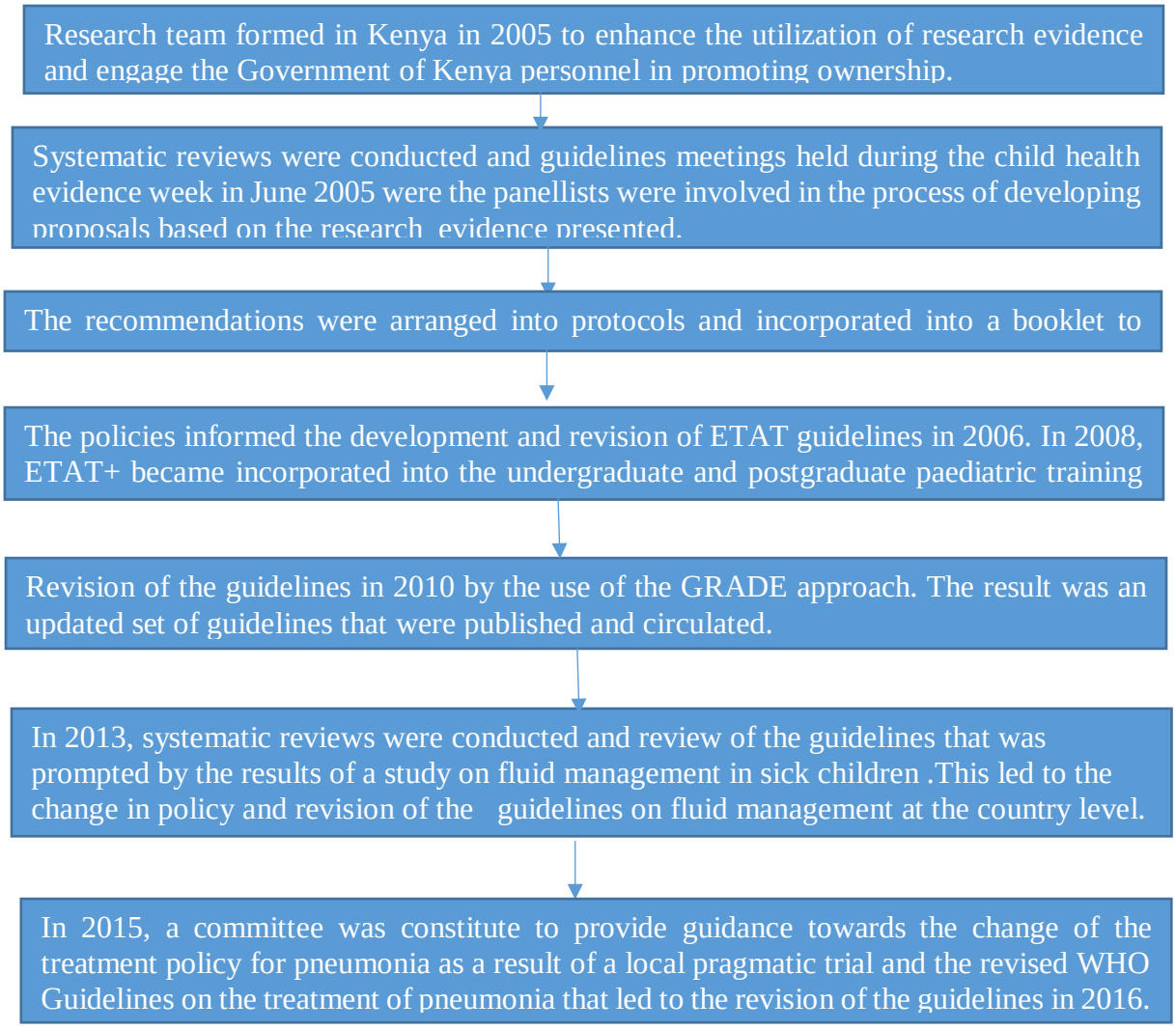

Figure 2: Algorithm for adoption of the 2013 revised WHO guidelines for the treatment of childhood pneumonia

*GRADE- Grading of Recommendations, Assessment, Development and Evaluations.

1.2.6 Evidence that Necessitated Change

Deaths due to childhood pneumonia are usually due to severe and very severe pneumonia (3). Prompt identification, timely referral and availability of proper higher care that involves inpatient care, oxygen and parenteral antibiotics is vital to the treatment of pneumonia and reduction in the mortality caused by the illness. Based on this information the WHO undertook an evidence based review in order to develop a strategy that would enhance the percentage of patients with pneumonia who receive the correct treatment.

A systematic Cochrane review was conducted by Lodha *et al* (15) comparing several antibiotic regimes so as to identify the most efficacious antibiotic for community acquired pneumonia (CAP) in children. There were a total of 29 studies that enrolled 14,188 patients. The patients were from predominantly Asian countries. The randomized control trials compared various antibiotics used for CAP. Only the studies that had radiologically confirmed pneumonia or those that utilized the WHO case definition of pneumonia were considered .The primary outcome was clinical cure or treatment failure. The main results were that for children with pneumonia, cotrimoxazole was less effective compared to amoxicillin with clinical failure rates - odds ratio 1.33 (95%CI 1.05- 1.67) and benzyl penicillin clinical cure rates - odds ratio 2.64(95% CI 1.57 - 4.45). Parenteral penicillin in combination with Gentamicin was superior to Chloramphenicol monotherapy (rehospitalisation rates OR 1.61; 95% CI 1.02 to 2.55). No difference was found between parenteral penicillin and amoxicillin failure rate OR 1.03(95%CI 0.81 - 1.31), co- amoxiclav was superior to amoxicillin cure rate OR 10.44(95% CI 2.85-38.21).The conclusion was that for ambulant patients the treating community acquired pneumonia with amoxicillin was better than cotrimoxazole. Injectable penicillin was superior to cotrimoxazole for inpatients and the use of penicillin together with gentamicin was more effective compared to chloramphenicol monotherapy. There were similar clinical failure rates with the use of injectable penicillin and oral amoxicillin.

The World Health Organization recommends that children with severe acute malnutrition and complications such as septic shock, hypoglycaemia, hypothermia, skin infections,

respiratory tract infections or who appear sick or have an altered level of consciousness should be admitted and treated with parenteral antibiotics(16) .

A subgroup analysis of a randomized control trials of infants between the ages of 3 and 59 months old who presented with cough and difficulty in breathing or cough and lower chest wall in drawing was done by Jeena P *et al* (17).This trial was conducted in southern Africa. 523 participants were enrolled into the study, of these 464 had a known HIV status. 23 %(106) of them being HIV positive. A comparison was made between parenteral penicillin and oral amoxicillin in the management of these patients. The clinical outcomes were treatment failure on the second and fourteenth day. The findings were that HIV positive patients with lower chest wall in drawing pneumonia had a higher failure rates with the WHO recommended treatment of injectable penicillin or amoxicillin at second and fourteenth more often than the HIV non -infected (40.7% vs24.3% OR 2.8 CI 1.35, 5.5). On the basis of these results, the WHO panel discouraged the use of oral amoxicillin for children living with HIV diagnosed with pneumonia. They recommended either parenteral ampicillin or penicillin in combination with gentamicin or ceftriaxone as the initial regimen for HIV positive and exposed patients under the age of 5 years with severe or very severe pneumonia(18).

In a randomized multicentre equivalence study, Addo-Yobo *et al* compared amoxicillin parenteral penicillin in the treatment of severe pneumonia defined as cough or difficulty in breathing and lower chest wall in drawing in children aged 3 -59 months(19). The study was conducted in eight African, Asian and South American countries in tertiary level hospitals. Patients with severe pneumonia as per the WHO definition were admitted for 48 hours, if they improved they were allowed home to complete five days of amoxicillin. A total of 1702 children were enrolled. They were randomized to either the amoxicillin arm n=857 or to injectable penicillin n=845 for 48 hours, reviews were done at the 5^{th} and 14^{th} day after enrolment, the primary outcomes being treatment failure at 48 hours. The outcomes were: treatment failure was equal in both groups at 19% (161 patients in the penicillin arm; 167 patients amoxicillin arm; Risk difference – 0.4%; 95 % CI -4.2 to 3.3) at 48 hours; children age 3-11 months; OR 2.72(95% CI 1.95 - 3.79) tachypnea (1.94, 1.42 - 2.65) and hypoxemia (1.95, 1.34 - 2.82) at baseline predicted treatment failure by multivariate analysis. The

conclusion was that parenteral penicillin and amoxicillin are equivalent in the management of severe pneumonia in supervised setting.

Another review by an international panel appointed by WHO (26) to review the literature on childhood pneumonia and to develop recommendations for management of non-severe pneumonia by primary level health workers, concluded that the best first line agent is amoxicillin twice a day for three to five days. Another Cochrane review of three randomised control trials that included 5,763 children was done by Haider BA *et al*. All the randomized control trials compared three vs five days of treatment while holding the antibiotic constant. The outcome was cure rates at completion of treatment. The results were that a shorter three day course was as efficacious as the five day course for severe pneumonia. In the two arms, no significant differences were found (RR 0.99; 95% CI 0.97 to 1.01).

Hazir *et al* (21) conducted an RCT at seven sites in Pakistan to determine whether treatment with injectable ampicillin as an inpatient was equivalent to home treatment with high dose amoxicillin children with severe pneumonia. 2037 children aged between 3 and 59 months with severe pneumonia as per the WHO definition of history of cough and or difficulty in breathing with lower chest wall in drawing and no danger signs were recruited. They were randomized to either hospital admission and injectable ampicillin 100mg /kg /day in four divided doses for 48 hours followed by 3 days of high dose oral amoxicillin at 80-90mg/kg/day in two divided doses (n=1012) to complete 5 days of treatment or to home based treatment with oral amoxicillin at 80-90mg/kg/day in two divided doses n=1025 for 5 days. The patients were reassessed on the $1^{st,}$ 3^{rd}, 6^{th} and 14^{th} days after recruitment. The measured outcome was treatment failure. The findings were that there were 87(8.6%) treatment failures among the hospitalized group and 77(7.5%) in the homebased treatment group risk difference1.1% 95 %CI -1.3 to 3.5) by day 6. The interpretation being that home treatment with high dose amoxicillin is comparable to admission and treatment with injectable penicillin in children with severe pneumonia and no other comorbidities.

1.2.7 Revised WHO Classification and Treatment of Childhood Pneumonia at the Health Facility

Based on the evidence above, the World Health Organization revised the classification and treatment of childhood pneumonia (3).

Table 1: Revised WHO classification and treatment of pneumonia at the health facility

History of cough or difficulty in breathing, age 2-59 months

Clinical signs and symptoms	Category of pneumonia	Management
One of the danger signs; persistent vomiting, convulsions, unconscious, stridor in a calm child or severe malnutrition	Severe pneumonia	First dose of antibiotic and referral to a facility for injectable antibiotic and supportive therapy
Fast breathing and or chest in drawing	Pneumonia	Oral amoxicillin and home care advice
Cough and cold	No pneumonia	Home care advice

1.2.8 Evidence Rejected and a Local Study Recommended

The evidence that led to the new WHO pneumonia guidelines was discussed and reviewed during the process of developing the paediatric guidelines in Kenya. During this process, the evidence was downgraded to moderate quality due the limited number of African children that were included in the studies (22). It was noted that most of the supporting evidence was generated from large multicentre studies involving Asian children. The panellists discussing the guidelines were concerned on how generalizable the results from primarily Asian patients were to sub-Saharan Africa where the mortality from pneumonia may be higher. On this basis the Kenyan experts rejected the adoption of oral amoxicillin in the place of injectable penicillin for lower chest wall in drawing pneumonia and recommended a local study(22). This local study was conducted by Agweyu *et al* as a multicentre non inferiority randomized control trial at six Kenyan hospitals (23). The study enrolled 527 children between the ages of two and fifty – nine months classified as severe pneumonia patients according to the older WHO guidelines including 302 (57.3%) children with comorbidity. The subjects were assigned to two arms - oral amoxicillin therapy or injectable penicillin. The primary outcome

was treatment failure at 48 hours. The results were that 7.7% (20 / 260) patients in the amoxicillin group had treatment failure while in the benzyl penicillin arm (8.0%) of patients failed treatment with a risk difference -0.3 %,(95%CI -5.0% to 4.3%). The conclusion was the confirmation that amoxicillin is equivalent to benzyl penicillin in management of non-severe pneumonia Kenyan children.

1.2.9 Revision of the Guidelines February 2016

Subsequently the MOH national pneumonia guidelines were updated and released in February 2016 (Fig 3).

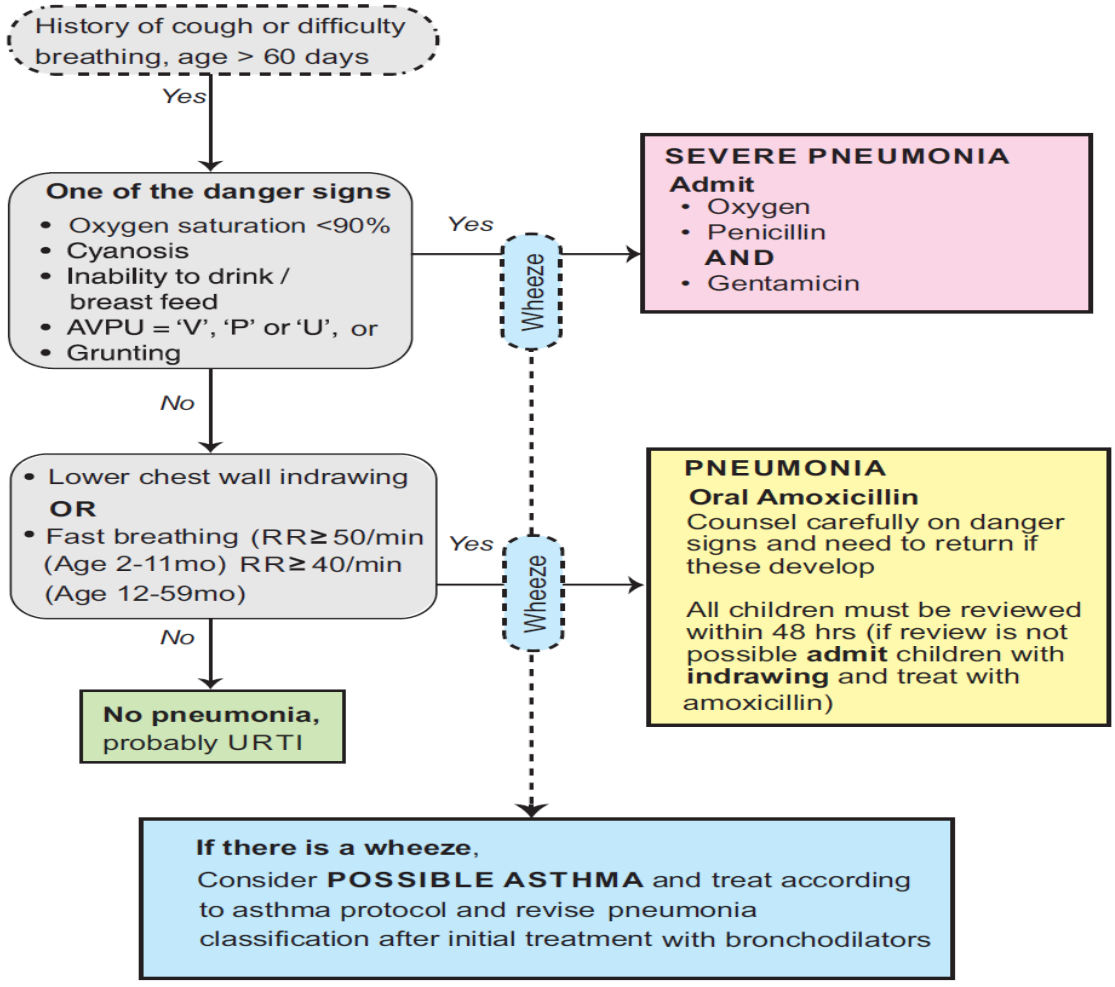

Figure 3: New guidelines for the management of pneumonia in children aged 2-59 months

1.2.10 Dissemination of the New Pneumonia Guidelines

The ETAT+ Training Course was first conducted in 2006 in Kenya as part of an intervention strategy that had been demonstrated to be effective in improving care at the district hospital level (11).This training is aimed at improving the skills of the health workers who take care of the sick child .It also promotes the adoption of evidence based guidelines. Since 2008, the ETAT+ training has been integrated in the curriculum of the undergraduate medical students and the post graduate paediatric students at the University of Nairobi. Postgraduate students in paediatrics at the University of Nairobi are primarily responsible for the admission and review of sick children at Kenyatta National Hospital. They have all received training on the revised guidelines for the treatment of pneumonia in children.

1.2.11 Value of the Clinical Practice Guidelines and Assessment of their Uptake

Clinical practice guidelines are defined by the Institute of Medicine as 'systematically developed statements to assist the practitioner and patients' decisions about appropriate health care for specific clinical circumstances(24). They are tools to make care more consistent and efficient represent a link between what the health care providers practice and the scientific evidence on the best practice. In a systematic review on the effect of clinical guidelines on medical practice Grimshaw et al reviewed 59 evaluations of clinical practice guidelines(25). 55 of those studies showed significant improvement in the care process after the introduction of the guidelines.

Other potential benefits of using clinical practice guidelines are an improvement in the quality of clinical decisions made by medical practitioners and reassurance on the appropriateness of their plan of management (25) . They also support quality improvement as they are an accepted point of reference for audits of the clinicians and / or the hospital practice as the tests, treatment plans and goals of treatment endorsed in the guidelines are ready process measures to rate compliance to the best practice (26).

1.2.12 Potential Harms of Clinical Practice Guidelines

The most important limitation of Clinical Practice Guidelines (CPGs) is that they may not be appropriate for individual patients as some of the guidelines are inflexible, therefore

providing inadequate room for the clinicians to consider patients' personal circumstances, history or even personal preferences(27). Other limitations maybe due to the processes of guideline development in that they may be biased by developers opinions and personal preferences or by inaccurate scientific information that may lead to flawed recommendations that are harmful to both the patients and the health care providers(26).

1.2.13 Implementation of the Guidelines: Challenges and Success Rates

Ayieko *et al* (28) conducted a cluster randomised trial at eight Kenyan district hospitals. This was a multifaceted intervention to implement WHO guidelines that form part of the IMCI approach and to improve admission practice for paediatric care. In this study, four of the eight hospitals were randomly assigned to full intervention that included training of the staff, provision of the job aids and evidence based guidelines, supervision and face-to-face feedback. The guidelines were introduced with ETAT+ training in the form of a booklet for reference. The other four had the control intervention that was instructive training, job aids, written rather than face-to-face feedback and guidelines provision. The primary outcome measured at 18 months was the process of care measures. These measures reflected the standards as defined by the clinical guidelines and focused on the diseases that account for the majority of paediatric admission and death: pneumonia, malaria, and acute gastroenteritis with or without dehydration. These encompassed the assessment, supportive and therapeutic care offered. The outcome indicators represented the adherence to key policy recommendations and included Vitamin A prescription, recognition of missed opportunities for immunization, provider initiated testing and counselling for HIV and a score of 0-4 demonstrating the correct knowledge by the caregiver at discharge, of the child diagnosis and the drugs prescribed at discharge .The results were an overall improvement in both groups from the baselines for all the outcome measurements. At the end of 18 months, the mean completion of the assessment tasks were higher in the intervention sites as compared to the control sites mean =0.94vs0.65 ,adjusted mean difference 0.54 (95%CI 0.05-0.29). The other notable improvement was the difference in the uptake of the recommended clinical guidelines for example, adoption of once daily gentamicin dosage was 89.2% in the intervention group vs. 74.4% in the control with 17.1% difference 95% CI (8.04%-26.1%)). In addition, the proportion of children receiving the incorrect dosage of drugs – inadequate gentamicin

dosage, was reduced in the intervention group 2.2% vs 9.0% in the control with -6.8% difference 95% CI(-11.9%to -1.6%).

Clinical practice guidelines for treatment of pneumonia have been accessible since the 1990's (29). Adherence to the clinical practice guidelines has been shown to improve health outcomes(28,30,31). In Kenya the clinical practice guidelines were developed for the management of common, serious childhood illness(14). They have been available since 2006, when they were introduced through ETAT+ training and there after the disseminated through the 'Basic paediatric protocol' (32). In the assessment of the performance of health workers in the management of seriously sick children, Irimu *et al*(33) conducted an uncontrolled before and after study as the clinical guidelines were being introduced and the ETAT+ training conducted. A comparison was made of quality performance indicators for pneumonia, dehydration and severe acute malnutrition before and after the intervention. The interventions being the dissemination of the clinical practice guidelines and ETAT+ training of the medical staff involved in the care of paediatric patients. A comparison was made in the pre-intervention period in 2005 and the post intervention period in 2009 using quality indicators for three diseases: Pneumonia, dehydration and severe acute malnutrition. The indicators assessed four processes in the care of the patients: Assessment, classification, treatment and follow up of patients. The findings were that in the pre-intervention period in 2005, the care of the patients was not in keeping with existing guidelines and 9 out of 15 indicators had a score of below 10%. In the post intervention marked improvement was noted in compliance to the guideline recommendations achieving an absolute effect size of over 20% that was noted in 7 out of the 15 key indicators. For example, in the assessment of pneumonia, the intervention resulted in a significant improvement based on a group of composite indicators used (+21.7%, 95% CI: 21.7to 32.6%). In the classification of severity of pneumonia syndrome, there was a large improvement (+58%, 95% CI: +51.9 to 65.2%) post intervention.

In explaining the take up of the paediatric guidelines in a Kenyan tertiary hospital, Irimu et al conducted a mixed method research at Kenyatta National Hospital(34). It included quantitative and qualitative components. The quantitative arm was an uncontrolled before

and after design that sought to explore the intervention dose – effect relationship while the qualitative arm was based ethnographic research methodology. Some of the findings were that the accessibility of knowledge within the hospital and the University of Nairobi was limited. The professionals did not have a culture of self-reading aimed at improving practice while the curriculum used in the training of the paediatric residents did not encourage frequent search of the latest updates on best practices on patient management.

There was a general appreciation of the guidelines but failure to implement them. The reason for this may be because the CPGs focus on the management of common serious illness in paediatrics while the senior paediatricians' viewed this as a simple task hence they did not give it much attention. The attitude portrayed was that the understanding of uncomplicated diseases did not characterize a paediatrician.

1.2.14 Cost of Treating Pneumonia using the New Guidelines

Implementation of the new revised guidelines would result in cost reduction. Lorgelly PK et al (35) in England estimated and compared the cost of treatment of children with CAP with oral amoxicillin and intravenous penicillin. 232 children diagnosed with pneumonia were randomized to a controlled non blinded equivalence trial. A cost minimization analysis was conducted concurrently. The costs incurred by the health system, patients and the community were considered in the analysis from preadmission to full recovery. The results were that oral amoxicillin and injectable penicillin had similar efficacy. The children treated with intravenous penicillin had an extended inpatient stay 3.12 vs 1.93 days $P<0.01$, with the parenteral treatment being more expensive than oral treatment. Treating CAP with amoxicillin save the health system £473 to £518 per child per admission. This demonstrates that oral amoxicillin is an economical treatment for most of the children with CAP.

Shanshan *et al* and the severe Acute Lower Respiratory Tract Infection (ALRI) in young Children working group conducted a cost effectiveness analysis for the management of pneumonia in 74 countries with a considerable burden of childhood mortality(36). They estimated and made a comparison of the resources required, direct medical expenditure and affordability of managing childhood pneumonia using the 2005 and the revised 2O13 WHO

guidelines for management of pneumonia in children aged 2-59 months. The conclusion was that management as per the 2013 guidelines was very economical. Effectuation of the revised guidelines would result in a **39.5%** reduction cost of treatment in comparison with the previous guidelines. This could in turn save up to USD 1.16(0.68-1.23) billion in the seventy four countries.

1.2.15 Conceptual Framework: Theory of Planned Behaviour

Studies done show that adherence to clinical practice guidelines reduces mortality and morbidity due to disease, promotes rational use of antibiotics with overall improvement in the patient outcome and reduction in the costs of health care provision.

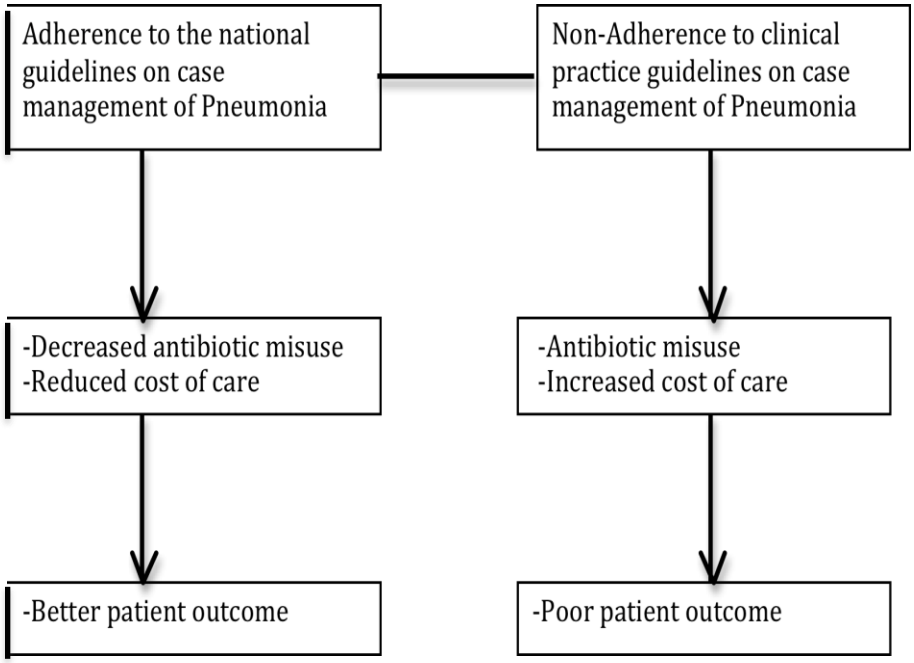

Figure 4: Conceptual framework of theory of planned behaviour

2.0 STUDY JUSTIFICATION AND UTILITY

Pneumonia is the number one cause of admission to KNH paediatric wards. Pneumonia and diarrhoea contribute to 55% of admissions and 45% of deaths in patients under the age of 5 years (33). With a total bed capacity of only 240 beds in the four paediatrics wards, the bed occupancy is always above 100%. The number of admissions per year is usually above 14,000 with limited resources in terms of the nurses, doctors and nurses to attend to these patients. The adoption of the revised WHO guidelines on classification and treatment of pneumonia in health facilities would result in re- classifying children with lower chest wall in drawing as pneumonia and not severe pneumonia therefore significantly decreasing the number of admissions and the cost of treatment per child. The current study seeks to establish the uptake of these guidelines at KNH since their dissemination in February 2016.

3.0 RESEARCH QUESTION

What is the level of the uptake of the 2013 WHO revised classification and treatment of childhood pneumonia guidelines at Kenyatta National Hospital?

3.1 Primary Objective

To determine the proportion of children whose antibiotic treatment prescribed by the admitting clinician is consistent with the national pneumonia guidelines.

3.2 Secondary Objectives

1. To determine adequacy of assessment of clinical signs required for pneumonia severity classification.
2. To determine proportion of children whose severity of pneumonia classification by the admitting clinicians is consistent with the national pneumonia guidelines.
3. To describe the supportive treatment (supplemental oxygen, nasogastric feeds and/or intravenous fluids) prescribed for children with pneumonia.
4. To take an inventory of the equipment and consumables required for management of pneumonia of any severity.

4.0 RESEARCH METHODOLOGY

4.1 Study Design

The study was a cross-sectional retrospective study that involved the audit of the records of the patients admitted to KNH paediatric wards with the admission diagnosis of pneumonia.

4.2 Study Site

Kenyatta National Hospital is the national referral hospital in Kenya. There are four general paediatric wards i.e. 3A, 3B, 3C and 3D. Admissions are done daily from the paediatric emergency unit at the paediatric filter clinic by a paediatric trainee doctor. There are approximately 14,000 admissions to the paediatric ward each year of children aged 0-12 years. Patients receive inpatient care provided majorly by 70-80 paediatric registrars who are supervised by about 25 paediatricians. The nursing care is provided by a total of 126 nurses, with 12- 24 working per shift.

The patients are first seen by the triage nurse who takes a brief medical history and the vital signs usually the temperature, respiratory rate, weight and at times the oxygen saturation depending on the patient's condition. The triage nurse would then direct the patients to either the paediatric emergency unit where they would be seen by the paediatric registrar or to the clinical officer trained in paediatrics. The paediatric registrar then takes the history, examines the patient and requests for the necessary investigations. He/she will then make the decision on whether the patient gets admitted or not. All the paediatric registrars, the clinical officers and majority of the nurses working at the paediatric filter clinic have been trained in ETAT+, a 5 day training for dissemination of the Ministry of Health Basic Paediatric Protocol.(32).
The criteria for admitting pneumonia patients is based on the MoH guidelines in the Basic Paediatric Protocol February 2016 edition which is accessible to all clinicians either as a hard copy or in soft copy. The admission notes are recorded either using the Paediatric admission record form, which is available as free text, or a combination of the two. The treatment is usually recorded in the treatment sheets provided by the hospital. Before admission to the wards the nurse administers the first doses of the prescribed treatment. The nurse then accompanies the patient and the caregiver to the admitting ward. On arrival in the wards, the paediatric registrar on call reviews the patient, and if necessary he/she may adjust the already

prescribed treatment. The consultant on call also reviews the patient, usually within 24 hours of admission during the post admission rounds. In the year 2017 a total of 981 children between the ages of two and fifty nine months were admitted with the diagnosis of pneumonia. This number was significantly lower than the previous years. This was attributable to the industrial action by the doctors in the first three months of the year. At the medical records, the records are archived using the CD10 codes(37).

4.3 Study Population

Clinical records of children aged 2-59 months admitted at KNH paediatric wards with the diagnosis of pneumonia during the period between 1st April and 30th November 2017.

4.3.1 Inclusion Criteria

- Patients aged 2-59 months
- Patients with cough and /or difficulty breathing lasting less than 14 days.
- Patients with admission diagnosis of pneumonia of any severity admitted in paediatric admission wards from 1st April 2017 to 30th November 2017.

4.3.2 Exclusion Criteria

All patients with other conditions that make the use of pneumonia guidelines inappropriate were excluded. These were defined as patients with an admission diagnosis of meningitis, renal failure, diabetic ketoacidosis, cardiac disease, vomiting everything, malignancy, pulmonary tuberculosis, those with severe acute malnutrition or wheeze on auscultation. Patients readmitted and those referred from other hospitals were excluded on analysis for antibiotic prescription.

4.4 Sample Size Determination

The desired sample size was determined using the formula

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

$n = 1.96^2 \times 0.5(1 – 0.5) / 0.05^2$

Where;

n – Sample size

z – Statistical level of confidence (95%)

p – Expected prevalence or estimated proportion of children with correct antibiotic prescription

d - Precision

Proportions used were obtained from literature review on the performance of the health workers in the management of the critically ill children at KNH (33). In this study, Irimu *et al* found that the prescription of the proper dosages of crystalline Penicillin increased from 51.7 in the ETAT pre intervention period in 2005 to 90% in 2009. However, that may have changed so the **p** was set at 50%. The margin of error was set at 5% to allow the study to achieve adequate precision and provide sufficiently reliable estimates. Using these assumptions, the minimum sample size was calculated to be 384. Retrieval rate of the medical records from the archives was 84 % from the study by Irimu *et al* (33).To cater for this the sample size was increased to 457 (120% of 384).

4.5 Data Collection Procedures

Data collection was carried out by the principal investigator and a research assistant. The research assistant was a clinical officer who was trained on the data collection methods.

Clinical records of children aged 2-59 months with an admission diagnosis of pneumonia during the period of 1st April 2017- 30th November 2017 were retrieved. This was a complete census of all eligible files available during this period. The identification numbers of the records of patients admitted during the study period was noted down from the admission registry in the various paediatric wards. This was given to the data clerk at the hospital records office to retrieve the records.

At the medical records, the records are archived using the ICD10 codes. The code for pneumonia is J.18.It includes:

J18.0 Bronchopneumonia, unspecified

Excludes: bronchiolitis (J21.-)

J18.1 Lobar pneumonia, unspecified

J18.2 Hypostatic pneumonia, unspecified

J18.8 other pneumonia organism unspecified

J18.9 Pneumonia unspecified

Data were obtained from these records directly entered into an E tool .These data were extracted from the inpatients records into a primary data collection tool developed in Research Electronic Data capture (REDcap). REDcap is a software solution that was designed for the development and deployment of electronic capture tools(38) in clinical studies. The tool is a web based structured questionnaire. The hard copy of the tool is attached in appendix 3.

A standard operating procedure manual was developed to guide on details of the data collection for example where the data was to be obtained .Treatment data were to be obtained only from the treatment sheets not the from the clinician admission notes. The data extracted included demographics, the signs and symptoms recorded at the time of admission, the classification of the severity of pneumonia and the management prescribed. Data capture procedures are summarized in Figure 5 below

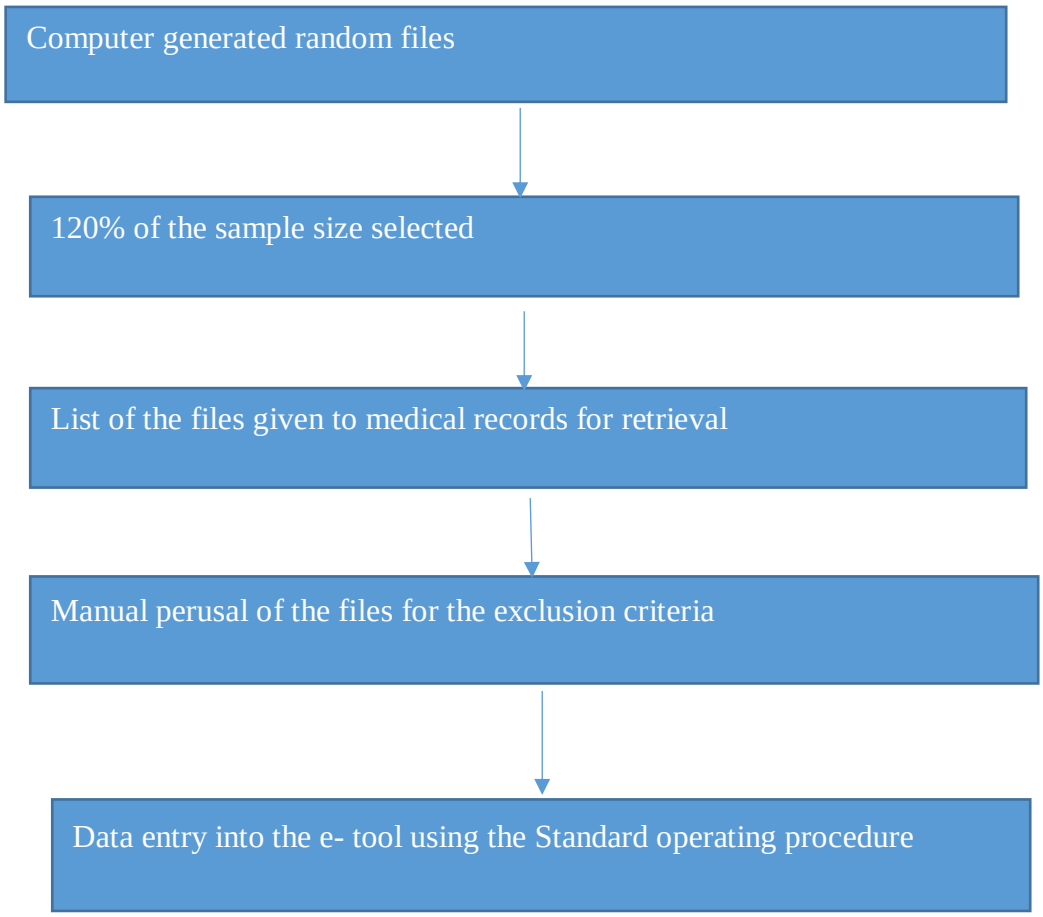

Figure 5: Flow chart of data collection procedure

5.0 ETHICAL CONSIDERATIONS

5.1 Authorization to Conduct the Study

Permission to collect and analyse data was obtained from the Kenyatta Hospital- University of Nairobi Ethics and Research Committee (KNH-UON ERC). Approval to conduct the study was also obtained from Kenyatta National Hospital research department.

5.2 Study Participant Consent

Consent was not sought from the individual study participants. This was cross-sectional retrospective study of anonymized patient records and as per the practice of such studies, individual informed consent is not required.

5.3 Health Records Protection

The identity of the patients was protected since the health records were anonymized. Data on the health personnel attending to the patient was not collected, this information remains confidential and will not in any way be used to penalize the practitioners. The entry of the data from the patients' records into the data collection tool was done strictly within the health information department at KNH where the records are kept.

6.0 DATA MANAGEMENT AND ANALYSIS

For the purposes of data management, data were cleaned using an in built data error check and any range check error was checked to confirm if it was a data entry error or a true error.

6.1 Data Analysis

Data are summarized using means, interquartile ranges and proportions where appropriate to represent the demographic characteristics of the sample and the completion of the patient management tasks as recommended in the guidelines. These analyses are presented using tables and figures. The analyses were performed using R version 3.2.5(R foundation for statistical Computing, Vienna, Austria, https://cran.r-project.org)

Adherence to four domains of care (assessment, classification, antibiotic and supportive treatment was assessed using the MoH national pneumonia guidelines as the audit criteria. For assessment the documentation of a sign as present or absent was considered as done while failure to document will be considered as not done. The symptoms were a history of cough or difficulty in breathing while the signs to be assessed were : respiratory rate, the level of consciousness as assessed using the AVPU scale, the ability to drink or breastfeed, the presence of grunting, cyanosis lower chest wall in drawing or oxygen saturation .

The tasks that were assessed are listed below:

1. Disease classification tasks- The classification expected is either severe pneumonia or pneumonia. The classification of the disease severity by the admitting clinician was considered correct if it was consistent with national pneumonia guidelines.
2. Treatment tasks- correct if it was consistent with national pneumonia guidelines if the treatment prescribed by the admitting clinician was in accordance with the national pneumonia guidelines in regard to and the frequency and drug dosages. Dosage was considered correct if it was +/-20%of that recommended in the guidelines.
3. Oxygen prescription was considered correct if oxygen was prescribed when the indication, mode of oxygen delivery and flow rate prescribed was consistent with national pneumonia guidelines. A child who was unable to feed was considered fed correctly if nasogastric feeds or intravenous fluids were prescribed as recommended

in the national pneumonia guidelines. Children with any degree of dehydration were excluded from this analysis on feeding methods.

6.2 Performance Indicators

Table 2: Performance indicators

Task	Expected action
Assessment History Clinical examination	All of the following must be recorded for proper retrospective classification of pneumonia Cough or difficulty in breathing Respiratory rate Lower chest wall in drawing Level of consciousness Ability to drink or breastfeed Grunting Cyanosis
Disease classification Only one action is expected	Severe pneumonia – Presence of any danger signs None severe pneumonia- none of the danger signs is present but has fast breathing and or lower chest wall in drawing.
Treatment The treatment prescribed based on the severity of classification supported by the CPGs in the booklet and the posters	Severe pneumonia- Crystalline penicillin and Gentamicin Non –severe pneumonia- Amoxicillin
Correct dosage (±20%) Proper dosage of the antibiotics based on the diagnosis and supported by the clinical guidelines	Crystalline penicillin 50,000/kg ±20% given 6 hourly Gentamicin 7.5mg /kg±20% once daily Oral amoxicillin ± 20% the dose recommended in the national pneumonia guidelines(4)
Oxygen Prescription – For all children with severe pneumonia and no evidence that oxygen saturation is above 90%	Check if oxygen when prescribed when indicated.
Initial maintenance feeds /fluids for all patients with ‘inability to drink ‘or AVPU <A and no diagnosis of acute gastroenteritis or dehydration.	Check if feeds /maintenance feeds were prescribed when indicated.

6.3 Quality Assurance

1. The research assistant was trained in data collection.
2. The use of the electronic data collection tool that had been piloted and used(39).
3. During data entry the person entering the data received message alerts for any inputs outside the specified ranged.
4. The electronic data collection tool has an internal validation mechanism for data quality validation.

6.4 Quality Control

Data quality control was undertaken by the principal investigator and statistician at different stages. Data quality checks were implemented close in time and place of data collection. The clerk was required to verify any potential errors in the database by referring back to the clinical notes. Data verification mechanisms were designed and incorporated into REDcap system to flag up omissions, errors and inconsistencies during the data entry and processing. At the data analysis stage, quality control was implemented through creating data summaries, and graphical exploration for each variable. The graphs and summaries were inspected for outliers and illogical or inconsistent entries and making corrections after verification using clinical notes.

7.0 STUDY RESULTS

7.1 Description of Study Participants

500 records were obtained for children aged 2-59 months admitted to KNH general paediatric wards between 1st April 2018 and 30th November 2018 with the diagnosis of pneumonia. Records of 110 children that had admission diagnosis that excluded them from the 2013 WHO pneumonia case management algorithm were excluded from the study – (Figure 6).

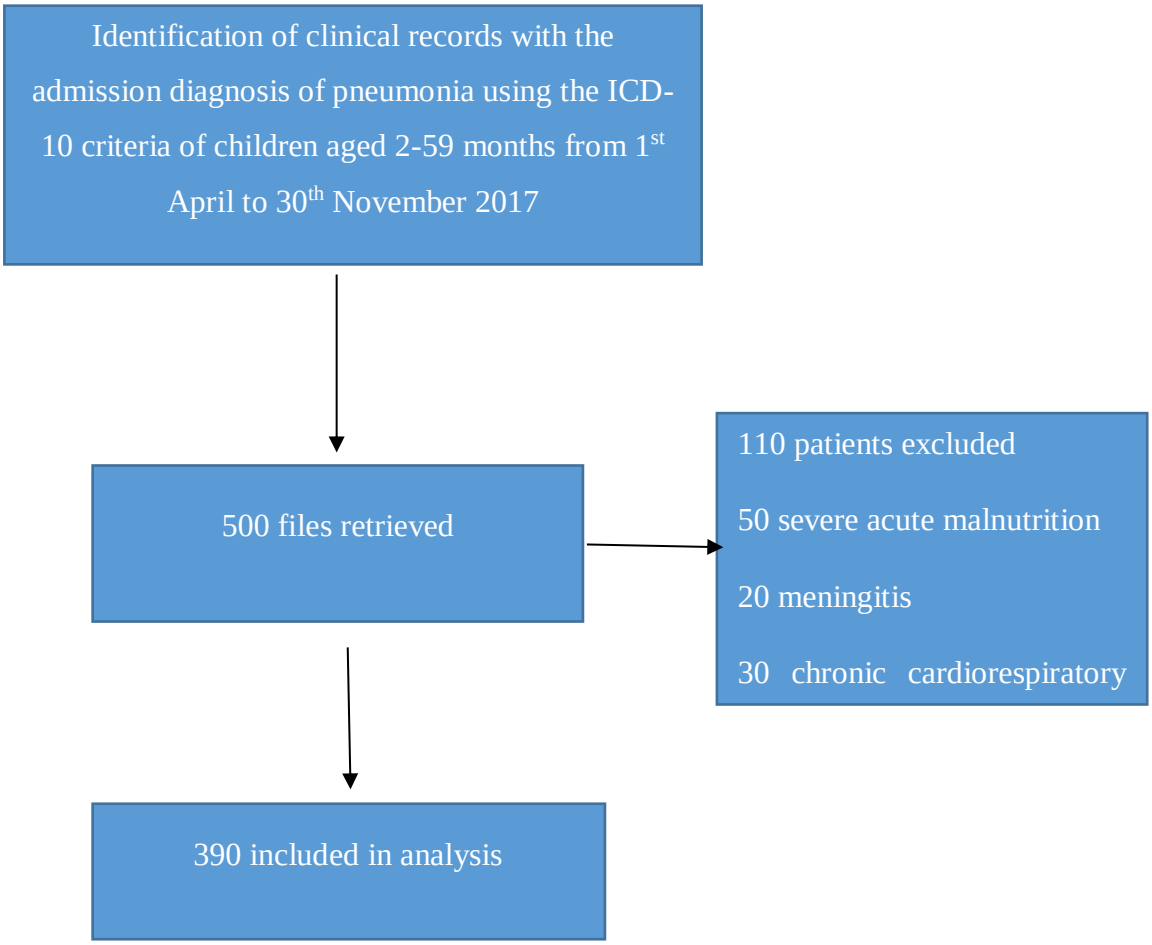

Figure 6: Study profile

<u>Study population characteristics</u>

The median age of the study population was 10 months IQR (5-18) (Table 3).

There were more boys than girls in the sample 216(55.38%) compared to 174 (44.62%).

The median length of hospital stay was 7 days IQR (4-11 days).

Table 3: Patient Characteristics

	Indicator	N=390
Age in months	2-6	89(22.8%)
	7-12	87(22.3%)
	13-1	86(22.1%)
	19-24	36(9.2%)
	25-30	26 (6.7%)
	31-36	3(0.8%)
	37-42	10(2.6%)
	43-59	9(2.3%)
	Undocumented	44(11.2%)
	Median IQR	10(5-18)
Sex	Female	174(44.62%)
	Male	216(55.38%)
Length of Hospitalization in days	0-3	63(19.63%)
	3-7	144(44.86%)
	7-14	114(35.51%)
	Median (IQR)	7(4-11)

<u>Use of paediatric admission record form</u>.

Thirty three percent of the patients were admitted using the paediatric admission record form.

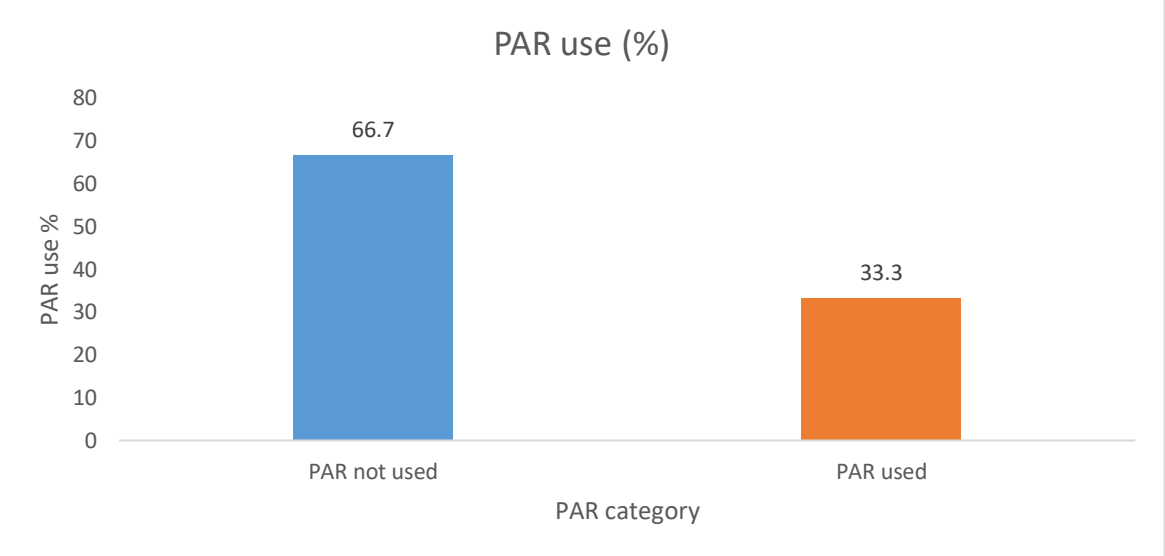

Figure 7: Bar graph showing percentage of PAR use

Comorbidities

Twenty five percent of the patients presented with comorbidities. The most common comorbid illness was Diarrhoea occurring in 7.9% of pneumonia cases. Diarrhoea defined by the WHO as the passage of three or more loose stools per day or more frequent passage than is normal for the individual was associated with dehydration in 1.3% of cases. Dehydration is a result of uncontrolled loss of body water and is caused by various conditions other than diarrhoea.

Diarrhoea is not always associated with dehydration hence the two conditions are presented separately.

Pneumonia and moderate malnutrition were present in 6.7 % of the patients while 0.8% of the patients had pneumonia; diarrhoea and moderate malnutrition. 2.1% of the patients had other comorbidities not represented in the Venn diagram below.

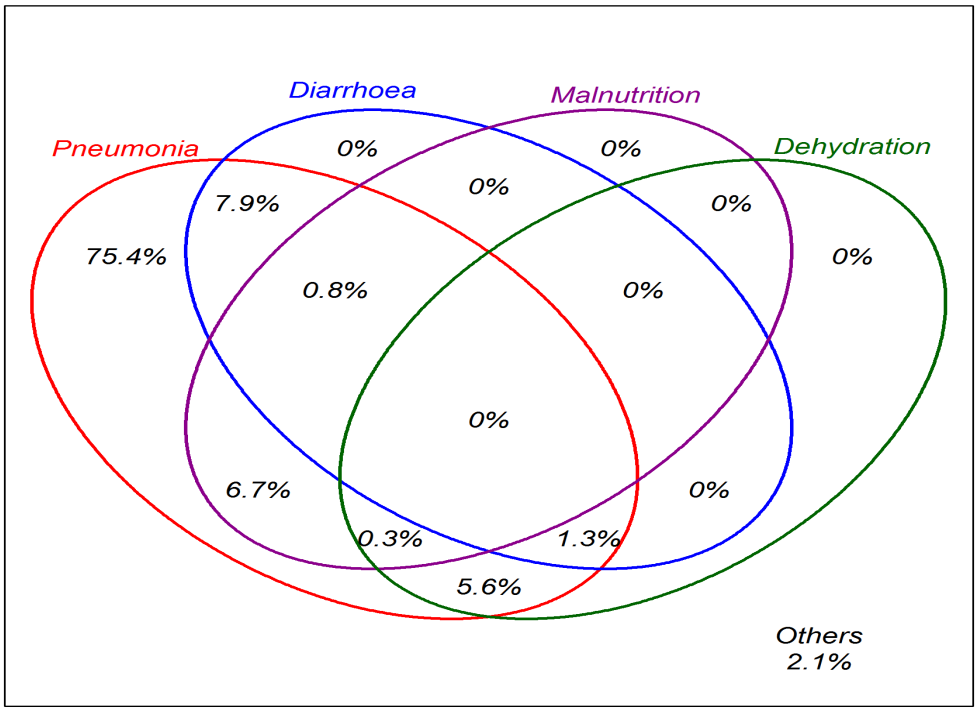

Figure 8: Distribution of co – morbid illnesses among the children with admission diagnosis of pneumonia.

7.2 Level of Adherence to the Clinical Practice Guidelines

7.2.1 Documentation of Essential Symptoms

History of cough and/or difficulty in breathing was the most common presenting symptom in 81.54% (318/390) and 77.44 %(302/390) respectively as shown in the table below. Of the 318 patients, 96.86% (308/318) had a cough present and 94.7% (286/302) had difficulty in breathing (Table 4).

Table 4: Documentation of essential symptoms in the clinician's admission notes

Indicator	Number of records with the symptom documented (%)	Presence of symptom /number of records symptom documented (%)
Fever	311/390 (79.74%)	296/311 (95.18%)
Cough	318/390 (81.54%)	308/318 (96.86%)
Cough >14 days	304/390 (77.95%)	0/304 (0%)
Contact with TB	222/390 (56.92%)	2/222 (0.9%)
Difficulty breathing	302/390 (77.44%)	286/302 (94.7%)
Diarrhoea	228/390 (58.46%)	76/228 (33.33%)
Diarrhoea >14 days	74/390 (18.97%)	0/74 (0%)
Vomits	230/390 (58.97%)	91/230 (39.57%)
Vomiting everything	79/390 (20.26%)	10/79 (12.66%)
Difficulty feeding	201/390 (51.54%)	79/201 (39.3%)

7.2.2 Documentation of the Key Clinical Signs among Sick Children Aged 2-59 Months

Eighty one percent (319/390) of the children had a documentation of the respiratory rate out of whom 159/319 (49.84%) had tachypnea (Table - 5). Tachypnea is defined as respiratory rate of ≥50 in children aged 2-11 months and ≥40 in children aged 12-59 months.

The presence or absence of lower chest wall indrawing was documented in 73% (288/390) of the patients out of whom 267/288 (92.70%) had lower chest wall indrawing.

Central cyanosis was the most commonly documented danger sign 290/390 (74.36%). Out of these patients with diagnosis documentation only- 1.38 % (4/290) patients actually had cyanosis. The least documented danger signs were oxygen saturation levels of <90%, 144/390 (36.62%) and the ability to drink 185/390(47.44%). Seventy percent (101/144) of the patients with oxygen saturation documentation were hypoxic with oxygen saturations of less than 90% while half the patients 96/185 were unable to drink (Table 5)

Table 5: Documentation of essential clinical signs in seriously sick children aged 2-59 months.

Clinical sign	Number of records sign documented/N, (%)N=390	Patient characteristic	Presence of sign/Number of records sign documented (%)
Axillary temperature	319/390 (81.79)	Fever>37.5	217/319 (68.02)
		Hypothermia<36.5	2/319 (0.83)
		36.5-37.5	100/319 (31.34)
Respiratory rate	319/390 (81.7)	Tachypnea*	159/319 (49.84)
Stridor	142/390 (36.4)	Stridor present	10/142 (7.04)
Central cyanosis	290/390 (74.36)	Central cyanosis present	4/290 (1.38)
Chest indrawing	288/390 (73.85)	Chest indrawing present	267/288 (92.71)
Grunting	230/390 (58.97)	Grunting present	147/230 (63.91)
Acidotic breathing	135/390 (34.62)	Acidotic breathing present	18/135 (13.33)
Crackles	283/390 (72.56)	Crackles present	221/283 (78.09)
Peripheral pulse	128/390 (32.82)	Normal	118/128 (92.19)
		Weak	10/128 (7.81)
Capillary refill	166/390 (42.56)	<2seconds	120/166 (72.29)
		≥2 seconds	46/166 (27.71)
Temperature gradient	157/390 (40.26)	Skin warm up hand	135/157 (85.98)
		Skin warm up to elbow	17/157 (12.59)
		Skin warm up to shoulder	5/157 (3.70)
Pallor	293/390 (75.13)	No pallor	207/293 (70.65)
		Mild/moderate pallor	65/293 (22.18)
		Severe pallor	21/293 (7.17)
Sunken eyes	144/390(36.92)	Sunken eyes present	23/144 (15.97)
		Sunken eyes absent	120/144 (83.33)
Skin pinch	161/390 (41.28)	Immediate	127 (78.88)
		1-2 seconds	29/161(18.01)
		≥2 seconds	5/161 (3.10)
AVPU	295/390 (75.64)	Alert	274/295 (92.88)
		Verbal response	1/295 (0.34)
		Responds to pain	18/295 (6.1)
		Unresponsive	2/295 (0.68)
Ability to drink	185/390(47.44)	Able to drink	96/185 (51.89)
		Unable to drink	89 /185(48.11)
Stiff neck	283/390 (72.56)	Yes	5/283 (1.77)
		No/soft	278/283 (98.23)

7.2.3 Adherence to the Guidelines on Assessment of Clinical Signs and Symptoms of Pneumonia

All of the following must be recorded for patients with cough or difficulty in breathing for proper retrospective classification of pneumonia.

- Respiratory rate
- Lower chest wall indrawing
- Level of consciousness
- Ability to drink or breastfeed
- Grunting
- Cyanosis or oxygen saturations

Out the 390 patients 69 (17.7%, 95% CI 14.0 to 21.85%) patients had all signs that are essential for pneumonia classification documented within clinical records (Table 6).

Table 6: Documentation of the key signs and symptoms for pneumonia severity classification

Domain of care	Composite and individual indicators	Patients who achieved the indicator (%)
Assessment of patients	**Composite indicator***	**69/390 (17.7%)**
	Level of consciousness	295/390 (75.64%)
	Ability to drink	185/390 (47.44%)
	Cyanosis	290/390 (74.36%)
	Lower chest wall indrawing	288/390 (73.85%)
	Respiratory rate	319/390 (81.7%)

Composite indicator * considered achieved if all the 5 clinical signs were documented

7.2.4 Adherence to the Guidelines on Disease Severity Classification

Of all 390 patients 246 (63.08%, 95% CI 58.07 to 67.88%) had an admission diagnosis of severe pneumonia. Out of these, seventy one percent (175/246) had classification of severe pneumonia consistent with the national pneumonia guidelines. This was tendency to classify the patients to more severe disease for patient with lesser severe disease. Thus, 25% (63/246) of the patients classified as severe pneumonia by the admitting clinician, had signs and symptoms consistent with non-severe pneumonia as per the pneumonia guidelines A quarter

of the study population (100/390) of the patients did not have adequate clinical signs documented for pneumonia severity classification.

Sixteen patients were classified as having very severe pneumonia, a classification that no longer exists in the current guidelines. Of the sixteen, fourteen of the patients were classified as severe pneumonia retrospectively, one as non-severe pneumonia and another did not have sufficient clinical signs recorded to be classified as either severe or non-severe pneumonia. Overall, 175 out of 390 patients, 44.87 %(95% CI 39.86 to 49.96%) were classified correctly according to the guidelines, main problem being that the clinicians erred towards greater severity classification. (Table 7)

Table 7: Comparison of the admitting clinician classification of pneumonia severity with retrospective classification according to the pneumonia guidelines

		Classification according to the guidelines.			
		severe	Non severe	Indeterminate*	Total
Classification according to clinician	Severe	175	63	8	246
	Non severe	7	0	4	11
	Very severe	14	1	1	16
	Unclassified	12	18	87	117
TOTAL		208	82	100	390

Indeterminate * Patients who did not have enough clinical signs documented to be classified retrospectively as either severe or non-severe pneumonia.

7.2.5 Adherence to Guidelines on Treatment

Patients were considered to have the correct treatment consistent with the clinical practice guidelines if the antibiotic treatment prescribed was the correct dose according to the weight of the child.

- Crystalline penicillin 50,000 units /kg /dose four times per day (+/-20%) and Gentamicin 7.5 mg/kg / once a day (+/-20%) for patients with severe pneumonia.
- Amoxicillin 40-45mg /kg twice daily for patients with non-severe pneumonia.

Only seventeen percent (43/246) of the patients classified as severe pneumonia received the correct treatment of combination of benzyl penicillin and gentamicin in doses consistent with the national guidelines. Other drugs that were prescribed for this community acquired pneumonia included: Ceftriaxone, ceftriaxone and amikacin, ceftazidime and meropenem. None of the patients classified as non–severe pneumonia received the guideline recommended treatment of high dose amoxicillin (Table 8).

Table 8: Adherence to the national guidelines on treatment of pneumonia

Pneumonia syndromic classification	Dosage recommended in the national guidelines	Patients prescribed treatment consistent with national guidelines(choice of antibiotics and correct dosage)
Severe pneumonia	Penicillin dosage (50,000 iu/kg ±20%) Gentamicin dosage (7.5 mg/kg ±20%)	43/238 (18.38%)
Non-severe pneumonia	Amoxicillin dosage (40-45mg/kg +20%) Frequency =12hourly	0/11 (0%)

7.2.6 Supportive Care Prescribed for Patients with Severe Pneumonia

Supportive care including oxygen for patients with danger signs and either enteral feeds or intravenous fluids in patients who have an altered level of consciousness or who are unable to feed is important in the management of children with pneumonia. Oxygen was prescribed at admission for 160/390 (50.16%, 95% CI 36.1 to 46.09%) children with severe pneumonia who had a danger sign present but no record of oxygen saturation>90%.Out of the 96 children with severe pneumonia who either had a reduced level of consciousness or inability to feed 86.45% (95% CI 77.96 to 92.59% were prescribed enteral feeds/intravenous fluids (Table 9).

Table 9: Supportive care documented at admission.

Care	**Proportion**
Oxygen ordered	160/319 (50.16%)
Feeds/IVF prescribed on admission*	83/96 (86.45%)

*patients with diarrhoea and dehydration were excluded

7.2.7 Availability of Essential Supplies in KNH for the Management of Pneumonia

The availability of essential supplies for the treatment of pneumonia including antibiotics, oxygen, intravenous fluids and nasogastric tubes were reported by the health workers (Nurses, pharmacists and paediatric registrars).Oxygen, penicillin and intravenous fluids were reported as always available by all health workers (Table 10).

Between 86% and 96% of health workers reported that gentamicin, amoxicillin, nasogastric tubes and PAR forms were always available.

Table 10: Availability of essential supplies for management of pneumonia of any severity in KNH as reported by the health workers (n=50)

	Always Available	Available most times	Rarely Available	Never available
Oxygen	50 (100%)	-	-	-
Gentamicin	45 (90%)	5 (10%)	-	-
Benzyl penicillin	50(100%)	-	-	-
Amoxicillin	49(98%)	1(2%)	-	-
Intravenous fluids	50(100%)	-	-	-
Nasogastric tubes	43 (86%)	7 (14%)	-	-
PAR form	48(96%)	2 (4%)	-	-

8.0 DISCUSSION

We sought to determine the level of adherence to the clinical practice guidelines for the treatment of pneumonia in children aged 2-59 years at Kenyatta National Hospital. Prior to the introduction of the Clinical practice guidelines and ETAT + training, care of ill children with common serious conditions was not in keeping with the recommendations by the World Health Organization and endorsed by the Ministry of Health in Kenya.

Irimu *et al* found that only 1.9 % (95% CI 0.6-4.3) of the patients in the pre –intervention period, the intervention being the introduction of the clinical practice guidelines and the ETAT training, were adequately assessed for pneumonia(33).This findings were consistent with earlier studies that assessed the uptake of international recommendations for care of seriously ill children in district hospitals in Kenya (30) , elsewhere in Africa(40) and other less developed countries(41). From our findings, only 17.7 % (69/390) of the patients had all the signs that are required for pneumonia severity classification documented in the clinicians admission notes. This is lower than Irimu *et al* findings in the post ETAT+ period where 29% (85/293) of the patients had all the essential signs documented.

The most frequently recorded presenting complaint was cough at 82%. The level of consciousness using the AVPU scale was the most recorded clinical sign, recorded in 76% of the patients. These results were close to Irimu *et al* findings in the post intervention period of 74.4%. It is important to document these signs as studies by Sehgal *et al* in India identified inability to feed and cyanosis as significant and independent risk factors for mortality in children with pneumonia (42). Lower chest wall indrawing was recorded in 74 % of our study patients. This was lower than Irimu's finding in the era post CPGs and ETAT+ introduction during which 81.2% of the patients were assessed for lower chest wall indrawing.

Inability to drink and oxygen saturation levels were the least poorly documented signs at 47% and 37% respectively. Yet, studies by Shann *et al* identified inability to feed and cyanosis as significant an independent determinant factor for mortality in children with pneumonia (43).) The WHO recognizes inability to feed as a danger sign and a predictor of death in critically ill children. These findings were similar to earlier studies in KNH(33) and in Tanzania where

only 7%(14/191) of the children had an assessment of the ability to drink recorded(40). Previously the reason for poor documentation practice was thought to be because of the less emphasis on this clinical sign that in the conventional paediatric textbooks and in the main stream academic teaching (44).

Hypoxemia is a major complication of pneumonia. It is generally defined as oxygen saturation (SPO_2) <90%(44). Hypoxemia increases the risk of death up to five times. The WHO estimates that at least 13.3% of children with pneumonia are hypoxemic (45). Hypoxemia is not readily recognized especially in resource-limited settings. Pulse oximetry is not readily available in resource limited settings(46). Clinical signs that indicate hypoxemia include central cyanosis, nasal flaring, inability to breast feed, grunting with every breath and depressed mental status(47). However, there is no single clinical sign that demonstrates adequate sensitivity and specificity for detection of hypoxemia.

Pulse oximetry is the most precise non-invasive method of diagnosing hypoxemia. Pulse oximeters are more affordable compared to the past and should be performed in all patient with respiratory illness and clinical signs of hypoxemia (44). Pulse oximetry is also important in monitoring of treatment and also in ensuring efficient use of oxygen by avoiding unnecessary use of oxygen. The low rate of adoption of measuring oxygen saturation could be explained by low uptake of evidence practices without active reinforcement(34).

Respiratory rate was recorded in 54% of the patients. This was higher than earlier studies done conducted in the district hospitals in Kenya were the rate was recorded in 41% (84/206) of the cases(31). Counting and documenting the respiratory rate is considered a nursing procedure and the admitting clinician may rely on the nurse to inform him/her of the respiratory rate. Morris *et al* in a study of vital sign monitoring in Kenyan hospitals found that about 43% of children did not have their vital signs (Respiratory rate, heart rate and temperature) documented in the admitting clinicians' notes ken at admission–(48).The admitting clinician documented all the vital signs in 57% of the cases and none of the vital signs was documented in 8.45% of the cases. Vital signs are essential for assessment of severe

illness, the clinician should therefore take a more active role in taking the vital signs, ensuring they are recorded in the admission notes and using them in patient assessment.

Fifty – six percent of the patients 175/390 were correctly classified according to the signs and symptoms recorded. This was close to the finding in Garissa Hospital in Kenya where 55%(46/83) patients were correctly classified (49). 63 patients classified as severe pneumonia were classified retrospectively as non–severe pneumonia. Clinicians erred towards greater severity classification. Overall 83 patients were classified as non-severe pneumonia using the documented signs and symptoms. None of these patients with non-severe pneumonia got the guideline recommended antibiotic which is high dose oral amoxicillin as discussed later. This demonstrates the slow adoption of the guideline though an outpatient setting would have been more appropriate for exploration of amoxicillin for non –severe pneumonia.

The results are comparable to studies done in Peru where most patients (100%) received intravenous treatment for uncomplicated pneumonia despite the availability of effective oral antibiotics(50).

Fourteen patients were classified as very severe pneumonia, a classification that no longer exists in the current guidelines which shows failure adoption of the new guidelines though the few numbers may suggest that these may have been by an isolated number of clinicians. A total of thirty patients did not have a classification of pneumonia derived from neither the local guidelines nor any international pneumonia guidelines

Poor documentation practice among healthcare workers has been demonstrated from earlier studies done in the district Hospitals in Kenya (31) and at Kenyatta National Hospital (34). Efforts to improve the documentation practice in Kenya by the use of a structured paediatric admission record form has been shown to greatly improve the documentation of signs and symptoms necessary for the identification and classification of common illnesses in children.(14).Encouraging the admitting clinicians in KNH to use the paediatric admission

record form is one the ways that could be explored in an effort to improve the documentation practice

Only 18.06% (43/238) of the patients correctly classified as severe pneumonia patients got the guideline recommended broad spectrum antibiotics. Patients who would have benefited from alternative treatment i.e. Patients admitted in the past two weeks before the current admission or referred from a different hospital where they may have been started on the first line antibiotics, were excluded from this analysis. This is lower than Irimu's findings at KNH in 2005 where 57 % (137/265) of children with pneumonia received the appropriate treatment of pneumonia in the correct frequency and dosage in the pre-intervention period. This improved to 89.9% in the post intervention period after the introduction of CPG's and ETAT+ training. My study considered correct continuum of care, thus correct classification with subsequent correct treatment while Irimu *et al* study considered one task only – correct dosage regards of whether classification was correct or not. My study shows that few patient benefit from correct continuum of care.

KNH is a national referral hospital. The spectrum of antibiotics available at the hospital is not the same as those provided by lower level hospitals. Stronger antibiotics like carbapenems are more readily available in KNH as compared to other facilities. The accessibility to these antibiotics may be a factor in the antibiotic preference by the clinician contributing to the reduced number of patients receiving the guideline recommended antibiotics.

In our experience, some of the health care worker preferred the use of other antibiotics such as cephalosporin or carbapenems to treat severe pneumonia. This may be because some clinicians hold the opinion that the guideline recommended treatment for severe pneumonia which is injectable benzyl penicillin or ampicillin and gentamicin are not effective therefore they prefer to use other antibiotics. A randomized control study by Agweyu *et al* is currently underway to compare two antibiotics amoxicillin clavulanic or ceftriaxone against the standard treatment for patients admitted with severe pneumonia(51).

None of the patients with non- severe pneumonia received the guideline recommended treatment of high dose amoxicillin. The belief that intravenous antibiotics are superior to oral antibiotics is common among health care workers and patients. This belief is not supported by quality evidence. An audit of therapeutic interventions in children in a Peruvian hospital found that most interventions offered were improper despite the availability of efficacious, scientific based interventions(50). All the 42 (100%) patients with uncomplicated pneumonia received intravenous antibiotics despite the availability of effective oral antibiotics.

Intravenous drug therapy may cause complications. These include: Localized infection like skin abscesses, phlebitis, thrombosis and the risk of sepsis. It prolongs the duration of the inpatients stay with attendant costs of treatment and the care givers costs. This can be prevented by use of oral treatment when it is proven to be safe, available and effective.
The emergence of multidrug resistance bacterial infection is a major concern worldwide. It is driven by irrational use of antibiotics. Antibiotic misuse is often driven by the patient demands, fear of litigation and inadequate knowledge on the potential harm of antibiotics. Antibiotic stewardship programs have been established worldwide with the aims of protecting the remaining antibiotics. This includes the selecting the appropriate antibiotic, method of administration , frequency of dosing and length of antimicrobial therapy with the aims optimizing the clinical outcomes while reducing unwanted effects like drug toxicity and emergence of drug resistance. Effective antimicrobial handling and a rigorous infection control Programme have been shown to be effective in the prevention of emergence of drug resistant organisms(53).

Among the patients who had inability to drink and or reduced level of consciousness, 86.45% (83/96) had enteral feeds or intravenous fluids prescribed while only about half the patients (160/319) who had a danger sign present and no documentation that the oxygen saturation was >90% had oxygen . This could be reflective of the poor documentation practice among the clinicians for tasks done but not documented rather than as an assessment of actual clinical practice.

Some clinical guidelines like the British thoracic society advise against the use of nasogastric feeds for children who are severely ill as the tubes may further compromise the breathing in the children especially infants who already have smaller nasal passages(53). In this study we considered either nasogastric or intravenous fluids as appropriate feeding modalities.

The challenge with intravenous fluids is that they are deficient in essential nutrients to meet the increased demand during an acute illness. Fluid monitoring is also a challenge n resource limited settings because of the limited number of nursing staff available. The on-going study by Agweyu *et al* will also seek to establish whether feeding via nasogastric tube is better than giving intravenous maintenance fluids in the management of children with severe pneumonia(51).

8.1 Study Limitations

Analysis was based on the clinicians' documentation of the assessment, classification and treatment of patients with pneumonia and subsequent data entry. There is potential selection bias from missing records that were not included in the study.

Also, due to the poor documentation practice, tasks may have been performed but not documented thereby providing conservative estimates of clinical guideline adherence.

9.0 CONCLUSION

There was poor adherence to the new clinical guidelines for management of pneumonia in assessment, classification and treatment of children with pneumonia at KNH.

The adherence to the guidelines in the assessment of pneumonia was 17.7%.

Patients classified properly according to the guidelines were 44.87%.

Only 18.07% of the patients received the guideline recommended antibiotic treatment for pneumonia.

Half of the children with severe pneumonia with a danger sign present but no documentation of oxygen saturation level of >90% had oxygen prescribed at admission while 86% of the patients who were unable to feed or with a reduced level of consciousness AVPU<A had intravenous feeds /fluids prescribed at admission.

The essential supplies for the management of pneumonia at KNH were reported as always available by the health workers, with only a few health workers reporting that the supplies were mostly available.

10. RECOMMENDATIONS

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

1. Improvement of documentation practices. There is need for a system that facilitates the use of a structured admission form.
2. There is need to reinforce the use of best practices that have been agreed upon in the care of patients during ward rounds and teachings.
3. There is need to implement routine morbidity audits to help improve the quality of care given as per accepted evidence based practices.
4. It may be useful to do a qualitative study in future to understand why clinicians despite having knowledge from trainings on the recommended clinical practice guidelines, still have poor documentation practices and non-adherence to the recommended guidelines.

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12.0 APPENDICES

12.1 Time frame

The following is the time frame of the study process:

PERIOD / ACTIVI	2017		2018										
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Concept Development	■												
Proposal Development		■	■	■									
Submission to KNH-UON ERC					■	■							
Data collection							■	■					
Data analysis and poster Presentation									■	■	■		
Thesis submission												■	

12.2 STUDY BUDGET

Category	Remarks	Units	Unit Cost (KShs)	Total (KShs)
Proposal Development	Printing drafts	1000 pages	10	10,000
	Proposal Copies	10 copies	600	6,000
	KNH/UON ERC	1	2000	2,000
	Stationery (pens, notebooks	10 packs	100	1,000
	Training research assistants	1 day	1,500	1500
	Research assistant	12 weeks		135,000
Data Analysis	Statistician	1		40,000
Thesis Write Up	Computer Services			5,000
	Printing drafts	1000 pages	10	10,000
	Printing Thesis	10 copies	600	6,000
Contingency funds				30,000
Total				324,000

12.3 Data Collection Tool

The data collection tool used for this study is a subset of the REDCAP study. Only a subset of this data was used in the current study. Data extracted included, demographics, the signs and symptoms that were recorded at the time of admission, classification of the severity of pneumonia and the management prescribed. All the data captured by REDCAP is shown in the 38-page form attached overleaf.