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THE PREVALENCE OF WHEEZE IN CHILDREN WITH CLINICAL PRESENTATION OF SEVERE/VERY SEVERE PNEUMONIA AND RESPONSE TO BRONCHODILATOR THERAPY AT KENYATTA NATIONAL HOSPITAL, NAIROBI.

A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Masters of Medicine in Pediatrics and Child Health, at the University of Nairobi.

By: Dr. Virginia Maina

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DECLARATION

I declare that this is my original work and has not been presented for any academic program in any other institution.

Sign.....

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DEDICATION

To my husband, Dr Kamau, for his support and patience and to our lovely children, Gachomo and Muthoni.

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LIST OF ABBREVIATIONS

ARI: Acute Respiratory Infections

BHR: Bronchial Hyper-responsiveness

GoK: Government of Kenya

GINA: Global Initiative for Asthma

Hz: Hertz

IQR: Interquartile Range

KAPTLD: Kenya Association for Prevention of Tuberculosis and Lung Diseases

KNH: Kenyatta National Hospital

mg: milligrams

mls: milliliters

OR: Odds Ratio

PEU: Pediatric Emergency Unit

RR: Relative Risk

RSV: Respiratory Syncytial Virus

SABA: short acting beta2-agonist

SD: Standard Deviation

SOP: Standard Operating Procedure

UON: University of Nairobi

WHO: World Health Organization

ABSTRACT

Background: Wheeze is a common presentation of respiratory disease in children. In developing countries, there is a high morbidity and mortality associated with bacterial pneumonia in young children and empiric antibiotic treatment is recommended. However in the presence of wheeze and signs of pneumonia, possibility of a reversible airways disease should be considered. The objectives of this study were to determine the prevalence of wheeze in children less than five years with a clinical presentation suggestive of severe/very severe pneumonia, to determine the proportion of the children with wheeze who improved following bronchodilator therapy and the factors associated with positive response to bronchodilator therapy.

Method: This cross-sectional study was carried out at the Paediatric Emergency Unit, KNH, from June to September 2009. A total of 459 children met the eligibility criteria and were enrolled into the study. 169 of them had wheeze and were commenced on inhaled salbutamol. GoK guidelines were adhered to during the study.

Results: The prevalence of wheeze in children with signs of severe/very severe pneumonia was found to be 36.8%. The median age of children with wheeze was 11.4 months (IQR 6.6-23.7 months), with a male to female ratio of 1.1:1.The proportion of children with wheeze who responded to inhaled salbutamol was 43.8%. Absence of fever ,OR 0.41[(95%CI 0.18-0.98), p=0.04] was the only factor that was independently associated with a positive response to inhaled bronchodilators in these children.

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Conclusion:

A third of the children with features suggestive of severe/very severe pneumonia had wheeze/rhonchi. Two out of every 5 children with wheeze responded to immediate use of inhaled salbutamol at the Paediatric Emergency Unit, leading to a 16% reduction of the overall number of potential pneumonia admissions.

Recommendation:

Bronchodilator challenge is recommended for children with wheeze and signs of severe/very severe pneumonia.

INTRODUCTION AND LITERATURE REVIEW

Pneumonia is a leading cause of mortality and morbidity in young children worldwide with highest incidences occurring in developing countries.[1] In the presence of wheeze and clinical presentation of pneumonia, asthma should be considered as a possible diagnosis and immediate initiation of bronchodilator therapy is recommended prior to further evaluation of the child.[2]

Wheezes and rhonchi are sounds whose duration is 250milliseconds or more. Wheezes have a hissing or less often a musical character, their dominant frequency is 400 Hertz (Hz); when wheezes are musical, they can generate frequencies of up to 1000Hz. Rhonchi are lower pitched; with frequency predominantly below 200 Hz .Wheeze may be audible or auscultatory.[3]

Wheeze is produced by oscillation of opposing walls of an airway narrowed almost to the point of closure. It may be high or low pitched, consist of single or multiple notes, and occur during inspiration or expiration. Wheezes originate from airways of any size from large extra thoracic upper airways to the intrathoracic small airways. Wheezing requires not only a narrowed or compressed airway but also sufficient airflow to generate airway oscillation and produce sound; thus the absence of wheeze in severe asthma may be an ominous finding suggesting impending respiratory failure.[4]

Wheezing is a common symptom of respiratory disease throughout childhood. By one year of age, one in four children have at least one wheezing episode and by six years of age, one in two children will have experienced an episode of wheeze.[5] Studies done in Africa show a wheeze prevalence of between 2% in Ethiopia and 26% in South Africa, with a higher occurrence in the urban areas compared to rural areas.[6, 7] The prevalence of

wheeze in Kenya according to the Kenya Association for Prevention of Tuberculosis and Lung Diseases is ten percent in children ten years of age.[8]

Wheeze as a symptom can either be acute or chronic/recurrent. Acute causes of wheeze in children under the age of five years include asthma, pneumonia, bronchiolitis, foreign body aspiration, peritonsillar abscess, retropharyngeal abscess. Chronic (recurrent) causes may be classified into two groups, structural and functional abnormalities. Structural abnormalities include tracheobronchomalacia, vascular rings, tracheal stenosis, tracheal webs, cystic lesions, tumors, lymphadenopathy, cardiomegaly, adenotonsillar hypertrophy, and retrognathia in Pierre Robin Syndrome. Functional abnormalities include asthma, gastro esophageal reflux, recurrent aspiration, cystic fibrosis, primary ciliary dyskinesia, bronchopulmonary dysplasia, retained foreign body, bronchiolitis obliterans, pulmonary edema and vocal cord dysfunction.[3]

Acute respiratory infections constitute a major cause of morbidity and mortality particularly in children less than 5 years of age. Pneumonia is the severe form of the acute respiratory infections. The proportion of childhood deaths attributed to ARI varies, with the highest percentage (22%) occurring in Africa.[1]

The etiology of ARI also varies among different parts of the world with more bacterial infections occurring in the developing countries, unlike the developed countries where viral infections predominate.[9] Developing countries are thus the focus of the WHO ARI programme, where the primary aim is to identify and provide timely antibiotic therapy to children with pneumonia. The secondary aim, on the other hand, seeks to identify children with wheeze and use of a bronchodilator therapy in the management of these children.[9]

Clinical features associated with pneumonia in young children include prodromal symptoms of an upper respiratory tract infection, typically rhinitis and cough. Fever, tachypnea, increased work of breathing accompanied by intercostal, subcostal, and suprasternal retractions and nasal flaring. Cyanosis and respiratory fatigue is often in infants with severe disease. Auscultation of the chest may reveal crackles and wheezing.[10]

Viral infections in children younger than 2 years of age, frequently result in bronchiolitis.The respiratory syncytial virus is the predominant pathogen in over 80% of the cases. Other viruses that have been implicated include parainfluenzae virus, influenzae virus, adenovirus and rhinovirus.[9] The viruses colonize the bronchiolar epithelium, where they replicate resulting in necrosis, as well as secretion of mucus and edema resulting in airway narrowing.[3]

Bronchiolitis typically presents with coryzal symptoms and mild fever before progressing to a lower respiratory tract infection with signs of respiratory tract obstruction i.e. an irritating cough, tachypnea, wheeze, chest in drawing, nasal flaring, suprasternal recession and difficulty in feeding and widespread expiratory wheeze is heard on auscultation[9].There is no response to bronchodilators in bronchiolitis.[11]

Asthma is a non infectious condition in which there is reversible airway obstruction. It is characterized by hyper responsiveness of the tracheobronchial smooth muscle to variety of stimuli, resulting in narrowing of the airways often accompanied by increased secretions, mucosal edema, and mucus plugging .The trigger factors for airway hyper sensitivity include infection, irritants such as cigarette smoke, pollution, exercise, weather changes, dust and cold air.[12]

Mast cells and inflammatory cells are recruited and they release chemical mediators and adrenaline stored in their granules, release phospholipids from membranes followed by further mediator synthesis. This result in bronchoconstriction of smooth muscles, lead to mucosal edema and produce viscid secretions. There is also involvement of parasympathetic neural reflexes.[10]

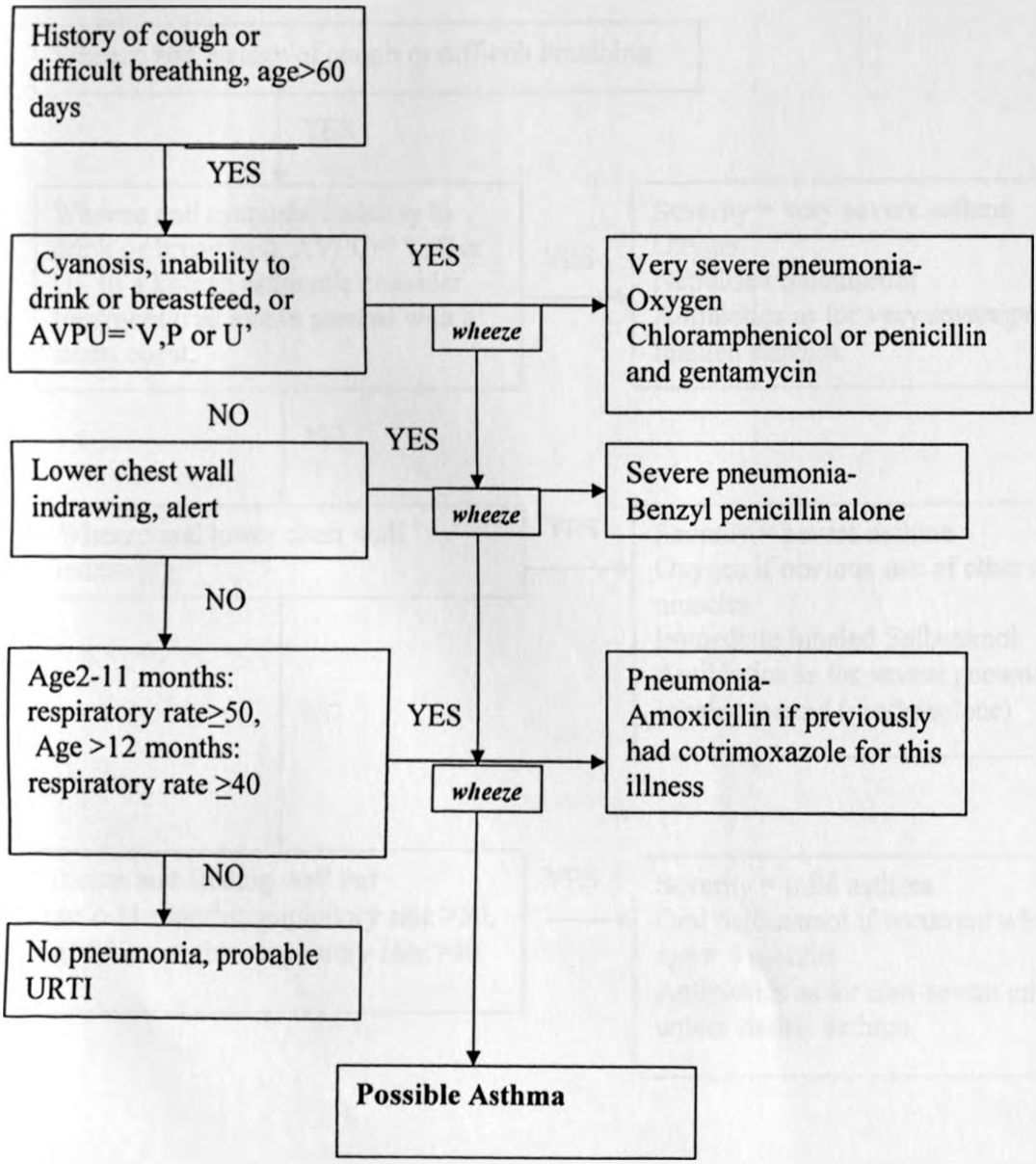
Asthma exacerbations can occur spontaneously or on exposure to allergens. Signs during asthma exacerbations apart from wheezing and prolonged expiration are tachycardia, rhonchi, paradoxical pulse, chest hyperinflation and use of accessory muscles of respiration. In extreme presentations, air flow may be so limited so and that the chest is quiet as the peripheral airways obstruction is so severe that the child is unable to generate sufficient turbulence in the large airways to produce a wheeze.[9]

The diagnosis of asthma in children under five is difficult. It relies on the patient's history such as intermittent episodes of wheezing that are usually the result of a trigger (upper respiratory tract infections, weather changes, allergens, exercise), seasonal variation, family history of asthma and/or atopy, and a good response to bronchodilator therapy.[6]

A young child presenting with the signs and symptoms of pneumonia, may be having an acute asthmatic attack since both diseases have a similar clinical presentation.

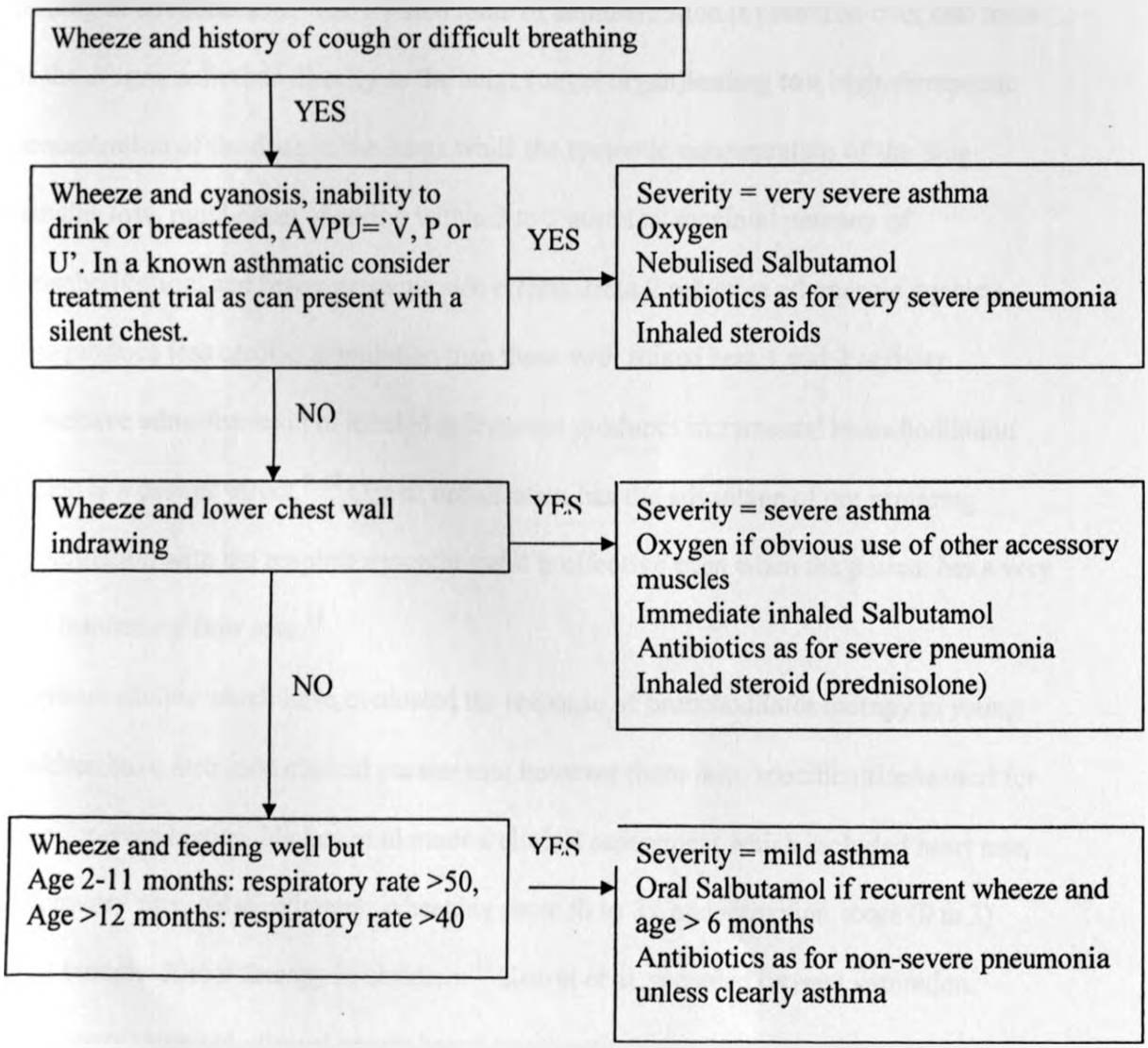
The Government of Kenya (GoK) and World Health Organization (WHO) have thus developed Paediatric protocols with the aim of aiding health workers in identification and treatment of pneumonia as shown in figure 1 below.[2,13]

Figure 1.Pneumonia protocol for children aged 2 months to 5 years (WHO/GoK Guidelines)



The Government of Kenya/WHO recommends immediate bronchodilator therapy during the admission of a young child with wheeze, prior to further evaluation as shown in figure 2 below.[2]

Figure 2: Admission management for a wheezy child



Management of wheeze

The primary drug of choice for relief of reversible airway obstruction is Salbutamol (Albuterol).It is a short acting beta 2 agonist which stimulates beta receptors by increasing cyclic Adenosine Monophosphate formation in the bronchial smooth muscle leading to its relaxation.[3] The inhaled route of administration is preferred over oral route as the drug is delivered directly to the lungs (target organ)leading to a high therapeutic concentration of the drug in the lungs while the systemic concentration of the drug remains low, rapid onset of action within 2 to 5 minutes, maximal potency of bronchodilation, and fewer systemic side effects. Beta 2 selective adrenergic agonists also produce less cardiac stimulation than those with mixed beta 1 and 2 activity. Repetitive administration of inhaled Salbutamol produces incremental bronchodilation which is a desired effect.[9, 12] Use of nebulization has the advantage of not requiring coordination with the respiratory cycle and it is effective even when the patient has a very low inspiratory flow rate.[11]

Previous studies which have evaluated the response of bronchodilator therapy in young children have also used clinical parameters; however there is no specific criteria used for a uniform evaluation. Hickey et al made a clinical assessment which included heart rate, respiratory rate, pulse oximetry, wheezing score (0 to 3), and retraction score (0 to 3) after bronchodilator therapy in children. [14] Korrpi et al, recorded oxygen saturation, respiratory rates and clinical scores based on wheezing and chest retraction as the outcome measures.[15] Chavasse et al reviewed the effect of inhaled albuterol in young children and the main outcome measure was improvement in respiratory rate.[16]

Studies on wheeze and pneumonia/asthma

A number of studies have specifically evaluated children aged up to five years presenting with wheeze and WHO defined signs of pneumonia and the response to bronchodilator therapy. Hazir T et al carried out a prospective study on 1622 children aged between 1-59 months with auscultatory/audible wheeze, tachypnea and/or lower chest wall in drawing. Improvement was noted if the signs such as tachypnea, lower chest wall indrawing resolved with bronchodilator use. Children who were classified as non severe pneumonia reported a 62% response, while only 27% of the children who were initially classified as severe pneumonia showed a positive response to bronchodilator therapy and were managed as acute asthma, no antibiotics were given. Predictors of subsequent deterioration that were identified in the study were absence of a family history of wheeze and fever above 100 degrees Fahrenheit.[17]

Lochindarat et al ,Thailand,at a referral hospital documented response to upto three doses of inhaled salbutamol in children aged 1 to 59 months. 534 children with wheeze and fast breathing (WHO defined non severe pneumonia) and lower chestwall indrawing(WHO defined severe pneumonia) were studied over a 16 month period.85.2% and 72% of the children with non severe pneumonia and severe pneumonia respectively responded to inhaled salbutamol. Age between 1 and 11 months was identified as an independent predictor of subsequent deterioration.[18]

Sachdev HPS et al, at an urban tertiary hospital, carried out a prospective study in children under five years of age with difficult breathing (as defined by WHO algorithm).The predominant condition was acute asthma at 54%.Other conditions were pneumonia with bronchospasms (18%), pneumonia without wheeze(10%) and other

diagnosis not related to the respiratory system such as congestive cardiac failure due to anaemia or congenital heart disease at 18%.[19]

STUDY JUSTIFICATION

Wheeze is the hallmark of narrowed airways and is a common presentation in children with acute respiratory symptoms. Wheezes/rhonchi are usually accompanied by fast breathing with or without lower chest wall indrawing due to use of respiratory accessory muscles. Both tachypnea and lower chest wall indrawing respond promptly to Salbutamol in children with primary hyper reactive airway disease. This is important because these (tachypnea and lower chest wall indrawing) are cardinal features used to categorize the severity of pneumonia, and appropriate bronchodilator (Salbutamol) challenge in a child with wheeze and tachypnea and/or lower chest wall indrawing may lead to a change in severity of the disease category and consequently alter the mode of treatment.

There is limited local data on the prevalence of wheeze among children attending the Paediatric Emergency Unit, KNH. There is also no data on the children who present with wheeze and features suggestive of pneumonia and their response to bronchodilator therapy at the Paediatric Emergency Unit. It would be useful to determine the proportion of children with wheeze/rhonchi who improve after bronchodilator therapy as this may lead to a potential decline on the cost of therapy and hospitalisation.

STUDY UTILITY

The results of this study will characterise the specific nature of the population of children (2-59 months) who present at the Paediatric Emergency Unit, Kenyatta National Hospital with wheeze/rhonchi and signs of severe/very severe pneumonia. The study will demonstrate whether bronchodilator therapy at the Paediatric Emergency Unit has an immediate response on the child, and if the response will lead to a reduction in the number of children with wheeze who are eventually admitted for hospital care. It will assess the effectiveness of the current government management guidelines that are recommended for use in Kenyatta National Hospital for children with wheeze and signs of severe/very severe pneumonia. The results of this study will give the Paediatric Health Management Team a useful estimate of the number of children who present to the Paediatric emergency with wheeze/rhonchi and signs of pneumonia, and thus enable effective planning, appropriate resource allocation and commodity procurement.This study may also act as a basis for further research projects.

RESEARCH QUESTION AND OBJECTIVES

RESEARCH QUESTION

What is effectiveness of nebulization with salbutamol in reducing admission rates of paediatric patients 2-59 months diagnosed with severe and very severe pneumonia with wheeze?

Hypothesis: Null hypothesis -Nebulization with salbutamol does not reduce the admission rates of paediatric patients under five years old with a diagnosis of severe and very severe pneumonia with wheeze.

Alternative Hypothesis - Nebulization with salbutamol reduces the admission rates of paediatric patients under five years old with a diagnosis of severe pneumonia with wheeze.

OBJECTIVES

Primary objectives

1. To determine the prevalence of wheeze among children presenting with signs of severe and very severe pneumonia at the Kenyatta National Hospital.
2. To determine the proportion of children presenting with wheeze/rhonchi and clinical features of severe/very severe pneumonia who show a clinical improvement following use of inhaled Salbutamol.

Secondary objectives

1. To describe the demographic and clinical correlates of children with wheeze/rhonchi and signs of severe/very severe pneumonia who show a clinical improvement after administration of inhaled Salbutamol.

METHODOLOGY

a) Study area- The study was carried out at Kenyatta National Hospital, Pediatric Emergency Unit. KNH is a national referral and teaching hospital located in Nairobi, Kenya. It serves patients mainly from low and middle level income bracket in Nairobi and its environs.

b) Study duration – This study was carried out over a period of four months, that is from June 2009 to September 2009.

c) Study population- Children aged 2-59 months who presented to Pediatric Emergency Unit during the study period.

d) Study design-descriptive cross sectional study

e) Sample size calculation-

Fishers Formula for prevalence:

$$N = \frac{Z^2 p(1-p)}{D^2}$$

Where -N = minimum sample size

Z = standard normal deviate for 95% confidence interval (= 1.96)

P = estimated prevalence of wheeze-10%.

D = degree of precision (5%)

N=138 children

f) Sampling method- consecutive sampling of eligible participants

g) Inclusion/ exclusion criteria

Inclusion Criteria:

- Age 2 to 59 months with signs of severe and very severe pneumonia according to the GoK/WHO criteria(see clinical definitions)
- Informed consent from parent or guardian

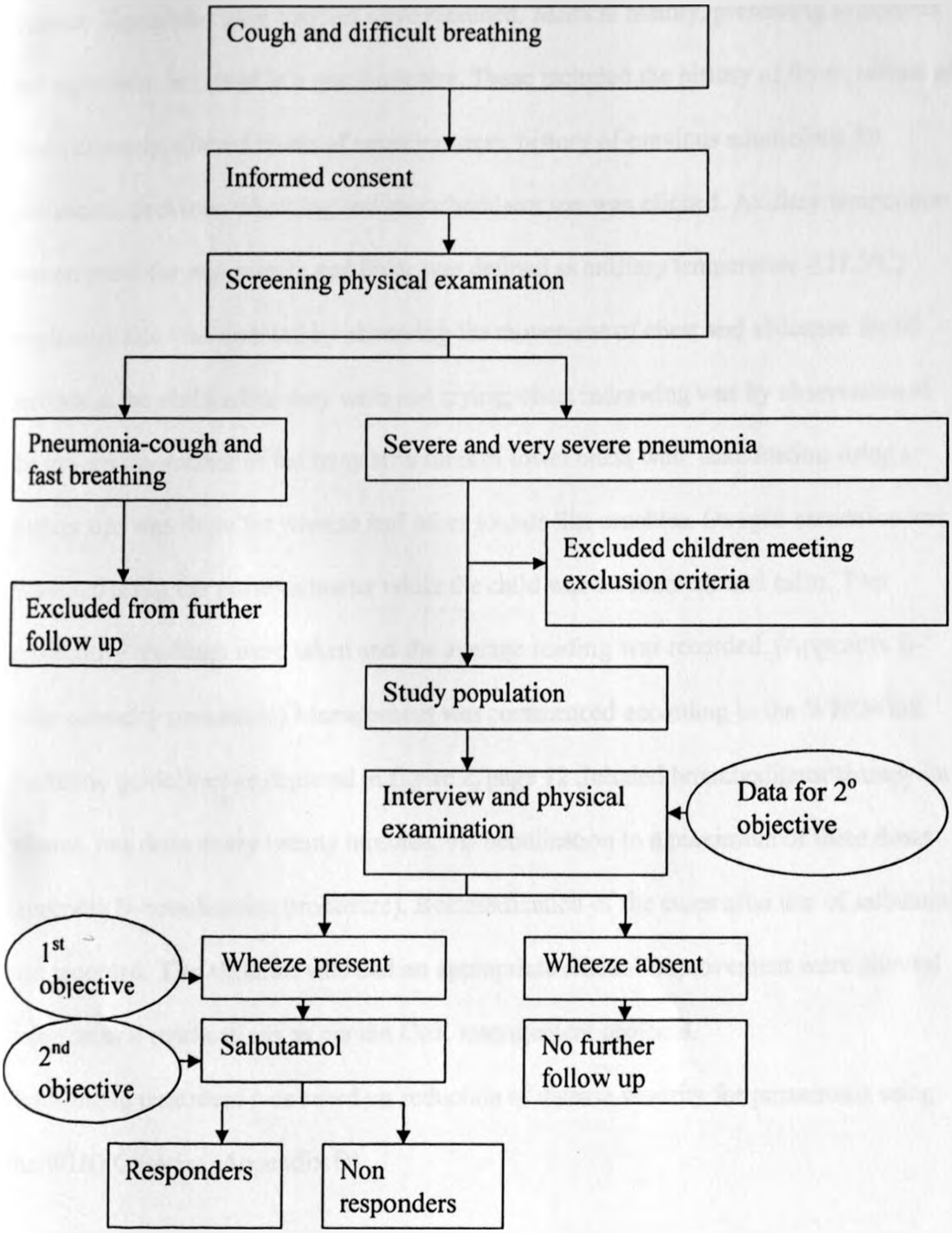
Exclusion Criteria:

- Known chronic renal or cardiac disease or presence of primary neurological abnormality likely to cause respiratory distress
- Established bronchiectasis or congenital abnormality of the lower respiratory tract
- Admission from outpatient clinic specifically for treatment of TB
- Failure to obtain informed consent

h) Materials

Nebulization was carried out at the Paediatric Emergency Unit using the hospital nebulizer. Oxygen saturation was measured using a pulse oximeter, Nellcor NPB-40 CA, USA. This oximeter has an accuracy of +/- 1SD for oxygen saturation values between 70% - 100%.

i) Figure 3 :Flow chart of patient flow and recruitment



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j) Study procedure: once the child met the inclusion criteria, the principal investigator gave the child's guardian an explanation of the study before requesting for consent. Those who gave consent were recruited. Medical history, presenting symptoms and signs were recorded in a questionnaire. These included the history of fever, refusal of feeds, cyanosis, altered levels of consciousness, history of previous admissions for pneumonia, previous wheezing and bronchodilator use was elicited. Axillary temperature was recorded for one minute and fever was defined as axillary temperature ≥37.5°C; respiratory rate was counted by observing the movement of chest and abdomen for 60 seconds in the child when they were not crying; chest indrawing was by observation of the inward movement of the bony structures of lower chest wall, auscultation using a stethoscope was done for wheeze and other sounds like crackles. Oxygen saturation was measured using the pulse oximeter while the child was on room air and calm. Two consecutive readings were taken and the average reading was recorded. (Appendix B-pulse oximetry procedure).Management was commenced according to the WHO/GoK Paediatric guidelines as depicted in figure 2, page 12 .Inhaled bronchodilator therapy for wheeze, one dose every twenty minutes, via nebulization to a maximum of three doses (appendix B-nebulization procedure). Reclassification of the cases after use of salbutamol was recorded. The children who had an appropriate clinical improvement were allowed home on oral medications as per the GoK management protocol.

Response to treatment was based on reduction of disease severity for pneumonia using the WHO Criteria. (Appendix D)

k) Ethical considerations

A written consent was sought from the Ethical and Research committee of Kenyatta National Hospital before embarking on the study. For the children recruited, consent from the parent/guardian was obtained before enrolment into the study (Appendix A). The importance and relevance of the study was explained to guardian/ parents. Information obtained was treated with the highest confidentiality and was used for the intended purpose only.

l) Data management

A pilot study was conducted to test all procedures involved in data collection and to standardize the collection of data to be performed. Data collection was based on a questionnaire in which the study population was described using demographic and clinical characteristics. Data entry and verification was done using Epi info. Analysis was conducted using STATA V.10 (Statacorp, Texas). Descriptive analysis was conducted for all the demographic and clinical variables. For continuous variables, such as age, a measure of central tendency and appropriate measure of dispersion like IQR was calculated. Prevalence was determined as the proportion of children with severe and very severe pneumonia who had wheezing. Confidence interval around this point prevalence was calculated using standard techniques. Correlates of wheezing were determined by comparing children with wheeze versus those without wheeze. Prevalence of response to wheezing was determined by proportion of children with wheeze who respond to treatment with bronchodilators.

Bivariate analysis: Correlates of response was determined by a sub analysis restricted to children with wheeze at baseline and comparing the children who responded versus those

who did not respond to the bronchodilator therapy. Each of the variables was cross tabulated against the outcome (response to inhaled salbutamol) and the Relative Risk and 95% Confidence Interval were calculated.

Multivariate analysis: This was conducted using Logistic Regression with response to inhaled bronchodilators as the outcome; and the significant variables in the bivariate analysis as independent variables.

RESULTS

The study was carried between the months of June 2009 to September 2009 at Kenyatta National Hospital, Paediatric Emergency Unit. We recruited 459 children with signs of severe and very severe pneumonia who met the inclusion criteria.

A: DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE GENERAL STUDY POPULATION.

Study participants were aged between 2 and 59 months with a median (IQR) age of 9.4 (5.3-17.2) months. Most (62.1%) of the participants were infants. Males were 49% giving a male to female ratio of 0.9: 1. Majority (81.6%) of the children gave a history of fever. One hundred and eighty two (42.7%) children had worsening of the cough at night. Only 22 (5%) children had cyanosis. In the past medical history, a third of the children were reported to have had wheezing episodes as is shown in table 1.

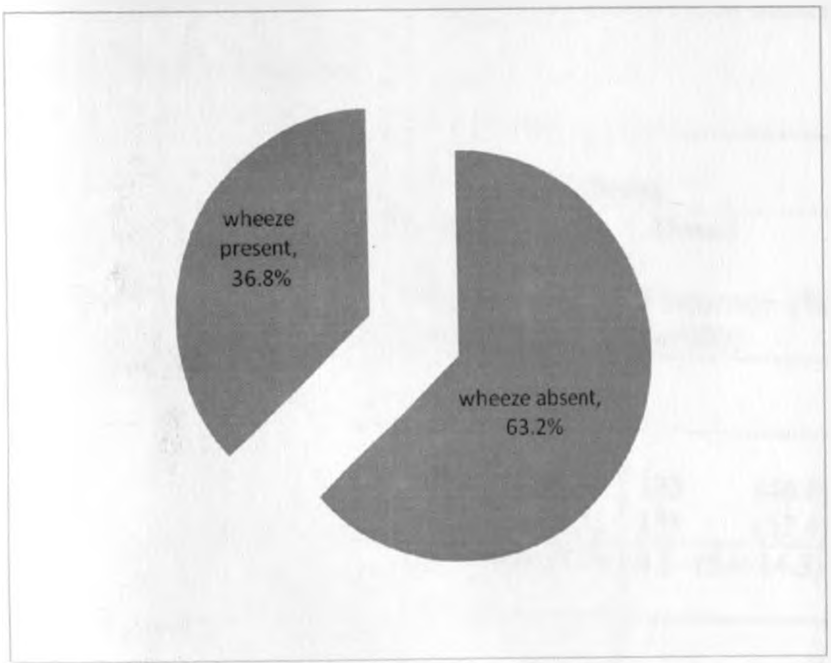
Table 1: Characteristics of the general study population

Demographic characteristics	**Frequency (n=459)**	**(%)**
Gender		
Male	225	(49.0)
Female	234	(51.0)
Age in months- median (IQR)	9.4	(5.3-17.2)
Clinical characteristics of the children on presentation to hospital		
Duration of cough (days)	4.0	(2.0-7.0)
Cough worse at night	182/426	(42.7)
History of fever	354 /434	(81.6)
Cyanosis	22/441	(5.0)
Positive family history of asthma	79/424	(18.6)
Past medical history		
Wheeze in last 12 months	129/427	(30.3)
Previous admission for pneumonia	101/437	(23.1)
Previous bronchodilator use	112/416	(26.9)

B) PREVALENCE OF WHEEZING AND COMPARISON OF CHIDREN WITH WHEEZE VERSUS THOSE WITHOUT WHEEZE

One hundred and sixty nine out of the 459 children (36.8%,95% CI 32.4%-41.4%) had wheeze, as shown in figure 1 below.

i) Figure 4- Prevalence of wheeze among children classified as severe and very severe pneumonia.



ii) Comparison of children with wheeze versus those without wheeze.

Children with wheeze were likely to be older compared to those without wheeze, median age 11.4 months versus 8.3 months respectively ($p < 0.001$).

Wheezing children were twice as likely to have worsening of symptoms at night, RR= 2.61[(95%CI 1.98, 3.42) $p<0.001$]. Cyanosis was infrequent but equally likely in children with wheeze and those without wheeze, 6 (3.7%) of 163 versus 16(5.8%) of 278 children ($p=0.334$).

Children with wheeze had a 51% lower likelihood of presenting with fever

compared to those without wheeze, RR 0.49[(95%CI 0.39, 0.63) p=<0.001]. Compared to children without wheeze, those who presented with a wheeze were more likely to have a family history of asthma in a first degree relative RR 1.93[(95%CI 1.52, 2.44) p=<0.001], report wheezing in the last 12 months RR [3.91(95%CI 3.04, 5.04) p=<0.001], and report previous use of bronchodilators RR [3.90(95% CI 3.04,5.01) p=<0.001]. This is presented in table 2 below.

Table 2: Demographic and Clinical characteristics of children with wheeze versus those without wheeze.

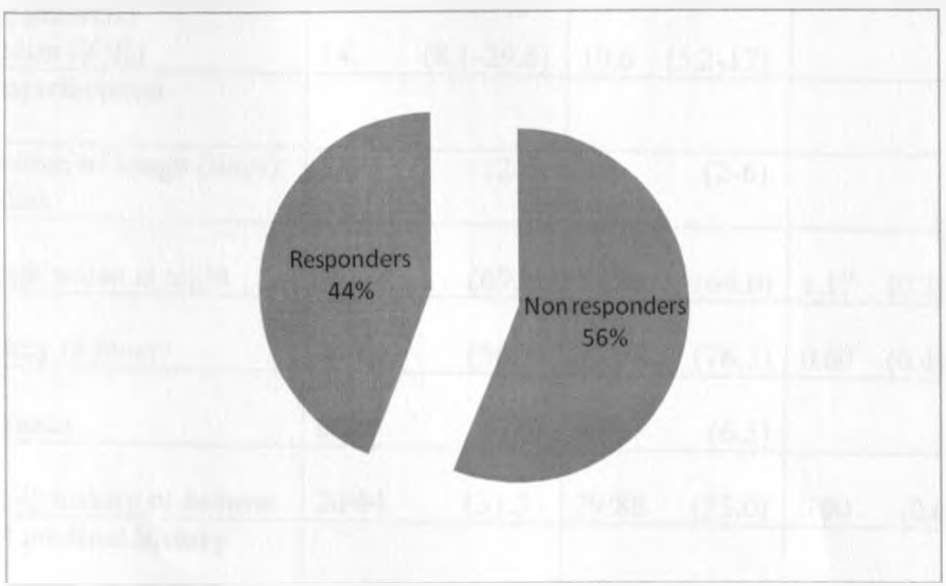
	Wheeze		Relative Risk	P value
	Present Frequency (%) (n=169)	**Absent** Frequency (%) (n=290)	**(95% CI)**	
Demographic factors				
Gender				
Male	90 (53.3)	135 (46.6)		
Female	79 (46.7)	155 (53.4)	1.18 (0.93-1.5)	0.166
Age (months) median (IQR)	11.4 (6.6-23.7)	8.3 (5.0-14.3)	-	<0.001
Characteristics				
Duration of cough (days) median	3.0 (2 - 7)	4 .0 (3 - 7)	-	0.068
Cough worse at night	102/154 (66.2)	80/249 (29.7)	2.61 (1.98-3.42)	<0.001
History of fever	105/153 (68.6)	249/281 (88.6)	0.49 (0.39-0.63)	<0.001
Cyanosis	6/163 (3.7)	16/278 (5.8)	0.73 (0.36-1.46)	0.334
Family history of asthma	49/152 (32.2)	30/263 (11.4)	1.93 (1.52-2.44)	<0.001
Past medical history				
Wheeze over last 12 months	99/156 (63.5)	30/168 (11.2)	3.91 (3.04-5.04)	<0.001
Previous admission for pneumonia	44/160 (27.5)	57/277 (20.6)	1.26 (0.97-1.65)	0.098
Previous bronchodilator use	88/146 (60.3)	24/260 (9.2)	3.90 (3.04-5.01)	<0.001

C: RESPONSE TO BRONCHODILATOR THERAPY

In this analysis, the children who had wheeze and signs of severe/very severe pneumonia were nebulized with salbutamol. They were subsequently categorized into two groups, responders and non responders.

Overall seventy four (43.8 %,(95% CI 36.2%-51.6%) of the 169 children who presented with a wheeze responded to nebulization with salbutamol. See figure 2 below. This accounts for 16% (74/459) of the overall number of children recruited into the study.

Figure 5: Proportion of wheezing children classified as severe and very severe pneumonia who responded to bronchodilator therapy.



(ii) Comparison of wheezing children classified as severe and very severe pneumonia who responded to bronchodilator therapy versus the non-responders

Older children were more likely to respond to bronchodilator therapy. The median age of the responders was 14 months (IQR 8.1, 29.8) compared to 10.6 months

(IQR 5.2, 17) for the non responders (p=0.009).

Children with history of fever were less likely to respond to bronchodilator therapy [RR 0.6(0.41, 0.87) p=0.01].However, response to inhaled bronchodilators was not significantly associated with gender, past medical history or other clinical characteristics as presented in table 3 below.

Table 3: Comparison of responders versus non responders of bronchodilator therapy

	Bronchodilator therapy		**Relative Risk**	**P value**
	Responders Frequency (%) (n=74)	**Non responders** Frequency (%) (n=95)	**(95% CI)**	
Demographic factors				
Gender				
Male	44 (59.5)	46 (48.4)		
Female	30 (40.5)	49 (51.6)	0.78 (0.55-1.10)	0.154
Age (months) median (IQR)	14 (8.1-29.8)	10.6 (5.2-17)	-	0.009
Characteristics				
Duration of cough (days) median	3.0 (2-6)	3.0 (2-6)	-	0.936
Cough worse at night	47/68 (69.1)	55/86 (64.0)	1.17 (0.79-1.72)	0.425
History of fever	34/60 (56.7)	71/93 (76.3)	0.60 (0.41-0.87)	0.01
Cyanosis	0/70 (0.0)	6/93 (6.5)	-	-
Family history of asthma	20/64 (31.3)	29/88 (33.0)	0.90 (0.6-1.36)	0.61
Past medical history				
Wheeze in last 12 months	46/65 (70.8)	53/91 (58.2)	1.39 (0.91-2.13)	0.11
Admission for pneumonia previously	19/65 (29.2)	25/95 (26.3)	1.09 (0.73-1.64)	0.685
Previous bronchodilator use	43/59 (72.9)	45/87 (51.7)	1.81 (0.48-1.37)	0.421

D. PREVALENCE OF ATOPY AND EFFECT ON RESPONSE TO TREATMENT WITH INHALED BRONCHO DILATORS

Among the children with wheeze and severe/very severe pneumonia evaluated for atopy, the prevalence of atopic dermatitis, allergic conjunctivitis and allergic rhinitis were 22%, 17.3% and 20.9% respectively. This is presented in table 4 below.

Table 4: Prevalence of Atopy among the study participants with wheeze

Characteristic	(n=262) (%)	95% Confidence Interval
Atopic Dermatitis	38 (22)	17.2 - 30.7
Allergic Conjunctivitis	28 (17.3)	11.8 - 24.0
Allergic Rhinitis	34 (20.9)	15.1 - 28.2

Children who responded to bronchodilator therapy were compared to those who did not respond using the atopic features at time of evaluation. Children with features of Atopic dermatitis and Allergic rhinitis responded more frequently to bronchodilator therapy, while children with Allergic conjunctivitis had a reduced likelihood of response to bronchodilator. Nevertheless these findings did not attain statistical significance. Response to inhaled bronchodilator is shown in table 5 below.

Table 5: The prevalence of various manifestations of atopy among children presenting with a wheeze and association with response to bronchodilator therapy.

Characteristic	Responders (n=70) (%)	Non responders (n=92) (%)	
Atopic Dermatitis	21 (30)	17 (18.5)	
Allergic Conjunctivitis	9 (12.9)	19 (20.7)	[illegible]
Allergic Rhinitis	16 (23.5)	18 (19.4)	1.03 (0.68-1.57)

E. EXPOSURE TO BIOMASS FUELS AND PETS IN THE HOUSEHOLD AND RESPONSE TO INHALED BRONCHO DILATORS IN WHEEZY CHILDREN

Kerosene (44.8%) was the most commonly used house hold fuel. Firewood was rarely used (5.5%).Only ten (6.1%) of the 163 children with wheeze were exposed to pets in the home. This is summarized in table 6 below.

Table 6: Prevalence of exposure to polluting bio-fuels and pets among children with wheeze.

Cooking fuel	**Frequency**	**(%)**
Firewood	8/145	(5.5)
Charcoal	39/145	(26.9)
Kerosene	65/145	(44.8)
Cooking gas	33/145	(22.8)
Presence of pets in the home	10/163	(6.1)

Use of kerosene at home was associated with non response to bronchodilator therapy. Kerosene was used by 52% of the non responders compared to 35% of the responders [RR 0.63 (0.43, 0.95) p=0.02].For the other house hold fuels there was no statistically significant association. This is presented in table 7 below.

Table 7: Association between bronchodilator response in children with wheeze and exposure to cigarette smoke / polluting bio-fuels in the home.

Characteristic	**Responders Frequency (%)**	**Non responders Frequency (%)**	**Relative Risk (95% CI)**	**P value**
Smoker in the household	11/65 (16.9)	21/95 (22.1)	0.81 (0.48-1.37)	0.42
	N=60	**N=85**		
Kerosene	21 (35)	44 (51.8)	0.63 (0.43-0.95)	0.02
Cooking gas	18 (30)	15 (17.6)	1.32 (0.91-1.92)	0.16
Firewood	4 (6.7)	4 (4.7)	1.15 (0.56-2.35)	0.72
Charcoal	17 (28.3)	22 (25.9)	1.0 (0.66-1.49)	0.98
Presence of pets in the home	4/70 (5.7)	6/93 (6.5)	0.93 (0.42-2.02)	0.85

MULTIVARIATE ANALYSIS

After adjusting to the age and household fuel, history of fever was the only independent factor in response to bronchodilators.

Children with a history of fever were less likely to respond to bronchodilator therapy. The odds of response to bronchodilators among children with fever was 0.4 times that of a child without fever [(OR 0.41 (0.18, 0.98) p=0.04].

Use of kerosene was not associated with response to therapy in the adjusted analysis, as shown in table 8 below.

Table 8: Independent factors associated with response to bronchodilators

	Odds ratio (95% Confidence interval)		**P value**
Age of the child (months)	1.02	(0.99-1.04)	0.11
Fuel used in household:			
Cooking gas	1.00	-	-
Firewood	0.90	(0.16-5.06)	0.90
Charcoal	1.02	(0.37-2.82)	0.98
Kerosene	0.59	(0.23-1.54)	0.29
History of fever	0.39	(0.18-0.87)	0.02

DISCUSSION

The prevalence of wheeze among children who presented with signs suggestive of severe and very severe pneumonia according to the WHO/GoK guidelines was 36.8% at the Kenyatta National Hospital.

Our findings were similar to studies reporting prevalence of wheezing among children with signs of pneumonia in tertiary hospital settings within other developing countries.[17, 19] The prevalence of wheezing in children with features of pneumonia diagnosis ranged from 22% in India to 38.2% in Pakistan.[17, 19] More recent studies have reported increasing prevalence as high as 50.7%.[18] In this latter study from Thailand, the period of observation spanned 16 months including two seasonal peaks possibly explaining the higher prevalence compared to our study.

Generally prevalence of wheezing in hospital based studies is higher than in community based studies. Further to this, in community based studies, lower prevalence has been reported in rural population compared to urban 2.1% versus 26.8% respectively.[6] Our study was in an urban hospital population and not surprising documented prevalence is higher. Other observed trends include higher prevalence of wheezing in developed countries than in developing nations.[7]The differences in prevalence may also be a reflection of the study design among the various references.

From our study, factors that were significantly associated with wheeze were older age of the child, cough at night, absence of fever, family history of asthma and previous bronchodilator use. Comparable to this study, Salem et al showed that in children aged

less than five years, 44.8% of the children with wheeze had a positive family history compared to 15.1% without a wheeze.[20] From our study, among the wheezing children, two thirds had previous wheezing episodes and about one third had been admitted previously with pneumonia. Similar observations have been made by Cardoso et al in Brazil.[21] During the three year study of children under five years, recurrent episodes of wheeze were observed in 47% of the children.[21]

Overall, 44% of children presenting with wheeze and clinical features of severe/very severe pneumonia demonstrated a clinical improvement following use of inhaled Salbutamol.This constituted 16% (74/459) of all the children enrolled into the study. In a similar study done in Pakistan, 26.8% children with wheeze responded to inhaled salbutamol delivered via a metered dose inhaler.[17] The Thailand study demonstrated a 72% response following administration of nebulized salbutamol. The participants were similar to our study population as they were aged between one and fifty nine months, however the participants were recruited if they had wheeze, tachypnea and/or lower chest wall indrawing and signs of very severe pneumonia.[18] The different rates of response may be attributed to patient selection (varying severity of illness) or method of administration of inhaled salbutamol.

Alves da Cunha in Brazil studied children under 5 years with fast breathing, and reported an 87.6% response to bronchodilators. The participants had less severe illness when compared to our study population.[23] Savitha et al reported that non response to bronchodilators occurred in children with pneumonia as suggested by presence of

pulmonary infiltrates in chest radiograms, 60% of children without pulmonary infiltrates responded to inhaled salbutamol compared to only 12.5% with pulmonary infiltrates.[24]

The only independent factor to bronchodilator response in our study was absence of history of fever. Similar findings were by Hazir et al where history of fever was the most sensitive (82.7%) predictor of non response to bronchodilator therapy.[17] Absence of fever was also associated with response to bronchodilators by Castro et al.[25]

Our study showed that kerosene use in the household was significantly associated with wheeze but not with response to bronchodilator therapy, while presence of atopy and exposure to tobacco smoke in the household were more likely in these children though they were not significant in bronchodilator therapy response. Dagoye in Ethiopia found that the main risk factor for wheeze in children under 5 years of age were kerosene use in the home and environmental tobacco smoke.[26] Use of biomass fuels like kerosene was significantly associated with wheeze, atopic dermatitis and allergic rhinitis.[27] In Connecticut and Virginia, USA, Triche et al studied infants with exposure to biomass fuels as indoor heating sources, and showed that use of kerosene was associated with episodes of cough.[28] However Salem et al found there was no significant association of wheeze and kerosene use or exposure to tobacco smoke.[20]

Our study strengths included continuous collection of data collection for 24 hours, seven days a week, throughout the study period which minimized the chances of selection bias arising from differences in characteristics of patients presenting to hospital on different

days e.g. weekends or different times of the day. It was conducted over a considerable time period of four months part of which was the cold season with a high number of acute respiratory infections. Importantly, we also achieved high rates in terms of completeness of information for children with the exposure of interest (wheeze). Conversely, the possible study limitations included recall bias by parents reporting past wheezing and the use of bronchodilators in prior illness. There may have been observer bias since the principal investigator classified the severity of illness and recorded the outcome after intervention. Use of standardized criteria of enrolment into the study and classification of severity of illness possibly minimized this bias. Despite these limitations, the findings added to the limited existing literature on the management of children with pneumonia and wheeze in Kenya and Africa as a whole. There is need to conduct similar studies in other facilities at all levels of care in our settings to improve on generalisability.

CONCLUSIONS

1. The prevalence of wheeze in children with signs of severe/very severe pneumonia is 36.8%.
2. Out of the 169 children with wheeze, 74 (44%) of these children responded to inhaled salbutamol administered at the emergency department.
3. The only independent factor associated with response was absence of fever.
4. Among wheezing children, history of wheezing, bronchodilator use and atopy other than atopic dermatitis are not predictive of response to bronchodilator therapy in the current illness.

RECOMMENDATION

1. Children with wheeze/rhonchi and features suggestive of severe/very severe pneumonia should be given inhaled salbutamol.

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APPENDICES

APPENDIX A: INFORMATION AND CONSENT FORM

PART A: INFORMATION SHEET

The following information is to enable you to give voluntary informed consent to your participation in this study. Please read the information carefully before signing the consent form [Part B].

STUDY TITLE: THE PREVALENCE OF WHEEZE IN CHILDREN WITH CLINICAL PRESENTATION OF SEVERE/VERY SEVERE PNEUMONIA AND RESPONSE TO BRONCHODILATOR THERAPY.

Purpose of study

I am carrying out a study to find out how many children present to Kenyatta National Hospital with wheeze and have cough/difficult breathing. I also want to find out how your child will respond to the medicine that is given for this problem. Your child's illness fits in the study and I am requesting for your child to be included.

Benefits for Participating

There is no monetary or financial benefit you derive from the study. If you participate, the information you will provide will help in evidence based practices and recommendations in children with a similar illness.

Risks for participating

Apart from the time taken away for the interview or completion of questionnaire (Approximately 30 minutes) which may take away time from other activities, no other risks are foreseen.

What participation will involve

Your child's participation in this study will only involve being observed as treatment takes place. I will work within your treatment schedule.

Confidentiality All information you provide will remain confidential. This information will only be accessible to the researcher and will not be relayed to any party unless your prior written permission is obtained.

Withdrawal

You may withdraw from participating in the study at any time and without giving reasons for your withdrawal. Failure to participate in this study will not be used against you.

Who has allowed this research to take place?

A committee from KNH has looked carefully at this work and has agreed that the research is important, that it will be conducted properly and that your child's safety and rights will be respected.

What if I have any questions? Please feel free to ask any questions about the study. If there is any part of this form that you do not understand, be sure to ask questions about it. You can also contact me after the interview for any clarification or questions on the study.

Dr V.Maina- M.Med
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OR,

To the Secretary,
KNH/UON-Ethical and Research committee
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PART B: CONSENT FORM

TITLE: THE PREVALENCE OF WHEEZE IN CHILDREN WITH CLINICAL PRESENTATION OF SEVERE/VERY SEVERE PNEUMONIA AND RESPONSE TO BRONCHODILATOR THERAPY.

Name of child: .....

Hospital Number: .....

Study Number: .....

I, being a parent/guardian of the child named above, have understood the information sheet (part A). I have had a chance to ask questions about the study and I have been assured that if I may have further questions about this study or my rights as a participant, I can ask the investigator listed above. I voluntarily agree to allow my child to participate in this study. I also understand that at any time that I may wish to withdraw from the study, I will do so without giving any reason and that such action will not jeopardize me /my child in any way.

Name of Parent/ Guardian: .....

Parent/guardian's signature: .....

Date: ...../...../..... (d/m/y) Time: .....am/pm

For the parent/guardian who cannot read:

Presence of a witness (a person who is independent from the study such as a member of staff not involved in the study) is mandatory.

Name of Parent/ Guardian: .....

Parent/guardian's thumbprint:

Name of witness: .....

Witness' signature: .....

Date: ...../...../..... (d/m/y) Time: .....am/pm

I certify that I have followed the standard operating procedure for obtaining informed consent from the above named parent/guardian.

Name of investigator: .....

Investigator's signature: .....

Date: ...../...../..... (d/m/y) Time: .....am/pm

APPENDIX B: STANDARD OPERATING PROCEDURES

NEBULIZATION

Patients with wheeze and cough/difficult breathing will be given inhaled Salbutamol and reassessed after up to 3 cycles of bronchodilator therapy, repeated (if necessary) at 20 minute intervals.

1. The procedure will be explained to the caregiver and the child transferred to an appropriate room within the Paediatric Emergency Unit
2. Place a mask of appropriate size attached to the top of the nebulizer over the child's nose and mouth.
3. Connect one end of the air tubing to the nebulizer compartment and the other to the oxygen regulator. Instill the bronchodilator (2.5mg salbutamol) and 2mLs of normal saline in the nebulizer compartment.
4. Administer salbutamol by nebulization using continuous oxygen flow at 6-8 liters per minute.
5. Nebulization takes place over 5minutes.
6. Reassess the patients after up to three cycles of bronchodilator therapy, repeated (if necessary) at 20 minute intervals.

Nebulization will be done in KNH Paediatric Emergency Unit using the hospital nebulizer.

PULSE OXIMETRY

Oxygen saturation will be measured using a pulse oximeter (Nellcor NPB-40). Pulse oximetry works by placing a pulsating arteriolar vascular bed between a dual light (red and infrared) source and a photodetector. The photodetector records the relative amount of each color absorbed by arterial blood and transmits the data to a monitor, which displays the information with each heartbeat.

Procedure

1. Explain to parent or guardian briefly on pulse oximetry and its value
2. Ensure the child is comfortably positioned and calm

3. Select an appropriately sized sensor probe for patient age and weight

4. Ensure a good capillary refill at a point closest to the selected site

5. Attach probe on the selected site (toe, finger or earlobe)

6. Hold the probe in position until a steady reading is obtained, observing to ensure a strong pulse wave and a heart rate

7. Document the pulse oximeter reading in the questionnaire

8. Repeat the measure after one minute and document value

9. Record average value of the two readings on the questionnaire.

APPENDIX C: STUDY QUESTIONNAIRE

Data collection form – Virginia Maina MMed Paed Thesis

Instructions

*Fill in the **blanks Y for YES** and **N for No** as appropriate*

Study No.....

Patient data

Patient Name.....

Number from Hosp Records .....

Gender (encircle) Male / Female

Age at admission (months).....

Date of admission(D/M/Y).....

Time of admission (24hrs).....

Body weight (kg).....

Medical history

Current

Duration of illness (days)...[_____]

Cough [_____]

Is the cough-nocturnal [_____]

Difficult breathing [_____]

Wheezing [_____]

Fever [_____]

Able to feed [_____]

Abnormally sleepy [_____]

Use of bronchodilators for this illness [_____]

Use of steroids (inhaled or oral) for this illness [_____]

Past medical history

Number of previous admissions for pneumonia [_____].

Previous wheezing [_____]

History of asthma family [_____]

Self [_____]

History of allergy [_____]

Exposure to cigarette smoke in the household [_____]

Name of cooking fuel used [_____]

Any pets in the house [_____]

Previous use of bronchodilators in previous illness [_____]

Previous use of steroids (inhaled or oral) [_____]

Clinical assessment-General

Edema [_____]

Temperature [_____]

Atopic dermatitis [_____]

Allergic rhinitis [_____]

Allergic conjunctivitis [_____]

Clinical sign	Pre- bronchodilator therapy	Post- bronchodilator therapy
Respiratory rate		
Heart Rate		
Lower chest wall indrawing		
Level of cosciousness (AVPU scale)		
Inability to drink or breastfeed		
Rhonchi		
Oxygen saturation		

Cardiovascular exam- Apex beat, normal [___] Heart sounds, normal [____]

Abdominal exam-Liver enlargement [____]

Number of salbutamol doses [____]

Patients clinical outcome:

Pneumonia classification-non severe pneumonia [_____]

-Severe pneumonia [_____]

- Very severe pneumonia [_____]

Discharged [___]

APPENDIX D: CLINICAL DEFINITIONS

WHO CRITERIA/GOVERNMENT OF KENYA PAEDIATRIC GUIDELINES

1. PNEUMONIA

Non severe pneumonia-cough or difficult breathing and tachypnea

Severe pneumonia- cough/difficulty in breathing plus lower chest wall indrawing.

Very severe pneumonia- cough/difficulty in breathing plus one or more of: cyanosis or oxygen saturation less than 90%, inability to drink/breastfeed, AVPU* less than A (or GCS** less than 14), grunting or head nodding.

*AVPU Scale for levels of consciousness. A=Alert, V= response to voice, P= response to pain, U= unconscious.

**GCS-Glasgow coma scale

2. ASTHMA

Mild-wheeze, cough or difficult breathing and tachypnea

Severe- wheeze, cough or difficult breathing and lower chest wall indrawing

Very severe- wheeze, cough or difficult breathing and cyanosis or inability to drink or AVPU<A

3. Tachypnea:Respiratory rates ≥60 breaths/minute among children aged < 2 months

≥50 breaths/ minute among children aged 2-11 months

≥40 breaths/minute among children aged 12-59 months.

4. Heart rates (normal for age)

2-12 months = <160beats/minute

1-2 years = <120 beats/minute

2-5 years = <100beats/minute

APPENDIX E

Asthma guidelines (Global Initiative for Asthma/ Consensus on the management of asthma in Kenya)

Table one:

	Mild	**moderate**	**Severe**	**Impending respiratory failure**
Breathless	Can lie down, walking	Prefers sitting, talking	At rest	
Talks	Sentences	Phrases	Words	
Alertness	Alert	agitated	Agitated	Drowsy or confused
Cyanosis	None	None	Present	present
Respiratory rate	Increased	increased		
Pulse rate	Increased	increased	Increased	bradycardia
Chest indrawing	None	Present	Present	Present
Wheeze	End expiratory	Loud	Loud	absent
Pulsus paradoxus	Absent (<10mmHg)	10-25mmHg	20-40 mmHg	absent

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Ref: KNH/UON-ERC/ A/269

30th July 2009

Dr. V. Maina
Dept.of Paediatrics & Child Health
School of Medicine
University of Nairobi

Dear Dr. Maina

RESEARCH PROPOSAL: "THE PREVALENCE OF WHEEZE IN CHILDREN WITH CLINCAL PRESENTATION OF SEVERE/VERY SEVERE PNEUMONIA AND RESPONSE TO BRONCHODILATOR THERAPY" (P119/4/2009)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and approved your above revised research proposal for the period 30th July 2009 –29th July 2010.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimen must also be obtained from KNH-ERC for each batch.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

DR. L. MUCHIRI
AG. SECRETARY, KNH/UON-ERC

c.c. The Chairperson, KNH/UON-ERC
The Deputy Director CS, KNH
The Dean, School of Medicine, UON
The Chairman, Dept.of Paediatrics & Child Health, UON
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