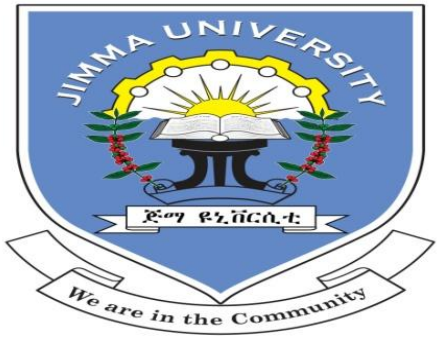
Clinical Response to Empiric Antibiotic Therapy and Its Contributing Factors among Children with Community Acquired Pneumonia Admitted to Jimma University Specialized Hospital, South West Ethiopia



By:

Shimelis Mekit (B.Pharm)

A RESEARCH PAPER TO BE SUBMITTED TO DEPARTMENT OF PHARMACY, COLLEGE OF PUBLIC HEALTH AND MEDICAL SCIENCES, JIMMA UNIVERSITY, IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN CLINICAL PHARMACY

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JIMMA, ETHIOPIA

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NOVEMBER, 2013

JIMMA, ETHIOPIA

CERTIFICATE

This is to certify that the thesis entitled **"Clinical Response to Empiric Antibiotic Therapy and Its Contributing Factors among Children with Community Acquired Pneumonia Admitted to Jimma University Specialized Hospital, South West Ethiopia"** was carried out by **Shimelis Mekit** under direct supervision the advisor(s) listed below. Further, the advisor(s) certify that this work has not been submitted in part or full in any University or Institution for any Degree or Diploma.

1. Name: _____ Signature: _____ Date: _____

2. Name: _____ Signature: _____ Date: _____

DECLARATION

I hereby declare that the work embodied in this thesis was carried out by me under direct supervision of **Mr.Tesfahun Chanie, & Dr.Tsinuel Girma**, Department of Pharmacy, College of Public Health and Medical Sciences, Jimma University. This work has not been submitted in part or full in any University or Institution for any Degree or Diploma. I further endorse that this work is the property of Jimma University and all rights in this regard are reserved with Jimma University.

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This thesis has been submitted with our approval as examiner.

External examiner

Name_____ Signed _____ date_____

Internal examiner

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ABSTRACT

Background**: Childhood community-acquired pneumonia (CAP) is a leading cause of morbidity and mortality worldwide, but studies on the clinical response of children hospitalized with CAP are limited. Among all cases of CAP, the estimated incidence of childhood hospitalization in developing and developed world is 8.7% and 0.3%, respectively. In Ethiopia, pediatrics Pneumonia is the top killer and the major cause of hospital admission and antibiotic use. Although published data to determine the clinical response to empiric antibiotic treatment are scarce in Africa, there are a number of risk factors which determine both burden of the disease for hospitalization and the clinical response for empiric antibiotic therapy.* ***Objectives: *to assess the clinical response to empiric antibiotics and its contributing factors of hospitalized children with CAP.*

Methods: *A prospective observational study was conducted from March 14 to July 16, 2013 at Jimma University Specialized Hospital Pediatric ward. Convenient sampling technique was used for selection of 126 children within ages of 1 month to 14 years. The medical records of all hospitalized Children with a diagnosis of severe community acquired pneumonia during the study period was reviewed using check list to extract data on clinical history and physical examination. Semi structured questionnaire was used to found information from the parents on socio demographics and risk factors. Data were analyzed using Statistical Package for Social Sciences for windows version 16 was used to identify the independent predictors of clinical outcome.*

Results: *Among children admitted to hospital male accounted 76(60.3%), mean for age in month was 26.34 and majority 58(46.0%) were found between the ages of 1-11 months. Eighty three percent were treated by crystalline penicillin. Those clinically improved within 48 hours of starting therapy accounted 73%. The predictors of clinical response were older age, un exposure to passive cigarette smoking OR 3.6 (95%CI, 1.5-8.7), non overcrowded family was OR 3.1 (95%CI, 1.18-8.33), current breast feeding, absence of history of fever at home, absence of fast RR at 24 after initiation of antibiotics.*

Conclusion and recommendation: *Clinical response were predicted by older age, children from non-overcrowded family, not exposed to passive cigarette smoke, currently on breast feeding, absence of history of fever at home. Therefore, health professionals should consider the family member to be advised if any smoker in the family member.*

Key words: *Clinical response, antibiotic therapy, pediatric, community acquired pneumonia.*

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ABBREVIATIONS AND ACRONYMS

ALRI: Acute Lower Respiratory Tract Infection

AOR: Adjusted Odd Ratio

BTS: British Thoracic Society

CAF: Chloramphenicol

CAP: Community Acquired Pneumonia

CXR: Chest X-Ray

EBF: Exclusive Breast Feeding

GAPP: Global Action Plan for Prevention and Control of Pneumonia

JUSH: Jimma University Specialized Hospital

MDG4: Millennium Development Goal 4

OR: Odds Ratio

PCVs: Pneumococcal Conjugate Vaccines

RCTs: Randomized Controlled Trials

RSV: Respiratory Syncytial Virus

SPSS: Statistical Package for Social Sciences

WBC: White Blood Cell Count

WHO: World Health Organization

1. INTRODUCTION

1.1. Background

Childhood community-acquired pneumonia (CAP) is an acute infection (of less than 14 days' duration) of the lower respiratory tract, which has been acquired in the community outside hospital. Severe cases are those at the highest risk of hospitalization, prolonged hospitalization and death. Antibiotic therapy is the mainstay of treatment for children with pneumonia requiring hospitalization. The choice of antibiotics for hospitalized children with (CAP) is usually empiric, based on clinical and radiological findings (1-2). There are a number of risk factors which determine both burden of the disease for hospitalization and the clinical response for empiric antibiotic therapy in the era of antibiotic resistance (3-4).

Childhood pneumonia is the leading single cause of mortality in children aged less than 5 years and is a common and potentially serious problem worldwide(1, 5).The incidence in this age group is estimated to be 0.29 episodes per child-year in developing and 0.05 episodes per child-year in developed countries(6).This translates into about 156 million new episodes each year worldwide, of which 151 million episodes are in the developing world(5-7). Ethiopia has an estimated 3,951,000 cases of child pneumonia annually and 112 Predicted number of deaths per thousand due to clinical pneumonia(5).

Therefore, require prompt identification and the most effective treatment in order to reduce CAP-related morbidity and mortality. Substantial evidence revealed that the leading risk factors contributing to pneumonia incidence are lack of exclusive breastfeeding, undernutrition, indoor air pollution, low birth weight, passive exposure to smoke, overcrowding and lack of measles immunization (3, 8). Unless the patient has bacteraemia or pleural empyema, aetiological diagnostics are limited and antibiotic treatment is empirical (9).

The determination of the aetiology of CAP in pediatric age, as shown in some studies on specific pathogen of pneumonia is difficult for several reasons such as: a definitive diagnosis requires the isolation of the microbe from the site of infection, demanding invasive procedures such as transthoracic needle aspiration or transtracheal aspiration(1, 2, 5). These procedures are

potentially harmful and, therefore, cannot be employed in routine diagnostics, isolation of a microbe from a blood culture is accepted as indirect evidence of the etiology of pneumonia. However, the yield from blood cultures is too low (5% to 15% for bacterial pathogens) to be relied upon(10). Of those attempt made, direct and indirect aetiological studies suggest that Streptococcus pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumonia and Haemophilus influenzae are the most common bacteria causing CAP (5, 8, 11).

In daily practice, an antibiotic is chosen empirically to treat children with CAP and etiology is rarely established (2, 3, 8). The empirical treatment of suspected bacterial pneumonia in a hospitalized child requires an approach based on the clinical manifestations at the time of presentation. Management of CAP in children involves a number of therapeutic decisions including the major one whether to treat or not with antibiotics and also what is the choice of the appropriate antibiotic drug and its route of administration (10). Children will therefore always need access to safe effective pneumonia treatments(11).

It has been suggested that on-admission clinical factors like age categories, respiratory rate (RR), fever, use of antibiotics prior to admission, history of breastfeeding, immunization status, oxygen saturation and radiographic features are all significant independent predictors of the likelihood of antibiotic treatment failure at 48 hr (10). The outcome measure was defined as the absence of any one of the following danger signs that included inability to drink; abnormal sleepiness; central cyanosis or convulsions; low oxygen saturation(defined as <90%) persistence of lower chest indrawing at 48 hr; life-threatening or serious adverse drug reaction; need to receive another antibiotic; a newly diagnosed co-morbid condition; and death(12) .

Typically, patients with uncomplicated community-acquired bacterial pneumonia respond to therapy with improvement in clinical symptoms (fever, cough, tachypnea, chest pain) within 48–72 hr of initiation of antibiotics. A child whose disease improves from severe pneumonia to non severe pneumonia or well status after 48 hours of therapy is sent home with orally administered antibiotics, whereas a child whose condition remains unchanged or worsens remains hospitalized and receives expanded antibiotic coverage(13).

Thus, few studies have assessed the time course of clinical response to predict the outcome of antibiotic therapy of childhood CAP using the duration of fever, respiratory rate & oxygen saturation and treatment failure at 48 hr separately without associating with risk factors (9, 12, 14**).** Limited study data(9, 14) are available on the expected response to treatment in children with CAP.

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1.2. Statement of the problem

Even in the face of significant progress, pneumonia remains the biggest threat to children's lives, and disproportionately affects the poorest children in the world. This condition is common in occurrence, is caused by a wide array of pathogens, is difficult to treat and involves/ impose a substantial cost burden (5, 11). Pneumonia kills more children under the age of five than any other illness in every region of the world. It is estimated that of the 9 million child deaths in 2007, 20% (1.8 million) were due to pneumonia. Approximately 98% of children who die of pneumonia are in developing countries especially in sub-Saharan Africa including Ethiopia and south-east Asia (5, 11-14). The estimated incidence of childhood hospitalization due to CAP is 8.7% of all cases of CAP in developing countries and 0.3% in the developed world(1, 5).

Technical Consensus statement of Global Action Plan for Prevention and Control of Pneumonia (GAPP) has concentrated efforts on addressing Pneumonia- the number one killer of young children as priority areas for improving child survival worldwide. Pneumonia is a significant problem in communities with a high rate of under-five mortality, and place a huge burden on families and the health system. Pneumonia control is therefore a priority and is essential in achieving Millennium Development Goal 4 (MDG4) an aim of reducing the national child mortality rates by two-thirds by 2015 compared to 1990 (13). MDG4 can only be achieved by an intensified effort to reduce pneumonia deaths.

Currently, Ethiopia is placed at the 5th in annual child pneumonia death and the last in achieving vaccine coverage (57%), children suspected pneumonia receiving antibiotic (5%), exclusive breast feeding (49%), and Pneumococcal conjugate vaccines (PCV) introduction status is 2012 as revealed by Pneumonia Progress Report of November 2012 (11).

Study conducted on determinants of under-five mortality in Gilgel Gibe Field Research Center South west Ethiopia revealed pneumonia as the major causes of death in under-five children as compared to other childhood illnesses(15). Other Study done in Ethiopia which aimed to analyze the characteristics of patients admitted under pediatric emergency ward of Tikur Anbessa Hospital and identify important causes of admissions and deaths showed that severe

pneumonia accounted for 38.3% of the total admissions and 41.9% of the deaths as major cause(16) .

Drug prescribing practice in a pediatric ward in Ethiopia, elicited Pneumonia as the first (36.53%) of Top ten diagnoses and antibiotics are the leading therapeutic class of drugs prescribed in pediatrics ward of Jimma University Specialized Hospital (JUSH)(17).

The severity of the symptom & response to antibiotic therapy depend on the age, risk factors, immune statuses, etiologic agents, history of breast feeding, nutritional status, environmental factors, and previous exposure to antibiotics (18-20). On the other hand, penicillin resistance in streptococcus pneumonia, an important cause of pneumonia in children is increasing rapidly (20-24). Expanded and continued use of antibiotics to treat pneumonia could make antibiotic resistance an increasing challenge in the future(14). This represents a well-defined and important area for research to assess current clinical response to CAP. .

Overall, it has the potential annual direct medical costs on children admitted to hospital. In addition, there are direct costs to families and indirect costs to the economy from parental time off work due to prolonged hospital stay (work loss and reduction of quality of life). There also, it cause frequent of physician visits, antibiotic and over-the counter drugs over consumption(17, 25-29), which contribute for antibiotic resistance as Childhood pneumonia continues to rank as the leading cause of hospitalization and death in children globally(30). In addition, in the previous most researches are concentrated on childhood pneumonia to reduce the unacceptable magnitude of child deaths from this disease(29-31)**,** associating mortality with poverty and with malnutrition; breast feeding ,poor vaccinations coverage(11, 31). This study was tried to evaluate current clinical response for antibiotic therapy which initiated empirically.

Overall, this study aimed to assess the clinical response to empiric antibiotic therapy in hospitalized children with community acquired pneumonia and its contributing factors, within 48 hours after starting therapy and during hospital stay at JUSH Pediatric ward from March 14 to July 16, 2013.

2. LITERATURE REVIEW

2.1. Definition of pneumonia

Pneumonia is defined as inflammation of lung tissue due to an infectious agent (1, 5). CAP can be defined clinically as the presence of signs and symptoms of pneumonia in a previously healthy child (of less than 14 days duration), due to an infection which has been acquired outside hospital. In developed countries this can be verified by the radiological finding of consolidation. In the developing world a more practical term -acute lower respiratory infection (ALRTI) is preferred, reflecting the difficulties in obtaining a chest radiograph(19, 21). Streptococcus pneumoniae is the leading cause of severe pneumonia among children across the developing world(32-33).

2.2. Epidemiology and disease burden

Childhood pneumonia is an important cause of morbidity and mortality worldwide. More than two million children younger than five years of age die from pneumonia every year, accounting for almost one-fifth of overall childhood mortality(5).

Bulletin of the World Health Organization of 2008 report revealed that, Childhood pneumonia is the leading single cause of mortality in children aged less than 5 years. Of all community cases, 7–13% are severe enough to be life-threatening and require hospitalization(22). This translates into about 156 million new episodes each year worldwide(11). This is a close approximation of the global incidence of childhood pneumonia since 95 % of pneumonias occur in the developing world(5).

2.3. Risk factors for CAP in children

Some studies explained risk factors related to host and environment that have impact on incidence of childhood clinical pneumonia in community in developing countries(5, 23). Children exposed to cigarette or wood stove smoke and children from lower socioeconomic levels have a higher incidence of pneumonia, as do boys compared with girls. Children who have underlying medical disorders such as sickle cell disease, bronchopulmonary dysplasia, gastroesophageal reflux, asthma, cystic fibrosis, congenital heart disease, and immunodeficiency syndromes are at higher risk for pneumonia and its complications (23, 29).

Not all risk factors were supported by different studies for their contribution of treatment outcome. In one randomized trial conducted in 9 locations in 8 countries, namely, Colombia, Ghana, India, Mexico, Pakistan, South Africa (2 sites), Vietnam, and Zambia, children who presented to the emergency department with a history of cough or difficulty breathing revealed association to some risk factors. In this study, immunizations not being up to date and antibiotic use for up to 48 hours before trial entry were both associated with two fold greater odds of treatment failure. In addition, baseline fast or very fast respiratory rate and baseline hypoxia were associated with greater odds of treatment failure. The apparent association of breastfeeding with treatment failure disappeared after adjustment for age(24).

Age also another risk factor as the result of study done in Finland, the median age of the 153 patients was 2.3 years (range 0.1–16.7 years). Twenty-one (14%) patients were 0 to 11 months of age, 46 (30%) 12 to 23 months of age, 49 (32%) 2 to 4 years of age and 37 (24%) were 5 years of age or older. Of the patients, 53% were boys(9). According to study done in Sudan, most of the patients of both sexes less than 2 years of age (41% less than one year, and 34% between 1-2 years). Analysis of parental education showed that 64% of the mothers and 50% of the fathers of these children had less than eight years of formal education. Parental occupations were diverse. While 28.6% were unemployed, only 4% were farmers and 7.4% were professional workers. Skilled labourers, unskilled labourers and employee group were 17.2%, 20.8% and 22.2% respectively. The most popular method of cooking was gas, followed by coal, then wood. Almost all of the study population had a direct source of chronic exposure to tobacco smoke, particularly paternal smokers, where fathers counted for up to 67% of the exposure. It is interesting to note that 11 of the mothers (5.0%) were smokers. The rest of the children were exposed to frequent tobacco smoke from visiting relatives and friends(34).

Study conducted in India found that, factors associated with treatment failure requiring change of antibiotics included overcrowding at home [RR (95% CI)-1.94 (1.35–2.38)], lack of exclusive breastfeeding [RR (95% CI) - 2.63 (2.16– 2.86)] and an abnormal chest radiograph [RR (95% CI)- 2.29 (1.22–3.44)]. Factors associated with prolonged hospital stay included overcrowding at home [RR (95%CI)- 2.59 (1.78–3.23)], lack of exclusive breastfeeding [RR (95%CI)- 2.56 (2.0– 2.93)] and an abnormal chest radiograph [RR (95%CI)- 2.99 (1.65–4.38)] mothers education less than graduation [RR (95%CI)- 1.5(1.19–1.7)], oxygen saturation of less

than 90% at time of presentation [RR (95%CI)- 2.06 (1.42–2.42)]. But, demographic profile, passive smoking, malnutrition etc were not found to be significant factors determining the outcome of hospitalized children with WHO defined severe pneumonia (31)

2.4. Clinical features during presentation

Children with CAP may present with fever, tachypnoea, breathlessness or difficulty in breathing, cough, wheeze or chest pain. They may also present with abdominal pain and/or vomiting and may have headache. Children with upper respiratory tract infection and generalized wheeze with low-grade fever do not have pneumonia(19, 23). Study done in Italia on 94 children with pneumonia which were eligible for the study at the Department of Paediatrics, University Hospital of Udine, Italy conveyed that doctors assessed 37 patients as "ill-looking" on admission, 19 (51.4%) of which were treated with parenteral antibiotics, that was used in 9 (15.8%) of the 57 "well looking" patients. From the 37 "ill-looking" patients, only 2 (5.4%) had fever >24 hours vs. 23/57 (40.4%) of "well-looking" children (33) .

On the other hand, Study done in Sudan showed that the most common presenting signs of patients were chest in-drawing (94%), followed by nasal flaring (77%), respiratory distress (64%) and grunting (46%). Less common presenting signs were cyanosis (8%), refusal of feeding (2%) and convulsions (1%) (34). Similarly, study done in Brazil showed that on admission, the most common complaints were cough (99.2%), fever (97.2%), difficulty in breathing (56.5%), and findings were tachypnea (75.2%), fever (49.7%) and crackles (33.8%). Severe malnutrition was diagnosed in 6 (3.9%) cases. chest indrawing (29.9%), nasal flaring (9.1%), grunting (3.9%), somnolence (1.3%), seizure (0.6%), cyanosis (0.6%). Nobody was unable to drink(8).

Other study done in Finland, the main causes of hospitalization were high fever, dyspnoea, malaise/lethargy, vomiting or poor appetite, before hospitalization, the median duration of fever in the 153 children was 2.0 days (range 0–11 days) (9).

2.5. Diagnoses of CAP

Different guidelines for Diagnosis and management of community-acquired pneumonia in childhood recommended that the diagnosis of CAP should be considered in any child who has an acute onset of respiratory symptoms, particularly cough, fast breathing or difficulty breathing. Diagnosis includes clinical evaluation, radiographic evaluation and aetiological investigations to: (i) establish whether pneumonia is present; (ii) assess the severity of pneumonia; and (iii) determine the causative organism(26,35).

2.5.1. Clinical features for diagnoses of CAP in children

Criteria for diagnosis based on signs and symptoms tend not be very specific. Early work on diagnostic features was mainly undertaken in developing countries to assist non-healthcare workers in identifying the need for antibiotics or referral for hospital assessment in areas without access to radiology. Studies on pneumonia are often difficult to collate as the clinical settings and criteria for diagnosis can vary widely (1)

The diagnosis of sign and symptom of severe and very severe pneumonia recommended for admission on Pocket Book of Pediatric Hospital Care for Ethiopia Guidelines for the Management of Common Illnesses in Hospitals are Cough or difficult breathing plus at least one of the following: central cyanosis**,** inability to breastfeed or drink, or vomiting everything**,** convulsions, lethargy or unconsciousness**,** severe respiratory distress**.** In addition, some or all of the other signs of pneumonia or severe pneumonia may be present, such as: fast breathing, nasal flaring **,** grunting**,** lower chest wall indrawing**,** abnormal vocal resonance (decreased over a pleural effusion, increase over lobar consolidation signs of pneumonia on auscultation (decreased breath sounds, bronchial breath sounds, crackles, pleural rub)(35).

2.5.2. Radiologic investigation

Radiology examination in England showed that Pleural fluid was noted in 65 (9%) patients: 28 (20%) together with lobar changes, 38 (9%) with patchy and two (2%) with perihilar. Empyema was noted in 24 patients, with 13 (9%)lobar and 11 (2.5%) patchy changes , for infants CXR appearance was not associated with severity, dyspnoea, RR, temperature or oxygen saturation, although infants with lobar changes were more likely to receive oxygen and NG feeds . Children with lobar changes were more likely to be pyrexial but had no association

with other signs or symptoms or with severe disease. Children with perihilar changes more often had severe disease, dyspnoea or a higher RR, or were given oxygen , and those with patchy changes were less likely to have severe disease (29)

Pulmonary infiltrate and pleural effusion were detected in 123 (80.0%) and 40 (26.0%) cases, respectively; pulmonary infiltrate was categorized as alveolar (95.1%), interstitial (1.6%) or alveolar– interstitial (3.3%); other radiographic findings were peribronchial thickening (5.8%) and atelectasis (4.5%) as Study done in Brazil l children(8).

2.6. Treatment of CAP in children

The Authors' of Randomized controlled trials (RCTs) comparing antibiotics for CAP in children under 18 years of age with CAP treated in a hospital or community setting concluded that for severe pneumonia without hypoxia, oral amoxicillin may be an alternative to injectable penicillin in hospitalized children; For children hospitalized with severe and very severe CAP, penicillin/ampicillin plus gentamycin is superior to chloramphenicol. The other alternative drugs for such patients are ceftrioxone, levofloxacin, co-amoxyclavulanic acid and cefuroxime(10). Atkinson et al., 2007 reported that Oral amoxicillin and IV benzyl penicillin were shown to be equivalent. Median time for temperature to settle was 1.3 days in both groups (36).

In 94 Italian children admitted to university hospital the result showed that Oral amoxicillin was started for 55 children, oral amoxicillin-clavulanic acid for 4 children, intravenous ampicillin for 21 children, oral cephalosporin (cephalexin) for 2 children, intravenous cephalosporin (ceftriaxone) for 6 children, and oral macrolides for 4 children. Vancomycin was started in one and quinolones in no case(33). Study In Brazil, conveyed that Penicillin and derivatives were the most commonly used empiric antibiotics throughout the studied period (37)

2.7. Outcome and complication

Study in Finland found that the study children rapidly recovered from CAP after initiation of antibiotic therapy and no one developed complications during the antibiotic treatment. Of the patients, 91% became afebrile within 48hr, fever lasting for $\geq$48 h was considered treatment

failure and was recorded in 13 (9%) of the 153 children and the median duration of hospital stay was 48 h (range 7–240 h) (9).

According to Study done on Italian children, after starting of antibiotics, the mean ± SD duration of fever was 23.0 ± 19.2 hours, being 15.6 ± 13.4 in <2 years, 18.9 ± 14.9 in 2-4 years and 31.2 ± 23.1 hours in ≥5 years old children. Fever decreased in 44 (47%) children within 12 hours, in 25 (27%) between 13- 24 hours, in 21 (22%) between 25-48 hours, and in only 4 (4%) children after 48 hours. Fever continued for >24 hours in 10/58 (14.7%) children aged <5 years compared with 15/36 (41.7%) children aged ≥5 years(33).

On the other hand, this Study reported that the treatment setting was significantly associated with the duration of fever. Finally, there were 6 patients with delayed recovery; fever continued >48 hours in four >7-year-old children, and two 3-year-old girls were treated for empyema for >2 weeks in hospital. On admission, four of these 6 children were "looking ill". When the 2 children with empyema and the only child with lung abscess were excluded from the analyses, the mean duration of antibiotic treatment was 7.4 ± 3.1 days in the 90 children with no severe complication. The mean duration of intravenous treatment with ampicillin was 3.3 ± 1.5 days. This study Concluded that Respiratory rate and erythrocyte sedimentation rates were associated with rapid decrease of fever(33).

According to Review in England showed, the length of hospital stay varied from 1 to 122 days (median 3; IQR 2, 5). Infants stayed significantly longer (infants: median 4; IQR 2, 7; children: median 3; IQR 2, 5). Children, but not infants, with severe disease stayed longer than with moderate disease as did those with effusions or lobar CXR changes (29).

Other study which recruited Children from eight centers in England for Comparison of oral amoxicillin and intravenous benzyl penicillin for community acquired pneumonia in children (PIVOT trial) showed that, the median length of hospital stay was significantly shorter in the oral group than in the IV group (1.77 days (25th–75th centile 1.2–2.0) and 2.1 days (25th–75th centile 1.8–2.9), respectively. In this study the median time for temperature to be, 38°C for 24 continuous hours was 1.23 and 1.3 days, respectively, in the IV and oral group(36).

For the Brazil children, Oxygen supplement during evolution was more common among patients in whom substitution for penicillin G occurred (26.9% vs. 7.6 %,). Major supportive complications of pneumonia include parapneumonic effusion, lung abscess, and necrotizing pneumonia(29, 34) .

Intravenous ampicillin was more effective than oral amoxicillin or macrolide (fever continued >24 hours in only 1 (4.8%), compared with 19 (28.8%) patients treated with amoxicillin or with those 2 (50.0%) treated with macrolide. In multivariate analyses, adjusted for age category, fever lasted in mean 11.1 hours less in children treated with ampicillin, than in those treated with amoxicillin(33). Study in Brazil conveyed that no significant difference was observed regarding the mean length of hospital stay during the study period 1991-2001, varying from 8.2 to 9.5 days(37). Some literatures from developing counties revealed that around 80% of hospitalized children were improved clinically during 48 hours after antibiotic therapy (38,39).

2.8. Conceptual frame work

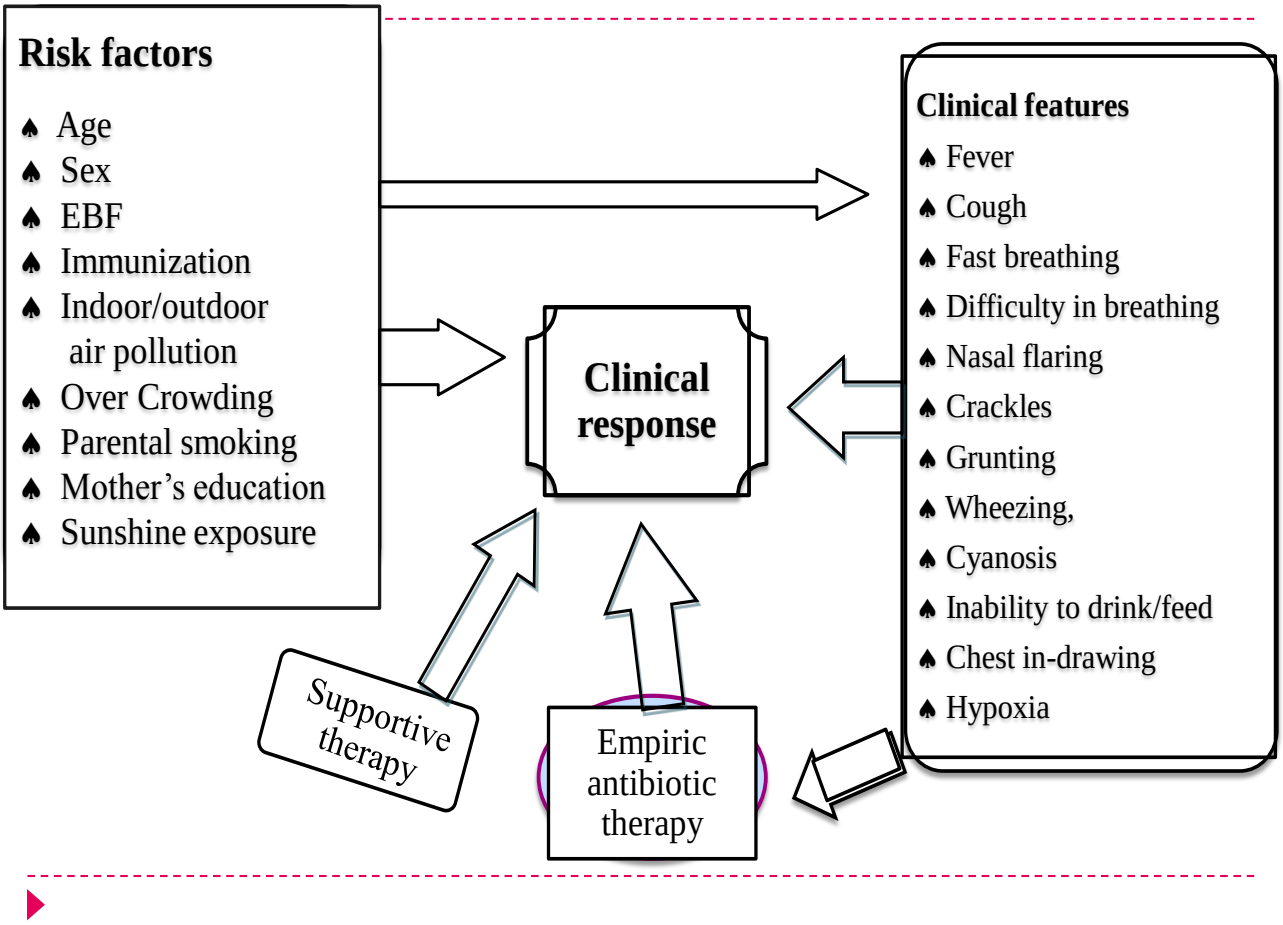


Figure 1: Relation between risk factors for CAP & clinical features to determine treatment outcome of hospitalized children with CAP

3. SIGNIFICANCE OF THE STUDY

Early identifying clinical response help to decide switching from parentral therapy to oral antibiotic therapy. Parentral antibiotic injections are painful for children and stressful for their parents and probably cost more than using oral therapy. As well as more detailed information generated about the clinical response and risk factors of the disease aimed to addressed, will guide new approaches to tackle the immense global problem of child deaths from pneumonia.

Comparison of different age group for antibiotic response to Childhood CAP (identified by WHO diagnostic criteria) lie a ground for duration of therapy which are needed in order to better guide patient treatment. This study will address the gap of other studies done only on prevalence & management of a pediatric pneumonia by assessing both burden of the disease for hospitalization and the response for antibiotic therapy. Provide current information to proceed with other study in the era of antibiotic resistance is a great threat as well as poor immunization coverage like in our country, Ethiopia is alarming.

Successful treatment of infections caused by bacteria depends on risk factors related with the infected host; will give clue for those health workers involved in the management of pediatric CAP at different level with limited training and little or no laboratory support in Ethiopia. At present, knowing which clinical findings in lower respiratory tract infections can best predict the outcome or the need for early referral, or which signs can most reliably be observed by primary health workers is helpful.

The present study was investigated this problem, based on close monitoring of clinical findings in children admitted in JUSH pediatric ward who have acute lower respiratory tract infections specifically severe CAP. The result of this study may assist policy makers, guideline developers to utilize current information for management of pediatric pneumonia at national & global level.

Therefore, it was the objective of this study to conduct a prospective observational study and assess the clinical response to empirical antibiotic therapy & associated factors for hospitalized children with clinically diagnosed CAP and identify potential predictors of improvement of symptom within 48 hours after starting therapy.

4. RESEARCH QUESTIONS & OBJECTIVES

4.1. Research questions

This particular thesis addressed the following three major research questions:

1. Are all age group of children with CAP clinically respond to empiric antibiotic therapy at equal rate?
2. Which independent variables of clinical feature have more predictive value to indicate clinical improvement during 48hours after antibiotic therapy of CAP?
3. What contributing risk factors are best fit in predicting treatment outcome of antibiotic therapy for children with pneumonia?

4.2. Objectives

4.2.1. General objective

This study was aimed to assess the clinical response and its contributing factors, in hospitalized children with community acquired pneumonia after starting empiric antibiotic therapy and during hospital stay

4.2.2. Specific objectives

- To determine the clinical response for empiric antibiotic therapy in hospitalized children with community acquired pneumonia within 48 hours after starting therapy and during hospital stay.
- To identify the clinical features which have more predictive value and an association of risk factors to indicate clinical improvement after antibiotic therapy of CAP.

5. METHODS AND PATIENTS

5.1. Study area and period

The study was conducted from March 14 to July 16, 2013 in the pediatric ward of Jimma University Specialized Hospital (JUSH), a teaching hospital located in Jimma town, Oromia Region in southwestern Ethiopia, 350 km from the national capital, Addis Ababa. JUSH has divisions such as surgery, gynecology and obstetrics, pediatrics, internal medicine, psychiatry, laboratory, tuberculosis, etc. It is the only referral hospital for over ten million people in the southwestern part of the country with 450 beds where a multidisciplinary team of diverse professionals provides a range of health services. In the pediatric ward, the specific study sites were Ward A, and Critical Ward**.** Ward A is a pediatric medical unit where stable patients and patients discharged from the other medical units receive further medical care, while Critical Ward is a pediatric medical unit where patients in critical condition are treated (40).

5.2. Study design

Prospective observational study was used among all children between 01 month to the age of 14 years, during the four month period from March 14 to July 16, 2013,126 children were included in the study.

5.3. Source population

All children who were admitted in Jimma University specialized hospital for CAP to pediatric ward with certain clinical features.

5.4. Study population

All hospitalized Children with a diagnosis of severe community acquired pneumonia during the study period March 14 to July 16, 2013.

5.5. Inclusion –exclusion criteria

5.5.1. Inclusion:

- All children aged 1 month to 14 years and those admitted to hospital with severe community acquired pneumonia by the decision of physician on duty was eligible if they

fulfill at least one of three major inclusion criteria set by WHO for CAP to be diagnosed: Respiratory symptoms or signs, or a history of fever & cough at home.

- plus at least one of the following signs on assessment during presentation:
  - ✓ Chest wall indrawing ✓ nasal flaring ✓ temperature >37.5°C
  - ✓ Grunting ✓ central cyanosis ✓ inability to breastfeed or drink
  - ✓ Vomiting ✓ unconsciousness ✓ severe respiratory distress

5.5.2. Exclusion

We have excluded the following cases presented with pneumonia to maintain homogeneity because the managements are different if co morbidity exists.

- Children with congenital disease (e.g. Congenital heart disease)
- Children with Concomitant disease (e.g. asthma ,heart disease)
- Immunologically suppressed children (e.g. HIV, TB, Malnourished etc
- Nosocomial pneumonia from another hospital or transfer

5.6. Sample size determination and sampling technique

In this prospective observational study single proportion formula for determining the sample size and convenient sampling technique for study subject selection was used.

Accordingly, the sample size for the number of pediatric pneumonia was calculated by considering 91% (P=0.91) from outcome of severe pneumonia in children admitted to emergency units of two teaching hospitals in Khartoum, Sudan (Salih K, *et al.* 2011) and 95% level of confidence (α=0.5), with tolerable error of 5% (d=0.05) as follows:

$$n = \frac{Z^2 1-\alpha/2\ P\ (1-P)}{d^2} \qquad n = \frac{(1.96)^2 \times 0.91\ (1-0.91)}{(0.05)^2} = 125.85 = \mathbf{126}$$

Where, n = final sample size of children with community acquired pneumonia needed for the study:

P = outcome after antibiotic therapy for pneumonia (91.0%)

d = tolerable error (0.05)

Z^2 1- α/2 = the standard normal deviation (1.96)

Therefore, the required number of children with pneumonia admitted to ward was planned to address 126 children during 2 month of study period from last year in the same period was averagely 62 children per month as reviewed from discharge summery which approximate our sample size. But we couldn't found the desired numbers that fulfill inclusion criteria within this two month. So, we extended the study period to four month from March 14 to July 16, 2013 and we have got the desired number 126 children.

5.7. Instrument and data collection procedure

Detailed data on socio-demographics information, clinical history and physical examination on admission, and daily evaluation during hospital stay for treatment and the final outcome was collected from the medical chart and recorded on a checklist. Data on risk factors, which determine clinical response and hospital stay, was collected using a pre designed semi structured questionnaire by asking parent after obtaining consent form. The questionnaire was originally developed in English and then translated into Afan Oromo and Amharic and these local languages questionnaires were used to collect the data using semi structured interview method. It was then back translated to English to facilitate reliable responses and to keep the original meaning of the instrument.

The content of designed semi structured questionnaire which contained information regarding family and socio economic conditions, include: Immunization status, residence, Lack of exclusive breast feeding, Indoor air pollution, Overcrowding, Parental smoking, Mother's experience as a caregiver, Mother's education, Day care attendance & occupational status, economic status, ethnic group, religion, housing style, method of cooking at home, and for previous exposure to antibiotics the parent was asked.

For all evaluations, the clinical response at 48 hr was used as the primary outcome measure. Fever is defined as an axillary temperature >37.5°C, on admission and every 12hours and tachypnea as RR by counting fully for 60 seconds. Temperature and a respiratory rate were measured in the ward every 12 hours. In addition, this prospective observational study was kept under follow up during their hospital stay to determine their outcome till 48 hours.

5.8. Variables in the study

5.8.1. Independent variable

- ✓ Temperature (fever)
- ✓ Respiratory rate (RR)
- ✓ Chest indrawing
- ✓ Age
- ✓ Socio economic status of mother
- ✓ Vaccination status
- ✓ Over-crowdeded
- ✓ Exposure to family member with ARTI symptoms
- ✓ Previous antibiotic exposure
- ✓ Parental smoking
- ✓ breast feeding
- ✓ Indoor air pollution

5.8.2. Dependent variable (outcome variable)

- ➢ Clinical response

5.9. Data entry and analysis

The socio-demographic, clinical feature and treatment outcome data was collectively documented for each patient on a questionnaire and checklist. Data entry template format was prepared in EpiData version 3.1 and the data was edited and entered in computer. Errors related to inconsistency were verified using data cleansing method. The data was exported to SPSS for window version 16.0, then recoded, categorized, sorted, editing and clearing of the data was also performed to facilitate analysis. The relationship of each predictor variable of clinical features to antibiotics therapy and clinical response was examined. Clinical features at admission among children who respond and failed to respond were analyzed as odds ratios. Descriptive statistics (frequencies and cross tabulation), bivariate analyses, and multiple logistic regressions were performed. The significant factors derived from the bivariate analysis were studied separately using adjusted odds ratio at 95% confidence interval. Those variables that show association with a cut of point $p \leq 0.05$ in bivarate was a candidate & run in multivariate logistic regressions to see the proposed association and to adjust the confounder. Then the net effect which shows significant association at $P \leq 0.05$ and AOR was reported.

5.10. Data quality assurance

A pretest was done on 13 patients for one week and after modification on questionnaire was made, the collected data was not used as main study. A pre-tested, questionnaire was used to collect data from the paediatric ward JUSH from March 14 to July 16, 2013. The data collectors were trained for 2 days on the data collection format and techniques of data collection by principal investigator. Data was collected by experienced four Bsc nurses currently working in pediatric ward JUSH of study area. The principal investigator had checked all collected data daily for the completeness & re-evaluation was made for missed information. Finally, before entry of the data fulfillment of information had checked by principal investigator. Data entry also was done by principal investigator. Data cleaning and editing were done before analysis.

5.11. Ethical considerations

Ethical approval of the research proposal was obtained from the Ethical Review Committee of Jimma University and a formal letter was written by the hospital medical director for doing the study in the hospital. The patient data from medical charts was accessed upon the approval of the research proposal by research supervisors and written informed consent was obtained from parents of children participating in the study. Privacy and confidentiality was ensured during the data collection, thus name and address of the patient was not recorded in the data collection format.

5.12. Dissemination and use of results

The result of the study will be disseminated to responsible bodies such as JU department of Pharmacy, Federal Ministry of Health, Ethiopian IMCI, Regional health bureau, zonal and district health offices and district administration of the study area etc. The study finding will be submitted to professional journals for publication so as to serve as base line for further studies.

5.13. Operational definition

Clinical response: In the absence of complications and danger signs, within two days there should be signs of improvement. We accepted as signs of improvement within and at 48 hours ("slower breathing" defined as a decrease in respiratory rate of more than 5 breaths per min or

a return to normal range for age as compared to previous 12 hours measurement, less chest indrawing, less fever, and improved ability to eat and drink).

Indoor air pollution: Is if the child exposed for air due to methods of cooking at home e.g. Wood, charcoal, gas or mixed smokes and if a family's kitchen is in the main house plus use their cooking room as bedroom.

Lack of exclusive breast feeding: is defined as receipt of any top feed including water in the first 6 months of life.

Length of hospital stays: duration of total hospital stays (from day of admission to discharge) in days.

Need for change in antibiotics: children required change in antibiotics from the primary regimen.

Overcrowded: is determined by calculating number of family members per room**. A** child who is not found to be in the following norm was labeled as staying in overcrowded house.1 Room 2 persons, 2 Rooms 3 persons, 3 Rooms 5 persons, 4 Rooms 7 persons, 5 or more rooms 10 persons (additional 2 for each further room)

Parents: include both biological parents and the guardians of the study participants

5.14. Definition of terms

Chest-wall in drawing: is the inward movement of the bony structures of the lower chest wall with inspiration. Lower chest-wall in drawing is also called "sub costal in drawing"/"sub costal retraction

Community Acquired Pneumonia (CAP): Pneumonia that has been acquired in the community in a patient who has not been hospitalized within 14 days prior to onset of symptoms

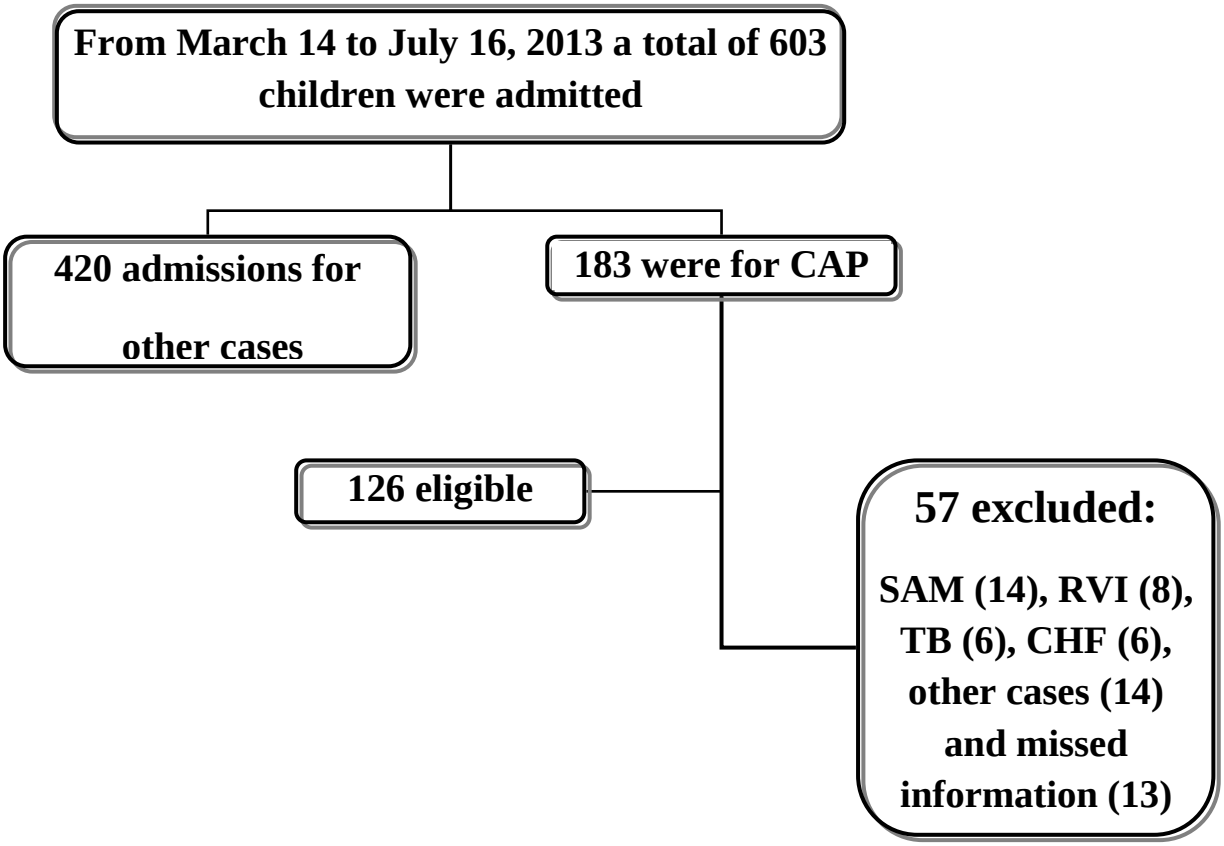
Grunting: This clinical sign is generated by a patient in severe distress in an effort to raise the peak end expiratory pressure to avoid collapse of the alveoli during expiration.

Rapid/fast breathing: is defined as when the age-specific respiratory rates become ≥60 breath/minute in neonates and infants aged <2 months, ≥50 breaths /minute in infants aged 2 to <12 months, and ≥40 breaths /minute in children aged 12-59 months,>30 breaths / minute for >59months (35).

6. RESULT

6.1. Socio-demographic information of study participants

There were a total of 603 admissions to the paediatric ward JUSH during the study period of four month (from March 14 to July 16, 2013) of this 183(30.3%) were ´due to CAP. Those who fulfil inclusion criteria and enrolled in the study were 126(68.9%). The remaining CAP case 57(31.1%) were presented with co morbidity and excluded (figure 4).



SAM=severe acute malnutrition, **RVI**=retrovirus infection, **TB**=tuberculosis, **CHF**=congestive heart disease

Figure 2: Flow chart of children enrolled in clinical response to antibiotic to therapy of CAP among hospitalized at pediatric ward of JUSH, Jimma, March 14 to July 16, 2013.

According to this study, male children accounted for 76(60.3%), mean for age distribution in month showed that 26.34 at range of (2-168). Fifty eight (46.0%) children were found between the age of 1-11 months and 82(65.1%) came from urban (table 1).

Table 1: Selected characteristics of children with CAP admitted to JUSH, Jimma, March 14 to July 16, 2013.

Characteristics (n=126)		Frequency (%)
Sex, male		76 (60.3)
Age in month	1-11	58(46.0)
	12-23	23(18.3)
	24-59	30(23.8)
	60-168	15(11.9)
Residence	Rural	44(34.9)
	Urban	82(65.1)
Occupation of mother	Governmental worker	16(12.7)
	Day worker	31(24.6)
	House wife	66(52.4)
	others *	13(10.4)
Educational status of father	Illiterate	33(26.2)
	Elementary	44(34.9)
	High school	15(11.9)
	Above high School	34(27.0)
Educational status of Mother	Illiterate	46(36.5)
	Elementary	39(31.0)
	High school	20(15.9)
	Above high School	21(16.7)
Monthly income (Ethiopian Birr)	<499	36(28.6)
	500-999	41(32.5)
	1000-1499	18(14.3)
	1500-1999	7(5.6)
	>2000	24(19.0)
Ethnicity	Oromo	88(69.8)
	Amahara	13(10)
	Gurage	8(6.3)
	Other**	17(13.6)
Religion	Muslim	88(69.8)
	Orthodox	29(23.0)
	Protestant	9(7.1)

* Nongovernmental employee, Farmer, Private worker and Merchant
** Dawuro, Tigrie and Kaffa

6.2. Environmental and host related profile of children with CAP

This study showed that 18(14.3%) children were living with a family member who have had symptoms of ARTI in the past one month, 75(59.5%) were come from overcrowded family, 92(73%) had siblings, 32(25.4) were slept with or shared bed with her/his siblings. Regarding

to exposure to cigarette smoke, 29(23%) were exposed to cigarette smoke in the family. The history of exposure to indoor air pollution was accounted 21(16.7%). The majority of the respondents were used mixed method of cooking at home 73(57%). Eighty one (64.3%) of the children was exclusively breast feed during the first six months of ages. According to immunization statues, 80(63.5%) were fully immunized for age, 33(26.2 %) were partially immunized/lack immunization for measles, and 13(10.3) were not immunized (table 2).

Table 2: Environmental and host profile of pediatric CAP in children admitted to JUSH, Jimma , March 14 to July 16, 2013.

Environmental and host profile		**Frequency (%)**
Had family member with ARTI symptom in the past month		126,18 (14.3)
Overcrowded *		126,75 (59.5)
Number of siblings in the family	<4	96,79(62.7)
	>=4	96,17(13.50
Slept with siblings (share bed)		96, 32(25.4)
Passive cigarette smokes		126, 29(23)
Exposure to indoor air pollution		126, 21(16.7)
Method of cooking at home (n=126)	Wood	44(34.9)
	Charcoal	8(6.4)
	Mixed **	74(57.8)
Exposure to antibiotic in past one month		126, 55 (43.7)
Exclusive breast feeding		123, 81(64.3)
Currently on breast feeding		126, 88 (69.8)
Immunization (n=126)	fully immunized for age	80(63.5)
	Partial immunized/lack for measles	33(26.2)
	not immunized	13(10.3)

N.B:* **Overcrowded:** is family members per room **.A** child who is not found to be in the following norm was labeled as staying in overcrowded house: 1 Room 2 persons ,2 Rooms 3 persons, 3 Rooms 5 persons ,4 Rooms 7 persons ,5 or more rooms 10 persons (additional 2 for each further room)

** **Mixed**: Wood and Charcoal and / or Kerosene

6.3. Clinical features at the time of presentation

As obtained from the care givers majorities 103(81.7%) of them have complaint of cough and followed by fever and difficulty of breath each accounted 67(52.3%). Clinical features assessed at the time of admission revealed that 123(97.6%) of the participant children were ill looking in general appearance. Major clinical feature were increased RR above age specific 114(90.5%), cough 107(84.9%), fever 85(67.5%) and nasal flaring 78(61.9%) (table3).

Table 3: Clinical features at the time of presentation for CAP in children Hospitalized at JUSH, Jimma, March 14 to July 16, 2013

Clinical features(n=126)		**Frequency (%)**
Chief complaint		
	Fever	67(53.2)
	Cough	103(81.7)
	Difficulty of breathing	67(53.2
	Vomiting	11(8.7)
	Feeding problems	7(5.6)
	Abnormal movement	2(1.6)
Clinical finding		
	General appearance(ill looking)	123(97.6)
	Fast breathing	114(90.55)
	Cough	107 (84.9)
	Fever	85 (67.5)
	Nasal flaring	78 (61.9)
	Difficulty of breathing	74 (58.7)
	Chest wall indrawing	71(56.3)
	Intercostals and sub coastal retraction	48 (38.1)
	Grunting	45 (35.7)
	Vomiting	43 (34.1)
	Wheeze	14 (11.1)
	Feeding problem	13 (10.3)
	Crepitation	6 (4.8)
	Unconsciousness	5 (4.0)

6.4. Frequency distribution of antibiotics used

From antibiotics administered, the highiest percentage accounted crystalline penicillin alone were given in 74(59%) and crystalline penicillin with salbutamol in 30(24%). The others given were ampicillin plus gentamycin 5(4%). The least administered drug was cloxacillin plus CAF and ceftriaxone plus gentamycine each accounted 2(2%) (figure 3).

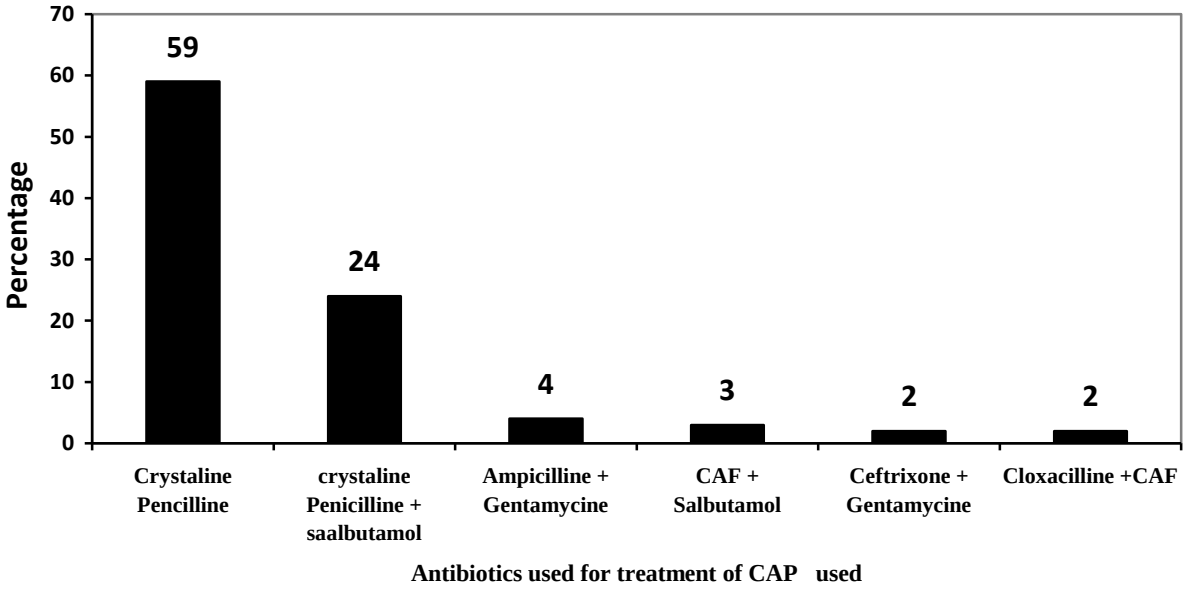


Figure 3: Antibiotics used during hospital stay for pediatric CAP on children admitted to JUSH, Jimma, March 14 to July 16, 2013.

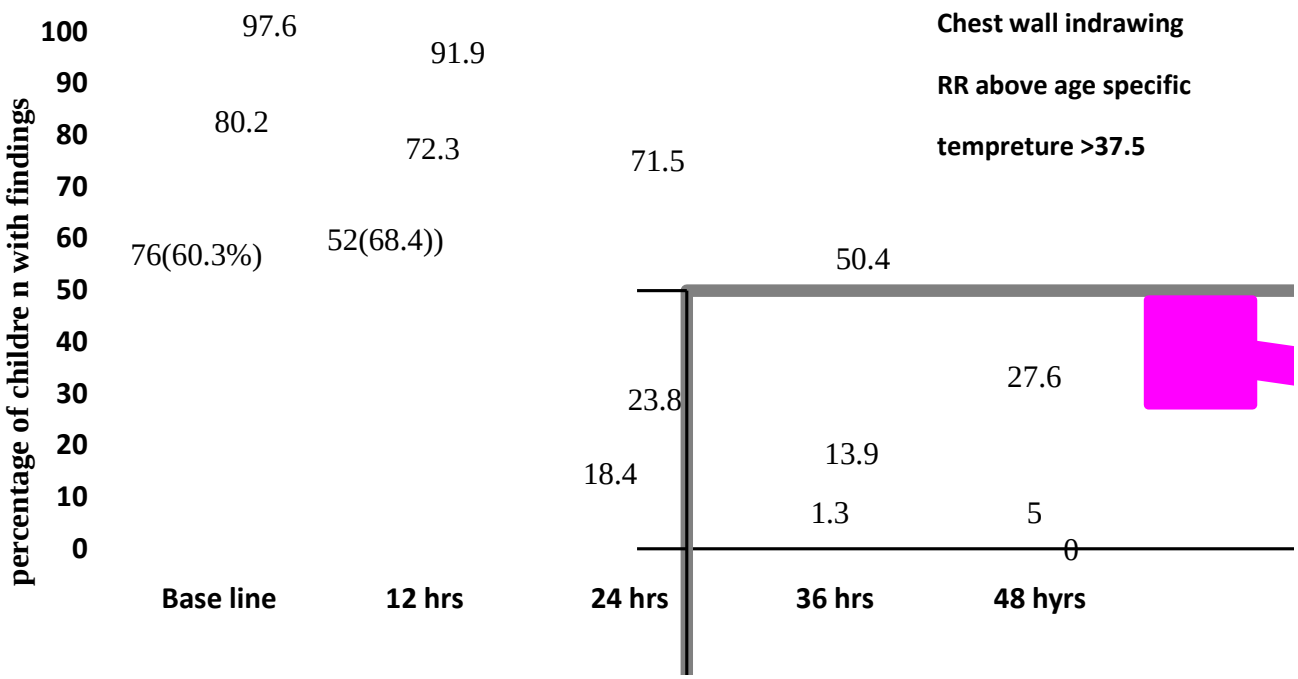
6.5. Children used supportive management

As displayed in the figure 4 below 107(85%) used oxygen therapy and 52(43%) were use antipyretics as supportive management during the Hospital stay at least for 6 hours (figure 4).

Figure 4: Children those used supportive management during hospital stay for pediatric CAP on children admitted to JUSH, Jimma, March 14 -July 16, 2013

6.6. Clinical findings after initiation of antibiotic therapy

The result of clinical response evaluation, that was found at different hours after initiation of antibiotics revealed that temperature was reduced from 101(80.2%) of baseline assessment to 73(72.3%) as compared to base line during the first 12hours which was 28(27.7%) difference in between. On the other hand, temperature was reduced from 73(72.3%) first 12hours to 24(23.8%) of 24 hours assessment, and showed difference in between 49(48.5%) children were afebrile. On the same time 77(76.1%) children were afebrile from base line to 24 hours. Ninety six (95.1%) of children were showed improvement in temperature at 48 hours from those who were febrile at base line 101(80.2%). Children achieved to age specific respiratory rate improvement from base line after initiation of antibiotic therapy to 12 hours, 24 hours, 36 hours and 48 hours were 10(5.7%), 35(26.1%), 60(47.1%) and 89(70%) respectively. Respiratory rate improvement between 12 hours evaluation was seen best after 36 hours of antibiotic therapy, which reduced from 62(50.4%) of 36 hours to 34(27.6%) of 48 hours. Children with persisted chest wall indrawing were only 1(1.3%) at 36 hours, which were 76(60.3%) at base line (figure 5).



Clinical response at different hours after antibiotic therapy

Figure 5: Percentage of clinical findings during hospital stay after the onset of antibiotic therapy on continuous assessment of chest wall in drawing, RR above age specific and temperature >37.5 ^{o}c on children admitted to JUSH, Jimma ,March 14 to July 16, 2013.

6.7. Children clinically improved at 48 hours

Based on assessment at 48 hours 92(73%) children improved by decreased in respiratory rate of more than 5 breaths per min or a return to normal range for age as compared to previous 12 hours measurement, absence of chest wall indrawing, less fever, improved ability to eat and drink. From those not improved 5(4%) were died (figure 6).

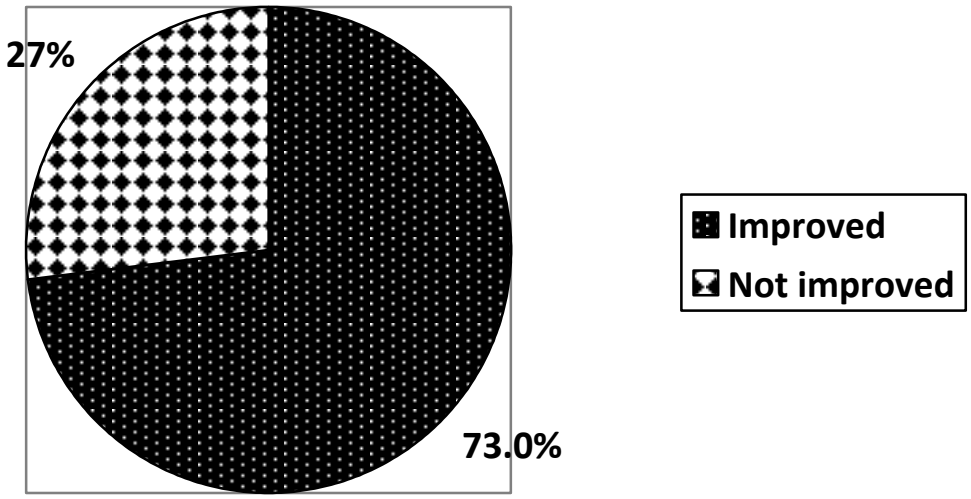


Figure 6: Clinical response of CAP on children admitted to JUSH, Jimma, March 14 to July 16, 2013**.**

6.8. Environmental and host related predictors of clinical response

The factors associated with Pediatric pneumonia were assessed and bivariat analysis was done to identify their correlation with clinical response for antibiotic therapy. Children within age category of 60-168 months were 3.94 times more likely to show clinical response as compared to those within the age category of 1-11 at the bivariate logistic regression[OR 95% CI 3.9[1.2 to 12.9)]. No significant difference were found in clinical response between sex (p= 0.305). On the other hand, the odds of clinical response were three times higher in children came from non-overcrowded family as compared to those of overcrowded family [OR (95%CI 3.14 (1.2-8.3)], p = 0.021. Among children who have had no history of exposure to passive cigarette smoke were 3.6 times more likely clinically respond as compared to those exposed to passive cigarette smoke [OR 95% CI 3.6 (1.5-8.7)], p=0.004. Those currently on breast feeding were associated significantly with better clinical response (p=0.041) by univariate analysis but not significantly associated by multivariate model. Although, statistically not significant there were difference in clinical improvement between fully immunized which was 42% higher than not immunized (table 4).

Table 4: Bivariate analysis of environmental and host related factors predicting clinical response of CAP of children admitted to JUSH, Jimma, March 14 to July 16, 2013.

Characteristics of Children (N=126)		Clinically response		Bivariate analysis	
		improved n= 92(73%)	Not improved n=34(27%)	p-val	COR (95% CI)
Age category	1-11	45(77.6)	13(22.4)		1.00
	12-23	17(73.9)	6(26.1)	0.725	1.22(0.4-3.7)
	24-59	23(76.7)	7(23.3)	0.922	1.05(0.4-3.0)
	60-168	8(53.3)	7(46.7)	**0.023**	**3.96(1.2-12.9)**
Sex	Male	58(76.3)	18(23.7)	0.305	0.7(0.3-1.5)
	Female	34(37.0)	16(47.1)		1.00
Immunization	fully immunized	56(70.0)	24(30.0)	0.611	1.43(0.4-5.7)
	Partially	26(78.8)	7(21.0)	0.890	0.89(0.2-4.2)
	Unimmunized	10(76.9)	3(23.1)		1.00
Day care attendant	Absent	40(72.7)	15(27.3)	0.987	1.007(0.5-2.2)
	Present	51(72.9)	19(27.10)		1.00
Educational status of Mother	Illiterate	31(67.4)	15(32.6)		1.00
	Elementary	26(66.7)	13(33.3)	0.467	1.55(0.5-5.0)
	High school	19(95.0)	1(5.0)	0.445	1.60(0.5-5.3)
	Above High School	16(76.8)	5(23.8)	0.120	0.17(0.18-1.6)
Family member with symptom of ALRTI	Absent	81(75.7)	26(24.3)	0.200	0.50(0.2-1.4)
	Present	11(61.1)	7(38.9)		1
Over crowded	No	37(86.0)	6(14.0)	**0.021**	**3.14(1.2-8.3)**
	Yes	55(66.3)	28(33.7)		1.0
Having siblings	absent	28(82.4)	6(17.6)	0.156	0.49(0.2-1.3)
	Present	64(69.6)	28(30.4)		1
Share bed with siblings	No	47(73.4)	17(26.6)	0.428	0.69(0.3-1.7)
	Yes	21(65.6)	11(34.4)		1
Passive Cigarette smoke	Not exposed	77(79.4)	20(20.6)	**0.004**	**3.59(1.5-8.7)**
	Exposed	15(51.7)	14(45.3)		1
Indoor air pollution	Not exposed	75(71.4)	30(28.6)	0.373	0.59(0.2-1.9)
	Exposed	17(81.0)	4(19.0)		1
Exposure to Antibiotic in the past one month	No	49(69.0)	22(31.0)	0.252	1.61(0.7-3.6)
	Yes	43(78.2)	12(21.8)		1
Exclusive Breast feeding	Yes	63(76.8)	19(23.2)	0.141	0.543(0.2-1.2)
	Lack EBF	27(64.3)	15(35.7)		1
Currently on breast feeding	No	23(60.5)	15(39.5)	**0.041**	**0.42(0.2-0.9)**
	Yes	69(78.4)	19(21.6)		1

N.B: ARTI =Acute respiratory tract infection, BF= Breast feeding

6.9. Clinical features predicting clinical response of pediatric CAP

The results of bivariate analysis were showed that, history of fever at home, absence of fast RR at 24 hours and 36 hours; absences of chest wall indrawing at 36hours were statically significant predictor of response. Although it was not statistically significant, the likelihood of showing clinical response based on clinical finding on admission were 4.481 times higher among children with absence of fast RR as compared to those who present with fast RR (OR 95% CI, 4.481(.556-36.115) (table 5).

Table 5: Bivariate analysis of clinical features that predict clinical response of CAP of children admitted to JUSH, Jimma, March 14 -July 16, 2013.

Clinical features (N=126)		**Clinically response**		**Bivariate analysis**	
		Improved n= 92(73%)	**Not improved n=34(27%)**	**p-value**	**Crude OR (95% CI)**
History of fever	Febrile	55(82.1)	12(17.9)	**0.016**	**0.4(0.2-2.8)**
	Afebrile	37(62.7)	22(37.3)		1.00
Fever finding	Afebrile	26(63.4)	15(36.6)	0.095	0.5(0.2-1.13)
	Febrile	66(77.6)	19(24.4)		1.00
RR on finding	Not fast	11(91.7)	1(8.3)	0.159	4.5(0.6-36.1)
	Fast	81(71.1)	33(28.9)		1.00
Cough	Absent	14(73.7)	5(26.3)	0.943	1.0(0.3-3.2)
	Present	78(72.9)	29(27.1)		1.00
Vomiting	Absent	65(78.3)	18(21.7)	0.065	2.1(0.9-4.8)
	Present	27(62.8)	16(37.2)		1.00
Nasal flaring	Absent	37(77.1)	11(22.9)	0.421	1.4(0.6-3.2)
	Present	55(70.5)	23(29.5)		1.00
Grunting	Absent	58(71.6)	23(28.9)	0.632	0.8(0.4-1.9)
	Present	34(75.6)	11(24.4)		1.00
Feeding problem	Absent	82(72.6)	31(27.4)	0.085	3.9(0.8-18.5)
	Present	10(76.9)	3(23.1)		1.00
Difficulty of	Absent	42(80.8)	10(19.2)	0.104	2.0(0.9-4.7)
breathing	Present	50(67.6)	24(32.4)		1.00
Chest wall	Absent	39(70.9)	16(29.1)	0.639	0.8(0.4-1.8)
indrwing	Present	53(74.6)	18(25.4)		1.00
IC&SC Retraction	Absent	57(74.0)	20(26.0)	0.749	1.1(0.5-2.5)
	Present	35(71.4)	14(28.6)		1.00
Fever at BL	Afebrile	47(64.4)	26(35.6)	0.138	2.4(0.8-7.7)
	Febrile	65(75.6)	21(24.4)		1.00
Fast RR at 12 hr	Absent	12(92.3)	1(7.7)	0.132	4.9(0.6-39.6)
	Fast	80(70.8)	33(29.2)		1.00
Fast RR at 24 hr	Absent	32(94.1)	2(5.9)	**0.004**	**9.14(2.08-40.7)**
	Fast	56(63.6)	32(36.4)		1.00
Fast RR at 36 hr	Absent	25(96.2)	1(3.8)	**0.001**	**28.4(3.6-223.2)**
	Fast	29(46.8)	33(53.2)		1.00

N.B **CC**: chief complain **CF:** clinical finding **RR**: respiratory rate **DOB**: difficulty of breathing **IC**: inter costal ,**SC**: subcostal **FRR;** fast respiratory rate **CWI:** chest wall indrwaing

6.10. Characteristics of the children predicting clinical response

In the final multivariate model, children who have no history of exposure to passive cigarette smoke, children came from non overcrowded family and children present with history of fever remained significantly associated with clinical response to antibiotic therapy. After adjustment made for multivariate model age category and currently on breast feeding were not significantly associated with clinical response, but the odds of currently breast feed was twice increased than those not on breast feed. This study tried to identify, history of fever at home, living in non overcrowded family and not exposed to passive smoke were the independent predictor for clinical response of childhood pneumonia.

Table 6: Multivariable model of clinical features and child profile that predict clinical response of CAP of children admitted to JUSH, Jimma, March 14 -July 16, 2013.

Child Characteristics (N=126)		**Bivariate analysis**		**Multivariate analysis**	
		p-valu	**Crude OR (95% CI)**	**p-value**	**Adjusted OR (95% CI)**
Age category	1-11		1.00		1.00
	12-23	0.725	1.2(0.4-3.7)	0.909	0.9(0.3-3.1)
	24-59	0.922	1.05(0.4-3.0)	0.483	1.6(0.4-6.5)
	60-168	0.023	4.0(1.2-12.9)	0.466	0.5(0.1-3.1)
Over crowded	No	**0.021**	**3.2(1.2-8.3)**	**0.047**	**2.9(1.02-8.4)**
	Yes		1		1
Passive Cigarette smoke	Not exposed	**0.004**	**3.6(1.4-8.7)**	**0.040**	**2.7(1.8-7.1)**
	Exposed		**1**		
Currently on breast feeding	No	**0.041**	**0.4(0.2-0.96)**	0.276	2.1(0.6-7.7)
	Yes		**1**		1
History of fever	Febrile	**0.016**	**0.4(0.2-0.8)**	**0.033**	**0.3(0.1-0.9)**
	Afebrile		**1.00**		1
Fast RR at 24 hr	Absent	**0.004**	**9.1(2.0-40.7)**	0.998	1.380
	Fast		**1.00**		1
Fast RR at 36 hr	Absent	**0.001**	**28.4(3.6-223.2)**	0.998	1.380
	Fast		**1.00**		1

7. DISSCUSSION

7.1. Discussion

This study provides insight into the clinical response to empirical antibiotics therapy for pediatric CAP and contributors as predicting factors in children admitted to Jimma University hospital pediatric ward. The study tried to investigate the clinical response of children presented for antibiotic therapy of CAP. The study followed simple and cheap approach that is recommended by WHO for developing countries for diagnosis and treatment monitoring of children admitted with pneumonia (35). This study enabled us to assess different characteristics of children such as socio demographic, socioeconomic, and environmental and host related factors with clinical feature to predict clinical response for antibiotic therapy of CAP with special focus on the improvement within 48 hours after starting therapy. By using logistic regression model, we were able to identify associated factors predicting the clinical response to antibiotic therapy.

In our study, the overall hospitalization due to pneumonia was 183(30%) of which around 126(69%) were enrolled. We observed children by assessing clinical features like temperature, RR, chest wall indrawing in the ward to see the clinical response with in 48 hour. Our finding revealed that 92(73%) of children admitted with SCAP showed Clinical improvement after initiation of empiric antibiotic therapy. This result is slightly lower than study done in Brazil on outcome of children hospitalized with CAP (82%) (7). In India, response rate was (80%) (13) and in Kenya, the observed response were (80%) (39). In Italy, over 90% of the children with CAP improved and were non-feverish within 48 hours. Differently, study in Turkey, of the 470 patients (93.8%) were treated successfully with ampicillin/sulbactam therapy with in72 hours(27), and it conclude that clinical cure rate was 93% and bacteriologic eradication rate was 92% after treatment for a minimum of 7 days with parenteral ampicillin/ sulbactam (27). On the other hand, most literature revealed the expected therapeutic success rate (80%) (32,42).

This difference is due to variation in operational definition of improvement at 48 hours in literature, method of assessment and medical equipment used. The other possible reasons for the difference in the clinical response among different studies may be due to variation in

methodology of the study, age of the study participants, geographic area, socio-demographic factor, type of first line antibiotics and the study time. In addition, the definition we used for clinical response may overestimate clinical failure rates. In Our study, clinical response decided based on assessment at 48 hours on children which were improved by decreased in respiratory rate of more than 5 breaths per minute or a return to normal range for age as compared to previous 12 hours measurement, absence of chest wall indrawing, less fever, improved ability to eat and drink

In clinical practice, most clinician would expect that a child with pneumonia would show some evidence of clinical improvement on antibiotics by 48 hours at the latest and if not would consider a change of antibiotics or an alternative diagnosis. However, what comprises "some evidence of clinical improvement" remains the critical issue (1,35,38).

In our finding, around 95% of the admitted children were afebrile at 48 hour of the study time. In fact, as many as more than 76% of the patients were afebrile on finding at 24 hours after starting therapy. This were comparable in study done in University Hospital of Udine, Italy, which revealed that delayed improvement assessed by fever at 48 hours was (<5%), and (75%) of the patient were non feverish as early as 24 hours after starting therapy (33). In similar way the result in Finland found that the study children rapidly recovered from CAP after onset of antibiotic therapy, of the 153 patients, 43 (28%) had fever lasting 24 hours after onset of antibiotic treatment and no one developed complications during the antibiotic treatment. Of the patients, 91% became afebrile within 48hr (9). This early response in temperature and becoming afebrile at 48hours of therapy may be due to use of antipyretics as additional supportive therapy in some children and this not guarantee until patient clinically stable. Literatures concluded that antipyretic and analgesics can be used to keep the child comfortable and to help coughing (4, 10, 21, 31).

We had assessed the value of clinical features in predicting improvement with in 48hour, on presentation as chief complaints: cough 103(81.7%), fever 67(53.2%), difficulty of breathing 67(54.2%) and vomiting 11(8.7%). From these only history of fever has statistically significant predictive value. Study done in Sudan showed that the most common presenting signs of patients were chest wall in-drawing (94%), followed by nasal flaring (77%), respiratory distress (64%) and grunting (46%)(34). Similarly, study done in Brazil showed that on

admission, the most common complaints were cough (99.2%), fever (97.2%), difficulty in breathing (56.5%), and findings were tachypnea (75.2%), fever (49.7%), chest indrawing (29.9%), nasal flaring (9.1%), grunting (3.9%) and nobody was unable to drink(8). On the other hand, study done in Turku, Finland, the main causes of hospitalization were high fever, dyspnoea, malaise/lethargy, vomiting or poor appetite, before hospitalization (9).

We found in our study, RR above age specific 114(90.5%), cough 107 (84.9%), fever 85 (67.5%), nasal flaring 78(61.9%), difficulty of breathing 74(58.7%), Chest wall indrawing 71(56.3%) and grunting 45 (35.7%). Even if these all have no significant association, comparing clinical findings on admission to associate with the likelihood of clinical response, among children with absence of fast RR the Odds were 4 times higher as compared to those who present with fast RR OR 4.481(95% CI 0.556 to 36.115). This is supported by one randomized trial, conducted in the pediatric departments of tertiary care facilities in 9 locations in 8 countries, namely, Colombia, Ghana, India, Mexico, Pakistan, South Africa (2 sites), Vietnam, and Zambia. Children who presented to the emergency department with a history of cough or difficulty of breathing revealed, baseline fast or very fast respiratory rate was associated with greater odds of treatment failure(24).

On the other hand, we found significant association on assessment after starting of antibiotics, RR at 24 hours, RR at 36 hours and chest wall indrawing at 36 hours were remain predictor of response. On comparison of the daily frequency of clinical findings showed that the only significant difference was tachypnea from the first 24 hours to 48 hours of treatment (69.8% vs. 27%, p =0.004). There also, high odd of difference between admission and first day of treatment: tachypnea (97.6% vs. 69.8%, OR=30%), fever (80.2% vs. 19%, OR=3), chest indrawing (60.3 vs.11%, OR=3.7), although statically not significant. In Brazil, significant differences were found between admission and first day of treatment: fever (46.4% vs. 26.3%, p = 0.002), tachypnea (73.6% vs. 59.4%, p = 0.003), chest indrawing (29.4% vs 12.7%, p=0.001) (7). Our result was similar with study done in Pakistan that stated RR measured any time was a good predictor of the likelihood of treatment failure but the measurement at the end of 24 hr of hospitalization had the maximum prognostic value (13).

It is well documented that the severity of the symptom and response to antibiotic therapy depend on the age, risk factors, immune statuses, etiologic agents, history of breast feeding, nutritional status, environmental factors, and previous exposure to antibiotics (18-21, 31-34)

Young age is an additional risk factor for severity of pneumonia and need for hospitalization (1,2,21,26). In this study, the major age group was found in the category of 1-11 months 58(46.0 %). Which is similar with another study done in Tikur Anbessa Hospital in Addis Ababa, Ethiopia, <1 yr (46.4%) (16).This also comparable with study done in other Africa's country, Sudan was 0 -11 (41%) (34). Study in India, showed highest percentage of this age group (71.5%) were infants less than 12 months of age (31). Furthermore, infants and young children tend to have more severe pneumonia with a greater need for hospitalization and a higher risk of respiratory failure (21).

In this finding, there were variation among different age categories in clinical response, those found in category of 12-23 months has higher odds by 22% than those in age 1-11; the good response was observed OR of 3.956 (95% CI: 1.207 to 12.970) for those 60 to168 months, which were more likely to respond early at 48 hour as compared of lower age (1-11) months and statistically significant (p=0.023) in bivariate analysis. But after adjustment for age association was disappeared in multivariable model.

A clinical tool designed to predict which child with severe pneumonia would have failure of antimicrobial therapy in the developing world found that the age of the child was one of the most important clinical predictors (highly significant for those , <6 months of age) [13].
Observation was also made by few previous studies, in Kenya, infancy was the strongest predictor of treatment failure and it was also associated with high fatality rate (38).

In other study, according to univariate analysis, age was a strong predictor of treatment failure (*P* <0 .001) .The odds of failure for the youngest children (<6 months of age) was 3.6 times the odds of failure for the oldest children (>12 months of age) (24). Regarding sex, there were no significant difference found between sex (p= 0.305).This is in accordance with others findings (7, 34,9).

Not all risk factors were supported by different studies for their contribution of treatment outcome. Some studies explained risk factors related to host and environment that have impact on incidence of childhood clinical pneumonia in community in developing countries(5, 23). A study done in India, determinants identified , were mothers education less than graduation, lack of exclusive breast feed, overcrowding were associated with treatment outcome (31).

We found that, fully immunized for age 80(63.5%), partially immunized/not immunized for measles 33(26.2%), not immunized at all 13(10.3%). Although, statistically not significant, there were difference in clinical improvement between fully immunized which has higher odd of 42% than not immunized. In one study, immunizations not being up to date was associated with two fold greater odds of treatment failure (24). In India, measles immunization not given by 9 months, were significant predictor of treatment failure (39).

Regarding to history of breast feeding, those who are exclusively breast feed had no association; those currently on breast feed were significantly associated with response. But after adjustment made association was not seen except the odds of currently breast feed was increased twice than those not on breast feed. This is consistent with other study, that revealed apparent association of breastfeeding with treatment failure disappeared after adjustment for age(24). Study conducted in India found that, lack of exclusive breastfeeding [RR (95% CI)-2.63 (2.16– 2.86)] (31).

Regarding living style of family, children came from non overcrowded family were responded higher as 3 times as compared to those of overcrowded family OR (95%CI. 3.139(1.184-8.325). This is supported by study conducted in India that found factors associated with treatment failure requiring change of antibiotics included overcrowding at home [RR (95% CI)-1.94 (1.35–2.38)] (31). This is because of speedily dissemination of droplet and exposes the child for different concentrated microbial to get access for respiratory tract while coughing.

Children exposed to cigarette or wood stove smoke and children from lower socioeconomic levels have a higher incidence of pneumonia (23, 29). This also contribute for the outcome of therapy, in our finding, children who have had no history of exposure to passive cigarette smoke were respond more likely as compared to those exposed to passive cigarette smoke odd

ratio of 3.593 (95% CI, (1.492-8.654) ,p=0.004. Literatures stated that children exposed to smoking in the home had an increased likelihood of hospital admission (4.3% vs 1.1%) had at least one hospital stay/year) and an increased likelihood of an emergency unit visit for respiratory illness (8.5% vs3.6%) (1). In addition to this, Nicotine has a definite anti-leucocyte action that explains this significant finding [7], which should alert people to the hazard of passive smoking and the need for concentrated efforts of health education. In contrast study done in India was not found to be significant factors determining the outcome of hospitalized children with WHO defined severe pneumonia (31). Over all, this study was tried to identify, living in overcrowded family and exposure to passive smoke were the independent predictor for clinical response of childhood pneumonia.

7.2. Strengths and limitations of the study

Strength

- ✓ The study was prospective observational which attend the children after admission by close follow up.
- ✓ The research tried to address family history and associated factors for pediatric pneumonia in accordance to their impact on response to therapy.

Limitations

- ✓ There were no attempts made to identify etiologic agents.
- ✓ The responses were not supported by radiologic examination and pulse oximetry.
- ✓ Antibiotics administered were not compared and confirmed by using sensitivity test for their effectiveness on different microorganisms.
- ✓ The study did not include those present with comorbidity.

8. CONCLUSION AND RECOMMENDATION

8.1. CONCLUSSION

The findings indicated that considerable characteristics of children associated with clinical response of pediatric pneumonia. This demonstrates that characteristics of the children like being in older age category, currently on breast feeding, absence of fast breath at 24 and 36 hours after antibiotics therapy not living in overcrowded family were showed associated with improvement in bivarete. Children not exposed to passive cigarette smoke, absence of history of fever at home, were showed predictive value for improvement of children within 48hours duration of hospital stay. Children come from overcrowded family has less likelihood of response. Passive Cigarettes smoke has strong impact for improvement of the admitted child.

8.2. RECOMMENDATION

According to the above findings we suggest that, FMOH, Oromia Regional health bureau, Jimma zone and different district offices of the zone should consider:-

- ✓ Health professionals should pay close follow up especially for clinical features, like history of fever at home to predict improvement of sign and symptoms.
- ✓ The health extension workers should give health education concerning family overcrowding, while they visit the household how to handle housing.
- ✓ The health professionals should consider the family member to be advised if any smoker in the family member, to stay apart from children while smoking or try to cease if possible.

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ANNEXE

Information Sheet, consent form and questionnaires for Study participants (English, Amharic and Afan Oromic Version)

A. English Version

1. Information sheet

I. Title of the study

Clinical Response to Empiric Antibiotic Therapy and Its Contributing Risk Factors of Community Acquired Pneumonia among Children Admitted to Jimma University Specialized Hospital, South West Ethiopia.

Name of the investigator: Shimelis Mekit

Name of the advisors: Mr.Tesfahun Chanie,

Dr.Tsinuel Girma

IV. Name of the organization: Jimma University, College of Public Health and Medical Sciences, Department Pharmacy.

V. Sponsored organization: Jimma University

This is a study description format for the study participants on the study Clinical response to Empiric antibiotic therapy for community acquired pneumonia in children hospitalized at Jimma University Specialized Hospital pediatric Ward, 2013.

VI. Purpose of the study

The purpose of this study is to assess the clinical response for empiric antibiotic therapy and contributing risk factor for community acquired pneumonia in hospitalized children within 48 hours & during hospital stay after starting therapy at JUSH pediatric ward

There for this study will give information on clinical features, & the variable which predict improvement of sign& symptom, risk factor contributing for outcome.

VII. Benefit of the study

- Health Education will be given on community acquired pneumonia & risk factor for family or care giver at the time of study. To Encourage breast feeding with infant, Limit

exposure to other children (i.e. day care) ,Emphasize children should not be exposed to passive smoking; Explore smoking cessation options for parents.

- This study will generate current information on immunization status, breast feeding History, Environmental factors contributing for pneumonia & for its clinical response at local area.

- This study will provide important base line data to produce further investigation by other at the study area.

VIII. Confidentiality of your information

All personal information about you & your child will be kept private & the nature of the questionnaire & records are also kept private.

IX. Voluntary participation

Participation is by willingness of both parents/guardians and child So you have the right to participate or not to participate in this study. No one affect you because of you are not participated in this study.

If you have any question

Contact: Shimelis Mekit፡- Phone: +251911089913.

This research will be conducted after obtaining permission from Jimma University Ethical Review Board and the management committee of Jimma University Specialized Hospital.

2. Consent form for study subjects

Name of Parent:_____

I have read the information sheet (or it has been read to me); I have understood that it involves the purpose of study to assess the clinical response for empiric antibiotic therapy and contributing risk factor for community acquired pneumonia in hospitalized children during hospital stay after starting therapy at JUSH pediatric ward. And also I have cleared about the benefits of the study and Confidentiality of my information. Therefore, I am volunteer to give the requested information and participate my child in the study. I am also volunteer that the

physical examination which will be taken from my child can be used on the future for further anlaysis of clinical response when necessary. I have asked some questions and clarification has been given to me. I have given my consent freely to participate in the study.

I_____ hereby give my consent for giving of the requested information and physical examination from my child as the researchers find best for me.

Participant's signature_____ _____Date_____

Investigator's signature_____ _____Date_____

Witness' signature 1._____Date_____

2._____Date_____

Thank you for your participation!!

2. Questionnaires for study participant children CAP

Questioner to assess clinical feature, risk factors, treatment outcome of community acquired pneumonia in children hospitalized at JUSH pediatric ward.

Patient identification

Age	sex	admission date	Card number	bed number	Ward	Code of child	
		___/____/____					

N.B. Age (in month), sex is M/F

Immunization status: ☐ Fully immunized ☐ Partially ☐ Unimmunized

To be filled by asking the parents (care giver) by trained data collectors

Part I. socio-demographic & **risk factors information for CAP in pediatric**

A. risk factors assessment for CAP in pediatric

1**. Residence:** ☐ Rural ☐ Urban

2. **Occupation of father:** ☐ Governmental workers ☐ non-governmental worker ☐ Farmer

☐ privat ☐ Merchant ☐ no occupation

3. Occupation of mother: ☐ Governmental workers ☐ non-governmental worker ☐ Farmer

☐ private ☐ Merchant ☐ no occupation

4. **Does Mother works outside home most of the time**? ☐ Yes ☐ no

5**. What is the Educational status of parents?**

Father: ☐ Illiterate ☐ Elementary ☐ High school completed ☐ Above high school

Mother: ☐ Illiterate ☐ Elementary ☐ High school completed ☐ Above high school

7. **Monthly income ____**

From1-499 ☐ **500-999** ☐ **1000-1499** ☐ **1500-1999** ☐ **≥2000** ☐

8. Ethnic group : ☐ Oromo ☐ Amhara ☐Tigre ☐ Kafa ☐ Gurage

☐ Dawiro ☐ Yem ☐ Other specify_____

9. **Religion**: ☐ Muslim ☐ Protestant ☐ Orthodox ☐ Catholic Other specify_____

10. is there any person with acute respiratory tract infection sign symptom (like cough, difficulty in breathing in the past one month in the family? ☐ yes ☐ No

11. Number of family members ☐ ≤3 ☐ 4-5 ☐ 6-8 ☐ >8

12. Number of room in the house _____

13. Is there any siblings of the study child in the house? ☐ YES ☐ NO

(If the answer is no for question 13, please jump to question 16)

14. How many siblings are there? ☐1 ☐2 ☐ 3 ☐ 4 ☐ >5

15. Does your child share his/her bed with siblings (slept with siblings)

16. Is there any family member who smokes cigarette? ☐ YES ☐ NO

17. Methods of cooking at home: ☐ Wood ☐ coal ☐ gas ☐ mixed

18. Do you use your cooking room as bedroom ☐ YES ☐ NO

19. Do this child treated for the same symptom by any drug in the past one month?

☐ YES ☐ NO

if YES for question 20, what type of drug, duration, please specify if antibiotic

_____

20. Where was the child treated?

☐ Traditional healer ☐ private clin ☐ government health institution

21. Duration of breast feeding (in moths) _____

22. Duration of breast feeding without adding other feed (e.g. water)

23. Is the baby currently on breast feeding? ☐ YES ☐ NO

Part II. Checklist for extracting data on sing & symptoms to be collected from medical chart and by assessing the child with CAP

A. Clinical features at base line on admission with pediatric community acquired pneumonia

1. Chief complaint _____,_____,

2. Duration of cough before admission (day)_____

3. Duration of fever before admission (day)_____

4. Duration of difficulty of breathing before admission_____

5. General appearance: ☐ ill –looking ☐ well –looking

6. Clinical features on assessment at the time of presentation as taken from patient profile data

(Please mark (X) as appropriate)

☐ Fever ☐ Increased RR ☐ Cough ☐Vomiting everything

☐ Unconscious ☐ Nasal flaring ☐ Grunting ☐ Cyanosis

☐ Feeding problem ☐ crackles ☐ Chest pain ☐ Difficulty in breathing

☐ Hypoxemia ☐ Chest wall in-drawing ☐ Somnolence ☐ wheezing

☐SOB ☐ other, specify: _____

B. Clinical findings on evaluation during hospital stay after initiation of antibiotics

Clinical variables	Baseline	Clinical finding at d/t Hours after antibiotic administration				
		12hrs	24hrs	36hrs	48hrs	60hrs
1. temperature						
2. respiratory rate						
3. Chest wall in -drawing						

N.B. for chest wall in drawing, please say yes if present & NO if absent.

C .Data on antibiotics or/ others drugs administered

Name of drug with strength	**Initial Dose**	**Frequency**	**Route of admission**	**Duration**	**Date & time of antibiotic changed to oral**	
					__/_____/_____	
					__/_____/____	
					__/_____/____	

D. Follow up- for assessment of outcome at 48hours duration after antibiotic therapy

(please mark (X) as appropriate)

☐ Improvement of sign /symptoms ☐ Not improved ☐ Initial drug is changed

☐ Iv antibiotic is switched to PO ☐ death/ Expired

☐ Complication is diagnosed e.g. effusion/empyema/ lung abscess/ bronchieactasis/ pneumothorax,

☐ Need additional therapy (e.g. fluid, oxygen, antipyretics)

☐ Others, specify_____

E. Discharge summery

1. Length of Hospital stay: _____(please write number of days or hours)

(Date of admission _____/_____/_____ : Date of discharge_____/_____/_____)

2. Discharged with :(please mark (X) as appropriate)

☐ Improvement ☐ Referred ☐ Died

☐ With unknown reason ☐ if other, specify_____

F. Is Concomitant disease diagnosed during hospital stay? ☐ Yes ☐ No

If yes, go to next questions

G. Diagnosed Coexisting disease

☐ Asthma, ☐ heart disease ☐ bronchitis ☐ TB ☐ Congenital heart disease (CHD),

☐ Down's Syndrome ☐Osteomyelitis or septicarthritis ☐if other disease ,specify_____

B. Amharic Version

1. የጥናቱ ማዘራሪያ ቅጽ

i. የጥናቱ ርዕእስ

Clinical Response to Empiric Antibiotic Therapy and Its Contributing Risk Factors of Community Acquired Pneumonia among Children Admitted to Jimma University Specialized Hospital, South West Ethiopia.

ii. የጥናቱ ዋና ተመራሚ ስም ሸመልስ ማክት
iii. የአማክሪዎች ስም አቶ ተሰፋሁን ጫኔ
ዶ/ር ጽኑኤል ግርማ

Iv. የድርጅቱ ስም ጅማ ዩኒቨርስቲ ሕበረተሰብ ጠፍና ሕክምና ሳይንስ ኮሌጅ

የፋርማሲ ት/ክፍል

ሀ. ምርምሩን ገንዘብ ያገዘው ጅማ ዩኒቨርሲቲ

Vi የጥናት አላማ በጅማ ዩኒቨርስቲ ሰፔሻላይዝድ ሆስፒታል ህፃናጽ ክፍል ለህክምና ከሚሞጡ በኮሚቲ አኳይርድ ኒሞኒያ ተመርምረው ተሻተው ለመታከም መድሃኒት (አንቲባዩቲክ) ከወሰዱ በኃላ ያላቸወን የመዛል ሂደት እና ተዛማጅ ምክንያቶ ለማወቅ ነው

Vii. ጥናቱ የሚሰገኘው ጥቅም ለቤተሰባቸው የጠፉ ትምህርት ስለ ኮሚቱ አካየርድ ኒምኒያ እና ተዛማጅ ምክንያቶች የግንዛቤ ማስጨጫ ትምህርት ይሰጣል ስለ ጠኑ ማጦባት ጥቅም ይበረታታል ስለ ልጆች እንከብ ከቤና ክትባት ጥቅም እንዲሠም ልጆችን ከሚደጨሩ የቤተሰብ አበላት በሚደጨብት ጊዜ አለማቹርብ

በአጠቃላይ ይህ ጥናት በአሁኑ ሰአት ያለወን ሚጃ ማእትም ስለክትባት ሁኔታ የጠኑ ማጦባት ልምድ እና የአከባቢ ምክንያቶችን ይጠቁማል ሁኔታ የጠኑ ማጦባት ልምድ እና የአካባቢ ምክንያቶች ይጠቁማል

በተጨማሪም ሌላ የጥናት ሂደት እንዲቀጥል ማስረታዊ ሚጃን ይቀርባል

viii. ሚስጥር ስለማጠቅ

ከርሶ የሚወሰዱ መረጃዎች ሚስጥራዊ ይሆናሉ

3. **ከተሳታፊዎች የሚቀርብ ጥያቄ**

የሚከተሉት ጥያቄዎች ስለ ወላጆች ማህበራዊ ሁኔታ እና ለኮሚኒቲ አደየርድ ኒሞኒያ በህፃናት ላይ ተያያዥ ምክንያቶችን ለማወቅ ይረዳል፡፡

☐የ ኮ ድ ቁ ጥ ር _____ ☐ቀ ን _____

☐የ ል ጅ ሚስ ጥ ር ቁ ጥ ር _____ ☐ዕ ድ ሜ(የ ል ጅ)____☐የ ወላ ጅ ሚስ ጥ ር ቁ ጥ ር _____

ክ ፍ ል ሀ ፡ መ ን ስ ኤ ያ ዊ ም ክ ን ያ ቶ ች ስ ለ ህ ፃ ና ት ኮ ሚ ኒ ቲ አ ደ የ ር ድ ኒ ሞ ኒ ያ ከ ቤ ተ ሰ ብ ለ መ ጠ የ ቅ

1.**መ ኖ ሪ ያ** ☐ገ ጠር ☐ከ ተ ማ

2. **የ አ ባ ት ስ ራ** ☐የ መን ግ ስ ት ሰ ራ ተ ኛ ☐የ ግ ል ድ ር ጅ ት ☐ግ ብ ር ና
☐የ ግ ል ስ ራ ☐ነ ጋ ዴ ☐ስ ራ የ ሌ ለ ው

3. **የ እ ና ት ስ ራ** ☐የ መን ግ ስ ት ሰ ራ ተ ኛ ☐የ ግ ል ድ ር ጅ ት ☐ግ ብ ር ና ☐የ ግ ል ስ ራ ☐ስ ራ የ ለ ኝ ም

4. እ ና ትዬ ው ብ ዙ ውን ጊ ዜ ከ ቤ ት ው ጭ ት ሰ ራ ለ ን ☐አ ዎ ☐የ ለ ም

5. የ ቤ ተ ሰ ብ የ ት ም ህ ር ት ደ ረ ጃ ፡

አ ባ ት ፡ ም ን ም አ ለ ተ ማ ረ ም☐ የ መ ጀ መ ሪ ያ ደ ረ ጃ ያ ጠ ና ቀ ቀ ☐ ሁ ለ ተ ኛ ደ ረ ጃ ያ ጠ ና ቀ ቀ ☐

ከ ሁ ለ ተ ኛ ደ ረ ጃ በ ላ ይ ☐

እ ና ት ፡ ም ን ም አ ል ተ ማ ረ ች ም ☐ የ መ ጀ መ ሪ ያ ደ ረ ጃ ያ ጠ ና ቀ ቀ ች ☐

ሁ ለ ተ ኛ ደ ረ ጃ ያ ጠ ና ቀ ቀ ች ☐ ከ ሁ ለ ተ ኛ ደ ረ ጃ በ ላ ይ ☐

6. **የ ወ ር ገ ቢ** ከ 1-499 ☐ ከ 500-999 ☐ ከ 1000-1499☐ ከ1500-1999 ☐ ከ2000 በ ላ ይ ☐

7. ብ ሔ ር አ ሮ ሞ☐ አ ም ሃ ራ☐ ት ግ ሬ☐ ከ ፋ ☐ጉ ራ ጌ ☐ዳ ው ሮ ☐

☐ሌ ላ ካ ለ ይ ጠ ቀ ስ _____

8. **ሃ ይ ማ ኖ ት**

መ ስ ሊ ም ☐ ፕ ሮ ቴ ስ ታ ን ት ☐ አ ር ቶ ዶ ክ ስ ☐ ካ ቶ ሊ ክ ☐ ሌ ላ ካ ለ ይ ጠ ቀ ስ _____

9. ባ ለ ፈ ው አ ን ድ ወ ር ው ስ ጥ ከ ቤ ተ ሰ ብ አ ባ ል መ ሃ ል የ ሙ ተ ን ፈ ሻ አ ካ ል የ ህ መ ም ም ል ክ ቶ ች ማ ለ ት ም
ሳ ል የ አ ተ ነ ፋ ፈ ስ ች ግ ር የ ታ የ በ ት አ ለ ?; አ ዎ ☐ የ ለ ም☐

10. የ ቤ ተ ሰ ብ አ ባ ላ ት ብ ዛ ት ☐ <3 ☐4-5 ☐6-8 ☐ >8

11. በ ቤ ቱ ው ስ ጥ የ ከ ፍ ሎ ች ብ ዛ ት _____

12. በ ጥ ና ቱ ው ስ ጥ የ ሚ ሰ ተ ፈ ው ል ጅ ወ ን ድ ም/እ ህ ት አ ለ ው ? አ ዎ ☐ የ ለ ም☐

13. የ ወ ን ድ ም/እ ህ ት ብ ዛ ት ☐1 ☐2 ☐3 ☐4 ☐ >5

14. በ ጥ ና ቱ ው ስ ጥ የ ሚ ሰ ተ ፈ ው ል ጅ የ መ ኝ ታ ው ን አ ል ጋ ከ ወ ን ድ ሞ ቹ ጋ ር ይ ጋ ራ ል ?;;

ይ ጋ ራ ል ☐ አ ይ ጋ ራ ም☐

16. በ ቤ ት ው ስ ጥ ሲ ጋ ራ የ ሚ ያ ጨ ስ ሰ ው አ ለ ?፡ - አ ዎ ☐ የ ለ ም☐

17. በ ቤ ት ው ስ ጥ በ ብ ዛ ት የ ማ ብ ሰ ያ አ ይ ነ ት ፡ - ☐ እ ን ጨ ት ☐ ከ ሰ ል ☐ጋ ዝ ☐ የ ተ ቀ ላ ቀ ለ

18. የ ማ ብ ሰ ያ ከ ፍ ሉ ን እ ን ደ መ ኝ ታ ቤ ት ም ይ ገ ለ ገ ሉ በ ታ ል ? አ ዎ ☐ የ ለ ም☐

19. ይ ህ ል ጅ በ ተ መ ሳ ሳ ይ ህ መ ም በ ባ ለ ፈ ው አ ን ድ ወ ር ው ስ ጥ ታ ክ ማ ል ን? አ ዎ☐ የ ለ ም☐

20. መ ል ስ ለ 19 ጥ ያ ቄ አ ዎ ከ ሆ ነ ይ ህ ን ይ መ ሉ

<u>የ መ ድ ሃ ኒ ት አ ይ ነ ት</u> የ ሚ ዋ ጥ ☐ ተ በ ጥ ብ ጦ የ ሚ ጠ ጣ ☐ በ መ ር ፌ የ ተ ሰ ጠ ው☐

በአፍ ከወሰደው በቀን ስንቴ ነበር፡ ሁለቴ☐ ሦስቴ☐ አራቴ☐

የወሰደውለስንት ቀን ነበር; 3ቀን☐ 5ቀን☐ 7ቀን☐ 10ቀን☐

21. ህፃኑ/ልጁዎ የት ነበር የታከመው;?

☐ባህላዊ ባለመዲሃኒት ጋ ☐የግል ክሊኒክ ☐የመንግስት ጤና-ተsም

22. ጡት ጠብቶ የነበረውበስንት ወር ነበር?_____

23. ከጡት በስተቀር ማለትም ውሃ ም ቢሆን ሳይሰጡት ለምን ያክል ጊዜ ጠብተል;_____

24. በአሁኑ ሰአት ጡት በመጥባት ላይ ነበር? አዎ☐ አይደለም☐

C. Afaan Oromo Version

Unka ibsa Qorannoo Hirmaattotaaf

I. Mata Duree Qorannoo

Clinical response to empiric therapy and contributing risk factors of community Acquired pneumonia among children admitted to Jimma University specialized Hospital, south west Ethiopia.

II. **Maqaa Dura bu'ummaan qoratu:-** Shimullis Makkit

III. **Maqaa Gorsitootaa:-** Obbo Tasfaahun Chaannee
Doctor Thinu'el Girmaa

IV. **Maqaa Dhaabbatichaa:-** Yunivarsiitii Jimmaa Koollejjii Sayinsii Hawaassaa Fayyaa fi Medikaalaa, Muummee Barnoota Faarmaasii

V. Dhaabbata Qorannicha Qarshiin gargaare:- Yuniversiitii Jimmaa

VI. **Kaayyoo Qorannichaa:-** Daa'imman dhukkuba "Kominittii akuayerdi nimooniyaa" yaalamuuf hospitaala ispeshiyalayizdii yuniversiitii Jimmaa kutaa Daa'immanii ciisannif qorichaan ykn "Antii biyootiksii"tiin erga yaalamanii booda jijjiirama agarsiisaniif sababoota walqabatan addaan baasanii beekuuf.

VII. **Fayidaa Qorannichaa:-** Matiidaaf yeroo Qorannoon kun gaggeessamutti barnoonni fayyaa waa'ee dhukkuba "Koominitii aku'ardi nimooniyaa" fi haalota isaan walqabatan irratti nii kennama. Hubachifnii bu'aa harma hoosisuu fi talaallii

akkasumas nama ykn gorsi maatii sigaaraa xuuxu biraa fageessuu irratti nii kennam. Walumaa galatti qorannoon kun odeeffannoo jechuunis waa'ee talaallii, muuxannoo harma hoosisuu fi sababoota naannoo nii ibsa. Dabalataanis qorannoon biroo akka adeemsifamuuf ragaa bu'uuraa nii dhiheessa

VIII. **Iciitii Eeguu:-** Odeeffanoon qorannoo kana irraa argamu iciitiin kan qabamudha. Kunis kan ta'u hirmaattotaaf lakkoofsa addaan baasu kennuun ta'a.

IX. **Hirmaannaa Qorannichaa:-** Qorannoo kana irratti kan hirmaatan fedhii guutuu keessanii fi daa'ima/Mucaa irratti hundoofneet ta'a.

- Wanta barbaachisaa ta'eef gaaffii gaaffattan yoo ta'ee

Shimallis Makkiti Bilbila:- 0911089913

2. **Consent Form (Afaan Oromoo Version).**

Ani obbo/addee/ Dubre _____

Waa'ee qorannoo kanaa hubachiisa taa'an dubbisee ykn naadubbifamee naagalee jira. Kaayyoon qorannoo kanaas furmaata dhukuba "Koominitii aku'ardi nimooniyaa" tiin daa'iimman erga wal'aansa ykn yaalii antii biotikiitiin hospitaala ispeshialaayizdii yuniversiitii Jimmaatti kutaa daa'immaniitti ciisanii wal'aansa irra jiran jijjiirama agarsiisanii fi sababoota wal qabatan beekuuf akka ta'e hubadheen jira. Dabalataanis faayidaan qorannichaa, akkaataan iciitiin itti eegamu ifa naa ta'ee jira.

Kanaafuu mucaa koo qorannicha irratti hirmaachisuu fi odeeffannoowwan gaafatame kennuu fi yaalii qaamaas akka gaggeeffamu eeyyama kooti. Qorannoon qaamaa mucaa kiyyaa irraa fudhatamu yoo qorannoo gara fuula duraatiif oole waliigallee jirra kanaafuu qorannoo kanarratti tolaan hirmaachuuf fedhakoo ta'uu mallottoo kootiin niimirkaneessa.

Maqaa nama mucaa hirmaachisuu_____ guyyaa _____

Mallattoo Qorataa _____ guyyaa _____

<u>Mallattoo taajjabaa</u>

1. _____ guyyaa _____
2. _____ guyyaa_____

3. Gaaffiwwan Hirmaattotaaf Dhiyaatu

Gaaffiwwan armaan gadii waa'ee maatii ijoollee haala jireenya hawaassummaa fi sababootaa fi wantoota dhukuba "Koominitii aku'ardi nimooniyaa" ijoollee ta'an beekuuf gargaara.

Lack. Koodii _____ Guyyaa_____
Lakka Iccitii Ijoollee_____ Umurii (ijoollee)_____

Kutaa "A" sababoota dhukkuba "Koominitii aku'ardi nimooniyaa" ijoolleetiin walqabatan maatii irraa gaafachuuf (Mallattoo"X" deebi kee irra kayi)

1. **Teessoo:** Magaalaa ☐ Baadiyyaa ☐
2. **Haala hojii Abbaa**
   Hojjetaa Mootummaa ☐ Kan miti mootummaa ☐ Dhuunfaa ☐
   Qote bulaa ☐ Daldalaa ☐ Kan hojii hinqabne ☐
3. **haal hojii haadaa**
   Hojjetaa Mootummaa ☐ Kan miti mootummaa ☐ Dhuunfaa ☐
   Qote bulaa ☐ Daldalaa ☐ Kan hojii hinqabne ☐
4. Haati mucaa yeroo baayyee manaa-alatti hojjettii Eeyyee ☐ Lakki ☐
5. **haala barumsa maatii**
   Abbaa:- kan hin baranne ☐ sad.1ffaa ☐ sad 2ffaa ☐ >sadd 2ffaa ☐
   Haadha:- kan hin baranne ☐ sad.1ffaa ☐ sad 2ffaa ☐ >sadd 2ffaa ☐
6. **Galii kan ji'aa:** 1-499 ☐ 500-999 ☐ 1000-1499 ☐ 1500-1999 ☐ >2000☐
7. **Saba**
   Oromoo ☐ Amaara ☐ Tigree ☐ Kafaa ☐ Guragee ☐ Dawaroo ☐ Yam ☐ kan biro haa ibsamu_____
8. **Amantaa** Musliima ☐ Pirotestaantii ☐ Kaatoolikii ☐
   Ortodoxii ☐ kan biro haa'ibsamu_____
9. Ji'a darbee keessa maattii keessaa namni dhukkuba mallattoo qufa'uu ykn rakkina hargansuu agarsiise jiraa? Eeyyee ☐ Lakki ☐
10. **Baayyina maatii** <=3 ☐ 4-5 ☐ 6-8 ☐ >8 ☐
11. Baayina kutaawwan mana jireenyaa _____
12. Mucaan kun Obboleessa/Obboleettii kan mana wajjin jiraatu qabaa? Eeyyee ☐ Lakki ☐
    Gaaffii 13ffaaf yoodeebiin keessan lakki ta'e gara gaaffii 16'tti ce'aa.

13. **Obboleessa/tti meeqa qaba?** 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐
14. Mucaan kun obboleessa/tii wajjin ciisaa? Eeyyee ☐ Lakki ☐
15. Maatii keessaa kan sigaaraa xuuxu jiraa? Eeyyee ☐ Lakki ☐
16. **Mana keessatti yeroo baay'ee kan ittiin bilcheeffatan**?

    Muka ☐ Kasala/cilee ☐ Gazii ☐ Walmakaadha ☐

17. Kutaa itti bilcheeffatan akka mana ciisichaattis itti fayyadamu? Eeyyee ☐ Lakki ☐
18. Mucaan kun ji'a darbe kana keessattimallattoo walfakaataadhaan dhukubsatee yaalamee jiraa?

    Eeyyee ☐ Lakki ☐

19. Deebiin keessan lakk.19 eeyyee yoo ta'e kana guutaa.

    Bifti qorichaa:- kan liqimfamu ☐ kan bulbulamee dhugamu ☐ kan waranamee kennamu ☐

    Yoo afaaniin fudhate guyyaatti si'a meeqa ture? Lama ☐ sadii ☐ afur ☐

    Kan fudhate guyyaa meeqaaf ture? 3 ☐ 5 ☐ 7 ☐ 10 ☐

20. Mucaan eessatti yaalame?

    Mana qoricha aadaatti ☐ Mana yaalaa dhuunfaatti ☐ Mana yaalaa kan mootummaatti ☐

21. Harma ji'a meeqaaf hodhe? _____
22. Harmaan alatti waan biro bishaanis dabalatee osoo hin kenniiif ji'a meeqaaf hodhe?_____
23. Yeroo ammaa harma ni hodhaa? Eeyyee ☐ Lakki ☐