Vaccination Coverage among Children with Measles at Agok Hospital, South Sudan

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A research project submitted in partial fulfillment of the requirements for the award of a Master's of Science degree in Tropical and Infectious Diseases, University of Nairobi Institute of Tropical and Infectious Diseases

DECLARATION

I declare that this research project is my original work and to the best of my knowledge has not been presented in any institution or for examination leading to the award of a degree or any other award. It is being presented for the award of a Masters degree in Tropical and Infectious diseases at the University of Nairobi.

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APPROVAL BY SUPERVISORS

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DEDICATION

The study is dedicated to the people of South Sudan affected by the political crisis; you have suffered, you have hit rock bottom, there is no other way than up! With effective policy and implementation, it is possible to eliminate measles in South Sudan.

To my late father Peter Mukekhe, you embraced education, knowledge and excellence, we are following your footsteps.

ACKNOWLEDGEMENT

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Table of Contents

| Vaccination Coverage among Children with Measles at Agok Hospital, South Sudan | i |
|--|------|
| DECLARATION | ii |
| APPROVAL BY SUPERVISORS | iii |
| DEDICATION | iv |
| ACKNOWLEDGEMENT | V |
| ABBREVIATIONS AND ACRONYMS | viii |
| LIST OF TABLES | ix |
| LIST OF FIGURES | x |
| ABSTRACT | 1 |
| 1.0 INTRODUCTION | 2 |
| 1.1 Background Information | 2 |
| 1.2 Statement of the problem | 4 |
| 1.3 Justification | 5 |
| 1.4 Research Questions | 6 |
| 1.5 Objectives | 6 |
| 1.6 Conceptual framework | 7 |
| 2.0 LITERATURE REVIEW | 9 |
| 2.1 Measles virus | 9 |
| 2.2 Measles disease | 9 |
| 2.3 Measles eradication | 11 |
| 2.4 Measles vaccine | 11 |
| 2.5 Measles Outbreak | 12 |
| 3.0 MATERIALS AND METHODS | 14 |
| 3.1 Study Site | 14 |
| 3.2 Study Design | 14 |
| 3.3 Population universe | 14 |
| 3.4 Sample Size Determination | 15 |
| 3.5 Sampling Method | 15 |
| 3.6 Procedures | 16 |
| 3.7 Data Management | 16 |
| 3.8 Limitations of the Study | 17 |
| 3.9 Ethical Considerations | 18 |
| 4.FINDINGS | 19 |

| 4.0 INTRODUCTION | 19 |
|--|----|
| Conclusion | 25 |
| 5 DISCUSSION, CONCLUSION AND RECOMMENDATION | 26 |
| 5.1 Discussion | 26 |
| Conclusion | 29 |
| Recommendations | 29 |
| 4.0 Budget | 30 |
| 5.0 Work plan | 30 |
| REFERENCES | 31 |
| Annex 1-Focus Group Discussion Guide: | 36 |
| Annex II-Consent form | 39 |
| Vaccination coverage among children with measles at agok hospital, south sudan | 39 |
| Title of Study: Vaccination Coverage among Children with Measles at Agok Hospital, South Sudan | 39 |
| Annex III: KNH-UON ERC research approval | 45 |
| Annex IV-South Sudan MOH research approval | 47 |
| | 47 |

ABBREVIATIONS AND ACRONYMS

CDC Centers for Disease Control

FGD Focus Group Discussion

GIT Gastrointestinal Tract

HBM Health Belief Model

IDPs Internally displaced people

IDSR Integrated Disease Surveillance and Response

IgM Immunoglobulin M

KI Key Informants

KNH Kenyatta National Hospital

MAM Moderate Acute Malnutrition

MOH Ministry of Health

M&R Measles and Rubella

NGO Non-governmental Organization

PCR Polymerase Chain Reaction

WHO World Health Organization

SAM Severe Acute Malnutrition

SC Stabilization Center

SSMOH South Sudan Ministry of Health

SSRNA Single Stranded Ribonucleic Acid

SSREC South Sudan Research Ethics Committee

UNICEF United Nations Children Fund

LIST OF TABLES

| Table 2: Interventions | Table 1: Presenting Signs | 20 |
|---|--|----|
| Table 4: Association between vaccination status and signs | Table 2: Interventions | 21 |
| Table 5: Association between vaccination status and intervention | Table 3: Association between vaccination status and demographics | 22 |
| Table 6: Association between vaccination status and outcome 24 Table 7 Research Budget 30 | Table 4: Association between vaccination status and signs | 22 |
| Table 7 Research Budget30 | Table 5: Association between vaccination status and intervention | 23 |
| · · · · · · · · · · · · · · · · · · · | Table 6: Association between vaccination status and outcome | 24 |
| · · · · · · · · · · · · · · · · · · · | Table 7 Research Budget | 30 |
| Table 8 Detailed work plan | Table 8 Detailed work plan | |

LIST OF FIGURES

| Figure 1. Map of South Sudan depicting Agok and other County hospitals supported by humanitarian | |
|--|----|
| agencies(MSF, 2018) | 4 |
| Figure 2 Conceptual Framework | 7 |
| Figure 3: Age distribution | 19 |
| Figure 4: Vaccination Status | 21 |

ABSTRACT

Background

Globally, cases of measles resurgence have been reported in recent years. The majority of the cases have been reported in Africa and in the Indian subcontinent and are associated with low measles vaccination coverage. In South Sudan, measles outbreaks with mortalities have been reported across different states. Despite static, outreach and intensified campaigns, measles cases remain high in South Sudan

Objective

The main objective of this study was to determine the proportion, characteristics and transmission patterns of patients aged 15 years and below who had received a measles-containing vaccine and were diagnosed with measles at Agok Hospital, Abyei region, South Sudan

Methodology

The study was cross-sectional and utilized secondary measles data from case finding surveillance reports in Agok Hospital. The population of interest was children under the age of 15 years diagnosed with measles from 2015 to 2018. The sociodemographic and clinical data was collected and analyzed by use of STATA version 13. Lastly the study sought to determine the measles vaccine effectiveness within the study area.

Findings

Among the 385 measles patients studied, 36.6% (140) had received a measles vaccine. The calculation presented a vaccine effectiveness of 43% contrary to the expected 85% after the initial vaccine administration. The measles patients presented with cough (97.1%), maculopapular rash (95.3%) and conjunctivitis (91.2%). Measles transmission in Agok was higher in children attending schools and living in the cattle camps during the dry season.

Conclusion

The children who got infected with measles and had not received the vaccine were more likely to have been admitted or died. The results highlight the need to increase vaccination coverage.

1.0 INTRODUCTION

1.1 Background Information

Resurgence of measles has been reported especially in countries with unstable political climate, low per capita, with refugees and internally displaced persons surge compounded by weak moribund health systems (Benjamin M Nkowane, Bart, Orenstein, & Baltier, 1987). The republic of South Sudan is a classic case that meets most of the aforementioned conditions in sustaining the persistence of measles. Despite the intensified actions by the South Sudan Ministry of Health (MOH) and health partners -WHO, UNICEF and other NGOs - to increase the measles vaccine coverage, reports of outbreaks persist. According to WHO 2017, all the 28 states of South Sudan have reported an outbreak of measles since the onset of the political crisis in December 2013(States, Preuve, Advi-, Grade, & Sage, 2017).

The persistence of outbreaks despite efforts to improve measles vaccine coverage in the country is a major concern. Some of the key explanatory models of the situation have been centered towards the high mobility of the population due to displacement and limited access to vaccination services in some remote locations due to inadequate cold chain systems (Metcalf et al., 2015). This study sought to determine the proportion of vaccinated children amongst the measles caseloads. The study is anchored on the reports of vaccinated children that still suffer the disease. The basis of the vaccinated versus unvaccinated children with measles has not been quantified in the republic of South Sudan with clear focus on the reasons behind it. It is still unclear if the potency of the vaccines was a contributing factor for the 15% primary vaccine failure rate. The study characterized the factors associated with the vaccinated population versus the unvaccinated population of patients with measles. Moreover, the patterns exhibited in the measles transmission are key in future plans to terminate transmission of the disease.

Globally, there have been reported cases of measles resurgence in the recent years (Paules, Marston, & Fauci, 2019). The majority of the cases have been reported in Africa and the Indian subcontinent associated with low measles vaccination coverage. In South Sudan, measles outbreaks have been reported across different states with high mortalities. The South Sudanese population affected by measles outbreak ranks second to cholera in the recent past, according to WHO 2016, and the leading outbreaks reported in children under the age of five years(Rull et al., 2018). Despite static, outreach and intensified campaigns, measles cases remain high.

Agok Hospital is located in the Southern part of Abyei region. It provides medical services to approximately 120, 000 population spanning neighbouring Counties and covering a radius of 80 km.

It has a bed capacity of 130 and offers maternity, emergency, surgical, nutrition and infectious diseases medical services. Agok town accommodates more than 100,000 Internally displaced persons (IDP) who fled from the neighbouring counties due to the ongoing political crisis in the country.

Abyei region serves as a safe haven for the displaced population of the neighbouring counties. The displaced population poses a risk to the community residing in Abyei region. The presence of Agok hospital and intensified community outreaches providing the Expanded Programme of Immunization (EPI) has significantly improved the measles vaccine coverage estimated at 70% by South Sudan Ministry of health (SSMOH). The data on immunization status of the IDPs is not well documented. Their movement is associated with increase in transmission rate of communicable diseases, some with epidemic potential like measles. The native community is predominantly of Dinka-ngok and Misseriya origin. The two communities have had past conflicts rooted in their food security and livestock rearing lifestyles causing further displacement. Furthermore, presence of natural resources especially oil in Abyei has led to contention since the signing of the comprehensive peace agreement in 2005 and eventual independence in 2011.

Abyei region is divided into five counties (Rumamer, Mijak, Ameth Aguok, Alal and Abyei town). Agok hospital is a referral facility serving the entire population of Abyei region. Whereas it is located in Rumamer County, Agok hospital receives patients from the entire region. The hospital is well equipped with medical supplies and medical expertise provided by local and expatriate medical staffs.



Figure 1. Map of South Sudan depicting Agok and other County hospitals supported by humanitarian agencies(MSF, 2018)

1.2 Statement of the problem

In the republic of South Sudan, and specifically in Agok, Abyei region, measles outbreaks have been reported consistently since 2011. There were 2,294 reported cases in South Sudan of suspected measles in 2016 with a case fatality rate of 1.22% (Rull et al., 2018) The ministry of health and the health partners responded by intensifying vaccination exercises through routine and mass measles vaccination (Nhilla, Khali, Baharchhara, Palong, & Palong, 2017). Despite these efforts, there has been persistent measles outbreak in the Country particularly in some states, Abyei region being one of them. Moreover, vaccinated children have been part of the patients admitted with measles (Giffen, 2016). It is vital to establish the determinants and proportion of the vaccinated children who suffer from measles in Agok so as to better plan and inform policy on the critical factors that may be aiding the outbreak persistence.

There is no documented evidence of a study carried out to evaluate the proportion of vaccinated children with measles in South Sudan. However, it is vital to establish whether the vaccinated children infected with measles comprise the 15% vaccine expected failure rate (Eom et al., 2018). South Sudan MOH is yet to fully implement the two-dose measles vaccine strategy that might curb

the vaccine failure rate. Moreover, other factors will be evaluated together with sociodemographic and clinical factors that might play a role in measles outbreak sustenance. Information on measles trends and severity helped determine the transmission patterns in relation to the established vaccination sites and activities.

1.3 Justification

The critical knowledge gap and policy information that this study addressed is the measles vaccination coverage and immunity conferred against a natural attack. The research analyzed reasons behind the sustained high prevalence of measles in Agok Hospital of South Sudan. Globally, measles is a common disease in many parts of the world including Africa, Asia, Europe and some parts of the pacific. It is estimated by CDC that measles affects 19 in every 1 million people (CDC, 2015). It is the leading cause of vaccine preventable infant mortality (CDC, 2015). The vaccine has drastically decreased the incidence of measles by 87%; from 145 cases to 19 cases per million from 2000 to 2016 according to CDC. Furthermore, the mortality rate has also remarkably decreased by 84% per year and thus 20.4 million deaths prevented deaths (W A Orenstein, Hinman, Nkowane, Olive, & Reingold, 2020).

South Sudan is one of the African nations with the highest incidence and reported constant measles outbreaks (Interior, Ministry 2013). This study sought to establish the reasons propagating the epidemic. A major contributing factor to this status is the constant unrest and civil war that has engulfed the young nation since 2013, and for more than 20 years before the independence. The civil war has resulted to hundreds of thousands of deaths and more than one million people displaced. The constant movement of the internally displaced persons has kept the measles virus in circulation. In addition, South Sudan Ministry of health has limited resources with which to cater for the health needs of the citizens. WHO, together with other multilateral and Non-governmental agencies, have been tasked with providing preventive and curative services to the population. Measles vaccination is provided at health facilities and outreaches with intense vaccination drives during suspected disease outbreaks. Measles vaccination coverage is reportedly still very low in the country even after the vaccination efforts that have been ongoing for the past five years. In 2011, the estimated measles vaccine coverage was 62%, the proportion has drastically gone down to 20% in 2017(World Health Organization, 2018). It has been reported that some of the vaccinated children contracted the virus and suffered the measles disease course.

Findings of this study did shed light on the proportion of the vaccinated children that suffer the disease during the outbreaks reported in the past 3 years in Agok Hospital. Agok Hospital is the only

referral hospital in the Abyei region. The region is surrounded by counties that experience constant political conflicts and insecurity. This has led to displaced population moving in and out of Abyei region hence propagating constant measles outbreaks in the area. The clinical and demographic characteristics of measles-infected children provided information on severity and outcomes of the infection in respect to the vaccination status. The study evaluated measles vaccine failure rate in the Agok population and established recommendations to improve the efficacy and safety. Moreover, due to high rate of population turn over and mobility in Agok, the study analyzed and established measles outbreak trends in relation to the children lifestyle and movement in the region (schools, churches, cattle camps). The data facilitated comparison of the transmission patterns that are exhibited in the area. The knowledge of the patterns will help in the determination of prevention mechanisms that may decrease the prevalence of the epidemic.

There is no evidence of a similar study having been carried out in South Sudan. Other studies that have been undertaken in the region are on measles vaccine efficacy and the behavioural factors influencing measles vaccine uptake. This study is expected to inform policy on the approaches that can be adopted to curb the persistent measles outbreak in unstable political environment.

1.4 Research Questions

- 1. Among children aged 15 years and below with measles, what proportion had received a measles-containing vaccine in Agok Hospital?
- 2. What are the socio-demographic and clinical characteristics of children with measles in the study area?
- 3. What measles transmission patterns are exhibited in Agok?

1.5 Objectives

1.5.1 General Objective

To determine the proportion, characteristics and transmission patterns of patients who had received a measles-containing vaccine, among children aged 15 years and below who were diagnosed with measles at Agok Hospital, Abyei region, South Sudan.

1.52 Specific Objectives

1. To determine the proportion of patients who had received a measles-containing vaccine, among children under 15 years diagnosed with measles at Agok Hospital, Abyei region, South Sudan.

- 2. To describe the socio-demographic factors and clinical characteristics of children with measles in Agok hospital, Abyei region, South Sudan.
- 3. To assess measles transmission patterns within the study area.

1.6 Conceptual framework

The health belief model (HBM) conceptualizing the access of health facility and medical utilization based on the illness perception and health seeking behaviour in the community is partly critical in the analysis of the measles outbreak. Several socio-demographic and clinical data were collected to facilitate the relationship link to the constant measles outbreak in the Abyei region.

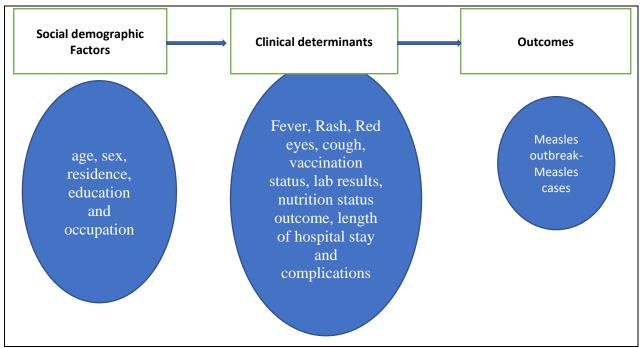


Figure 2 Conceptual Framework

The interrelationship between demographics (age, sex, residence, marital status, education and occupation) and clinical information (Fever, Rash, Red eyes, cough, vaccination status, lab results, outcome, length of hospital stay and complications) and transmission patterns (Homes, schools, cattle camps, IDP camps) were evaluated. The study sought to associate the proportion of the sociodemographic and clinical determinants to the development of measles disease during an outbreak.

The study area (Agok) contains mostly displaced population from the neighbouring counties. In addition, there are reported measles cases yearly since December 2013 and are mostly attended to and admitted at the Agok County Hospital. The vaccination data from the hospital provided

information on the trends and coverage in relation to the county population. Specific data on measles line listing were pivotal in the analysis of the proportion of vaccinated children versus the unvaccinated ones. Line listing is a disease surveillance technique utilized during a disease outbreak for continuous monitoring of the magnitude, effect and control of the specific epidemic. Furthermore, the validity of the data was ascertained by cross referencing with the patient files. Key informant interview of 12 health workers and 12 community leaders on the patterns of measles transmission in the latest reported outbreaks will help in prevention measures to be developed. The study provided information that may guide policy makers in decreasing complications and deaths that can arise from measles infection. In addition, the vaccination approaches may be tailored in a manner where vaccine cold chain systems are availed in proportion to the population spread, maintenance of vaccine potency and close monitoring of the vaccine administration safety.

The study determined the proportion of vaccinated children less than 15 years who developed measles and their socio demographic factors. The data provided information on the predisposing factors, severity, immunity status, socio demographic factors and medical care spectrum that contributed to the sustainability and severity of measles outbreaks. Since vaccination does not provide 100% immunity, the study evaluated other factors that might contribute to vaccine failure or resistance. The study explored the different transmission patterns exhibited by vaccinated children in the study area. The study provided a platform to postulate measures that can curb the transmission and decrease the incidence of the disease.

2.0 LITERATURE REVIEW

Measles is one of the most contagious diseases affecting humans (World Health Organization, 2012). The disease is caused by measles virus which is in the genus morbilivirus and frequently results in widespread outbreaks (Zipprich et al., 2015). Measles is one of the main causes of infectious childhood mortality in the world.

2.1 Measles virus

Measles virus has negative sense single-stranded RNA non-segmented genome and envelop with two Fusion (F) and Hemagluttinin (H) proteins (Fernandez-Munoz et al., 1999). The virus is highly contagious with a secondary infection rate of 90% and it is transmitted via aerosol route and direct contact (Diane E Griffin, Lin, & Nelson, 2018). The virus can also remain contagious for 2 hours in the air or on contaminated service. Measles virus is localized to humans and currently there is no evidence available showing the contrary. Infection with measles leads to development of long-term immunity against the virus.

Measles is a viral infection with systemic manifestations, the virus which is part of paramyxoviridae family. The measles infection is amplified in the lymphoid organs before spreading to the other organs in 10-14 days (Helfand *et al.*, 2018). Measles virus has the potential to inhibit the induction of interferon type 1 hence significantly decreasing the response of innate immunity (D E Griffin, 1995). The site of viral infection appears with the infiltration of immune cells to facilitate clearance of the measles virus. Measles virus is eliminated slowly from the lymphoid tissue. It takes around 6 months to be fully eliminated although recovery from the infection is shorter (Manirakiza, Kipela, Sosler, Daba, & Gouandjika-Vasilache, 2011). Due to the persistence of the measles virus in the lymphoid tissue, it facilitates the development and maturation of the immunity against the virus hence leading to lifetime immunity. Persistence of the virus in tissues can also predispose to the development of other diseases such as subacute sclerosing panencephalitis (Fernandez-Munoz et al., 1999).

2.2 Measles disease

Following infection with measles virus, the virus replicates in the epithelium of the respiratory system after which it spreads to the lymphoid tissue. Replication continues in the lymphoid tissue before causing primary viremia. Further spread to reticuloendothelial system with continued multiplication leading to secondary viremia. The spread leads to dissemination of the virus to

different area such as the skin and gastrointestinal tube (GIT). Measles disease presents predominantly with fever of above 38°C from 10-12 days after exposure with nonspecific symptoms such as malaise, lethargy and anorexia (Diane E Griffin et al., 2018). Moreover, the infected present with a triad of cough, coryza and conjunctivitis. Maculopapular rash is very common extending from the face to extremities as from the 14th day of exposure and lasting for 5-6 days. Furthermore, Koplik spots are present one to two days before the appearance of rash and disappear two days after the rash. Measles diagnosis is predominantly clinical although laboratory tests are available for confirmation. The laboratory tests commonly used include serology for IgM antibodies, molecular polymerase chain reaction(PCR) and viral culture for isolation (Helfand *et al.*, 2018).

Measles infection may have several complications. Due to diminished immune response, there's an increased risk of contracting bacterial infections such as pneumonia, giant cell pneumonia and otitis media. In addition, patients can also present with diarrhoea, sub-acute sclerosing panencephalitis (SSPE) with 1 in 1000 developing encephalitis. Encephalitis presents as deafness, mental disorders and seizures (Bellman & Dick, 1978).

Treatment of measles is predominantly supportive through rehydration, use of antipyretics and treating secondary bacterial infection. However, rivabirin has also been efficacious in managing SSPE. Prevention of measles can be achieved by vaccination with a target coverage of at least 90% (Cockbain, Bharucha, Irish, & Jacobs, 2017). Vitamin A supplementation has been reported to decrease deaths by 50%. It also decreases the possibility of developing visual complications.

There were major measles epidemics in the world occurring after every 2 to 3 years before the introduction of the measles vaccine in the year 1963 (Benjamin M Nkowane et al., 1987). The outbreaks led to mortality of approximately 2.6 million people every year. Even after introduction of the measles vaccine, there still exists a large number of deaths related to the disease. In 2016, approximately 89,780 humans especially children under the age of 5 succumbed to the infection.

According to WHO, Globally, vaccination has drastically decreased the incidence of the disease. Approximately 84% of associated mortality has been averted. In the 2000-2016 period, a total of 20.4 million deaths were prevented by the vaccine(World Health Organization, 2012).

The mortality rate of measles cases is about 3-6% in children with malnutrition especially vitamin A deficiency and impaired access to adequate health. The mortality rate increases rapidly to 30% in displacement scenery.

2.3 Measles eradication

For eradication of measles, the World Health Assembly established three milestones to be undertaken in 2010. The goal was to eradicate measles by 2015. The strategy included increase in routine coverage with the initial measles dose to more than 90% nationally and within counties at above 80%; to decrease the measles incidence to less than 5 cases per million and reduce the mortality arising from measles by more than 95%.

Measles & Rubella Initiative (M&R Initiative) is a global partnership that was launched in 2001. The initiative is directed by the American Red Cross, United Nations Foundation, Centres for Disease Control and Prevention (CDC), UNICEF and WHO. The M&R Initiative is devoted to ensuring that no child dies from measles or is born with congenital rubella syndrome; reducing measles deaths by 95% by 2015; and achieving measles and rubella elimination in at least 5 WHO regions by 2020 (World Health Organization, 2012).

M&R Initiative propelled a new Global Measles and Rubella Strategic Plan which covers the period 2012–2020 in 2012. The established Plan provides vibrant approaches for country immunization managers, working with domestic and international partners, to realize the 2015 and 2020 measles and rubella control and elimination goals.

2.4 Measles vaccine

Vaccination coverage has seen a drastic increase in the proportion of children receiving 1st dose of measles vaccine in their first year of life from 72% in 2002 to 85% in 2016 (WHO, 2016). It is recommended to have a second dose at 18 months to effectively cover the 15% children who did not develop immunity after the initial dose. Measles vaccine is one of the most successful prevention ventures developed. Measles vaccine has drastically decreased the incidence of measles by 87%. i.e from 145 cases to 19 cases per million from 2000 to 2016 according to CDC. Furthermore, the mortality rate has also remarkably decreased by 84% per year and thus 20.4 million deaths prevented deaths (Levels, 2017). The vaccine is safe, effective and inexpensive. The two pronged approach of

routine immunization and mass vaccination campaigns has been the proposed model for measles elimination (World Health Organization, 2012)

The efficacy of measles vaccine to avert disease and epidemics rest on the vaccine being potent and properly administered to persons capable of responding (Walter A Orenstein et al., 1985). Apposite measures are accessible to test the potency of vaccines and the response of the host. Potency testing is imperious in checking the formation of vaccines and their transference through the cold chain. In cold chain, vaccines from the field are tested to ensure that they have not lost potency. Serological studies can also be used to assess a vaccine's efficacy. Sero-conversion is beneficial to measure the induction of an immune response in the host and, in the absence of disease, indicates the persistence of antibody and immunity (Levels, 2017). Sero-prevalence studies monitors the prevalence of antibodies due to disease in the populace and designate the pattern of occurrence of disease.

Sero-conversion studies are predominantly beneficial in selecting appropriate age for vaccination. The two, vaccine potency testing and serological testing techniques, can play valuable roles in the formation and enactment of immunization programmes. The accomplishment of vaccinations performed under field conditions can be evaluated by computing the protection against the disease by epidemiological studies(Diane E. Griffin, 2018).

Vaccine efficacy is measured by calculating the attack rates of disease among vaccinated and unvaccinated persons and determining the percentage reduction in the incidence rate of disease among vaccinated persons compared to unvaccinated persons.

2.5 Measles Outbreak

Epidemiologically, an outbreak or epidemic signifies an abrupt increase in the number of cases reported of that disease above the normal in that sphere within a certain period of time. According to WHO, there is declaration of a measles outbreak when there are three or more confirmed cases identified within that specific area. The catchment population is limited to 100,000 and the time period to one month (WHO, 2017)

According to Kenichi Komabayashi (Komabayashi *et al.*, 2018), even in countries where measles has been eliminated and are in transitional immunological protection development stage, have a 60% chance of reporting an outbreak. The occurrence is associated with importation of genomic variants

of the measles virus. In countries such as South Sudan where the prevalence is high, moribund health system and highest mobility and displacement, the risk of outbreaks ranks among highest in the world.

Several studies have been conducted on measles epidemics in the world. In 2010, a study was undertaken on "sub-national variation in measles vaccine coverage and outbreak risk in Malawi" (Kundrick *et al.*, 2018), and a related study in 2015 Uganda, "Factors contributing to measles transmission during an outbreak" (Nsubuga *et al.*, 2018). Both studies concluded that in a crowded set up, exposure to measles facilitated occurrence of an outbreak and recommended second dose vaccination. A past study was carried out in USA to evaluate vaccine efficacy in children previously vaccinated at 12 months of age (J.S., T.J., & W.A., 1978), which employed a methodological approach that could be partly be useful in data analysis of this study. Comparative literature on vaccinated versus non vaccinated measles patients is limited and none has been carried out in South Sudan. The study will pioneer and open the region for larger studies to build the knowledge on the determinants of persistent measles outbreak. The study area is conducive as data on measles outbreak is available as reported by WHO IDSR (Giffen, 2016), yet there is need for more analysis and publication to inform policy.

3.0 MATERIALS AND METHODS

3.1 Study Site

This study was carried out in Agok Hospital, South Sudan. Agok Hospital is located in Abyei region. It provides medical services to a population of approximately 120,000 spanning neighbouring counties and covering a radius of 80 km. It has a bed capacity of 130 and offers maternity, emergency, surgical, nutrition and infectious diseases medical services. Agok town is home to more than 100,000 IDPs who have fled from the neighbouring counties due to the ongoing political crisis in the country. The area has experienced multiple measles outbreaks in the past years with the highest epidemics recorded between 2015 and 2017. The outbreaks have been persistent in the location despite efforts by the MOH and WHO to improve vaccination coverage.

3.2 Study Design

The study was cross-sectional utilizing both qualitative and quantitative methods to assess records on vaccination, characteristics and transmission patterns in children aged 6 months to 15 years and infected with measles in Agok hospital, South Sudan. We conducted an in-depth analysis of secondary data on measles outbreak. The study design was selected because of its strength in measuring multiple variables at the time of data collection.

3.3 Population universe

The study targeted secondary data of all children between the ages of 6 months to 15 years who had presented to Agok hospital with clinical features of measles between 2015 and 2017. Furthermore, data on laboratory confirmed measles cases was also included in the study.

3.3.1 Inclusion Criteria

All records of patients who met the measles clinical diagnosis criteria (generalized maculo-papular rash of more than three days duration, with fever of 38°C and at least one of the following; coryza, cough or conjunctivitis) and laboratory confirmed cases (IgM antibody) between 6 months and 15 years of age reported as from 2015 to 2017 in Agok Hospital.

Focus Group Discussion (FGD) included health care workers and community leaders - four clinical officers, four nurses, four community health workers and twelve local leaders in Agok, Abyei region.

3.3.2 Exclusion Criteria

During data collection, all patient records that were incomplete and lacked measles vaccination status were excluded from the study. The focus group discussion excluded participants who had not been residents of Agok for at least one year. The rationale being good knowledge of the past transmission patterns as the study focused on measles outbreak from 2015 to 2017

3.4 Sample Size Determination

Systematic random sampling technique was adopted. The sampling frame was the measles line listing and measles IgM antibody-positive patients as the sampling unit. Line listing is a disease surveillance technique utilized during a disease outbreak for continuous monitoring of the magnitude, effect and control of the specific epidemic. Systematic random sampling technique was used in review of measles patient data and records. Purposive sampling technique was used in the selection of health care workers and community leaders for the focus group discussion.

Sample size estimation was done using the formula,

```
\begin{aligned} &\textbf{n} = \textbf{Z}^2\textbf{pq/d^2}, \text{ where} \\ &\textbf{n} = \text{the minimum sample study size} \\ &\textbf{Z} = \text{the standard normal deviate at 95\% confidence interval (1.96)} \\ &\textbf{p} = \text{the proportion in the target population estimated to have characteristics being measured} \\ &(50\%) \\ &\textbf{q} = 1\text{-p} \\ &\textbf{d} = \text{degree of freedom (0.05)} \\ &\textbf{n} = \textbf{Z}^2\textbf{pq/d^2} \\ &\textbf{n} = &(\underline{1.96})^2\underline{0.5(1\text{-}0.5)} \\ &(0.05)^2 \\ &\textbf{N} = &0.9604/0.0025 = 384.16 \\ &\textbf{n} = 384 \end{aligned}
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Measles disease is epidemic prone without a global prevalence rate. Majority of the affected nations are developing countries with low measles vaccine coverage (Dabbagh et al., 2017). However, some developed countries have reported outbreaks in the recent past (Paules et al., 2019). This led to the study proportion estimate of the disease in the target population set at 50% for the study.

3.5 Sampling Method

Systematic random sampling technique was used to get the 385 records of measles patients in Agok hospital. The measles case finding surveillance reports for the period 2015-2017 were obtained from

Agok Hospital and numbered according to the dates of the outbreak (Chronologically from 2015 to 2017). The 385 research participants were selected from the sorted line lists. From the numbering that was done, every fourth record was selected until the sample size was achieved from 1642 patients listed. Thereafter patient files of the 385 selected participants were sought for data collection. Additionally, 15% of the total sample size was added as buffer to cater for incomplete data that may be included (n=442). The inclusion criteria for FGD was used to select the appropriate candidates for the study and informed consent signed before start of the discussion.

3.6 Procedures

Case definition- all records of patients who met the measles clinical diagnosis criteria (Generalized maculo-papular rash of more than three days duration, fever of 38°C and at least one of the following; coryza, cough or conjunctivitis) and laboratory confirmed cases (measles IgM antibody) 6 months up to 15 years of age reported as from 2015 to 2017 in Agok Hospital.

From the Agok hospital records and disease surveillance unit at the health cluster, health records for measles patients were obtained for review from 2015 to 2017, a random sample of 385 measles patient records were reviewed.

Apart from the secondary data, information on measles transmission patterns in Agok was also obtained from Focus Group Discussion (FGD) by use of an FGD guide. A total of 24 volunteers were sought divided into 12 health workers from Agok Hospital (4 Clinical officers, 4 Nurses and 4 community health workers) and 12 community leaders from Agok. The 24 volunteers were divided into 3 groups of 8 participants each. Group 1 comprised of only health workers, Group 2 all community leaders and group 3 split, half health workers and half community leaders.

3.7 Data Management

Socio-demographic and clinical data was collected from hospital records and entered into a preset excel document. Cross referencing the data with patient files and immunization records was done for validity. FGD was conducted by use of a structured FGD guide on transmission patterns observed within the study area. Data was entered into STATA version 13 for analysis.

Univariate analysis and presentation of socio demographic and clinical data was carried out using frequencies/proportions or measures of central tendency.

Bivariate analysis of dependent variables (e.g. immunization status) and independent variable (e.g.

age) was done using t-test. Chi-square test was used to analyze the association between immunization

status and residence.

Multivariate analysis was carried out by use of logistic regression to test association between

dependent variable (immunization status) with age, sex, residence, marital status, education and

occupation.

Data collected and the findings will be shared with Agok hospital and the local authorities. In

addition, the findings will be shared with the Ministry of health, and the Health Cluster. The findings

are intended to inform interventions for improving vaccination coverage in the area, better the

strategy and decrease the potential for the measles outbreaks. The findings will also be published in

a peer-reviewed journal.

Study determined the measles vaccine effectiveness within the study area. The secondary data that

was collected from Agok hospital records on measles patients included both the vaccinated and

unvaccinated children between the ages of 6 months and 15 years. The data provided comparison

between the proportion of measles disease in vaccinated population to that in unvaccinated

population hence the vaccine effectiveness could be determined by modifying the formula: (Musa,

Topalovic, Catic, & Smajlagic, 2018)

VE (%) = (ARU-ARV) X100

ARU

Where: VE- Vaccine effectiveness

ARU- Attack rate in unvaccinated

ARV-Attack rate in vaccinated

3.8 Limitations of the Study

The study involved collection of secondary data on measles cases from 2015 to 2017 in Agok

Hospital. The data collection process was prone to sampling and non-sampling errors. The measure

to mitigate against non-sampling errors was training of data collectors and use of 95% confidence

interval where the true values lie. Probability sampling was used to limit sampling errors in the study.

17

3.9 Ethical Considerations

The study protocol was submitted to KNH-UoN Ethics and Research Committee in Kenya and South Sudan Research Ethics Committee (South Sudan Ministry of Health) in South Sudan. The two ethical committees reviewed and approved the study. Before the participants were recruited for FGDs, it was imperative for full explanation and disclosure of the objective of the study, how the study will be conducted and what will be required of them. The benefit of the study was also shared in a simple local language. The principal investigator utilized a translator who maintained confidentiality and at the same time provided correct translation to the questions that were asked. Emphasis was placed on the fact that the study is voluntary and the participants can withdraw at any time during the study without fear of repercussions. The participants were assured of confidentiality of the data as it was coded and stored under lock and key with access only to the principal investigator and the supervisors. Before the enrolment of the participants, a consent form was signed after comprehensive explanation to the participants of the content. KNH-UoN ERC granted a waiver for obtaining informed consent for secondary data.

Due to the recurrent measles outbreaks in the study area coupled with intensified routine and mass vaccination, the expected outcome of the study was establishment of the proportion of vaccinated children with measles in Agok. Further to this, research findings deduced the measles transmission patterns exhibited in the study area in correlation with severity of the symptoms and the complications following the infection.

4.FINDINGS

4.0 INTRODUCTION

The results presented here are based on 385 cases of patients who were seen at Agok Hospital with a diagnosis of measles between 2015 and 2017. A total of 442 patient records had been included in the study but 57 patients were excluded for the analysis as they lacked data on the main outcome variable (vaccination status).

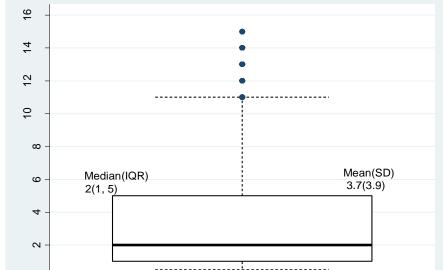
4.1 DEMOGRAPHIC

Figure 3: Age distribution

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The age of patients ranged from 6months to 15 years, with a median age of 2 years (IQR 4). Age above 10 years was considered as an outlier, 40 patients fell in that category.

16 4



The distribution of patients by sex was almost equal (female 49.4%, males (50.6%).

Table 1: Demographics characteristics

| Variable | Category | Frequency | Percentage |
|--------------------|-----------|-----------|------------|
| Sex | Female | 190 | 49.35 |
| | Male | 195 | 50.65 |
| Age | < 1 year | 83 | 21.56 |
| | 1-4 year | 201 | 52.21 |
| | 5-15 year | 101 | 26.23 |
| State of residence | Abyei | 266 | 69.27 |
| | Warrap | 94 | 24.48 |
| | Unity | 21 | 5.47 |
| | Aweil | 3 | 0.78 |

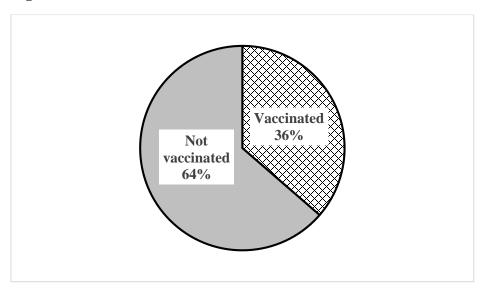
Majority 69.3% (266) of the patient were residents of Abyei state of Southern Sudan, followed by Warrap state 94(24.5%), while Aweil was represented by only 3(0.8%) patients.

Table 1: Presenting Signs

| Signs | Frequency | Percentage |
|----------------|-----------|------------|
| Cough | 373 | 97.2 |
| Rash | 367 | 95.3 |
| Fever | 366 | 95.1 |
| Conjunctivitis | 351 | 91.2 |

Out of 385 patients 373 (97.1%) of them complained of cough, 367 (95.3%) rash, while 351(91.2%) had conjunctivitis

Figure 4: Vaccination Status



Among 385 patients who presented in Agok Hospital with a diagnosis of measles, 36.4% (140) had received a measles-containing vaccine.

Table 2: Interventions

| Intervention | Frequency | Percentage |
|--------------------|-----------|------------|
| Hospital admission | 208 | 54.5 |
| Antibiotics | 358 | 95.98 |
| Vitamin A | 341 | 89.27 |

Only 12 (4.2%) patients had had a mouth swab done while 12.2% (36) had serum tested for diagnosis. Vitamin A was given to 341 (89.3%) patients and 358(96.0%) patients were given antibiotics. More than half 208 (54.5%) of the patients were admitted for treatment.

Outcome

3 (0.8%) died from measles all whom were unvaccinated.

Table 3: Association between vaccination status and demographics

| Variable | Category | Vaccination status | | p-value |
|------------|--------------|--------------------|------------|---------|
| v ai iaule | Category | Not Vaccinated | Vaccinated | p-value |
| State | Abyei | 160 (60.2) | 106 (39.8) | 0.025c |
| | Warrap | 66 (70.2) | 28 (29.8) | 0.137c |
| | Unity | 17 (81.0) | 4 (19.0) | 0.093c |
| | Aweil | 2 (66.7) | 1 (33.3) | >0.99f |
| Sex | Female | 115 (60.5) | 75 (39.5) | 0.211c |
| | Male | 130 (66.7) | 65 (33.3) | |
| Age | Median (IQR) | 2 (4.1) | 2 (3.2) | |

There was no difference in age between those vaccinated and those who had not been vaccinated (p>0.05). The proportion of females who were vaccinated was slightly higher 39.5% compared to that of males 33.3% though not statistically different (p=0.211). Compared to neighbouring states of Warrap, Unity and Aweil, Abyei had significantly (p=0.025) higher 106 (39.8%) proportion of those vaccinated.

Table 4: Association between vaccination status and signs

| Variable | Category | Vaccination | | n volue |
|------------|----------|----------------|------------|--------------------|
| v ai iable | Category | Not Vaccinated | Vaccinated | p-value |
| Fever | No | 8(42.1) | 11(57.9) | 0.045 ^c |
| | Yes | 237(64.8) | 129(35.2) | |
| Rash | No | 12(66.7) | 6(33.3) | 0.784^{c} |
| | Yes | 233(63.5) | 134(36.5) | |
| Red eye | No | 20(58.8) | 14(41.2) | 0.541° |
| | Yes | 225(64.1) | 126(35.9) | |
| Cough | No | 7(63.6) | 4(36.4) | >0.99 ^f |
| | Yes | 238(63.8) | 135(36.2) | |

^f Fisher's Exact Test, ^c Chi Square Test

Of those who had fever (n=366), only (35.2%) were vaccinated compared to those who had no fever (57.9%) were vaccinated, the difference was statistically significant.

There was no statistical difference (p=0.784) in the proportion of vaccinated children among those with rash (36.5%) compared to those who had no rash (33.3%).

There was no statistical difference (p=0.541) in the proportion of vaccinated children among those who presented with conjunctivitis (35.9%) compared to those without (41.2%).

The proportion of vaccinated children among those who presented with a cough (36.2%) was equal (p>0.999) compared to those who didn't have a cough (33.3%).

Table 5: Association between vaccination status and intervention

| Variable | Category | Vaccination s | Vaccination status | |
|--------------------|----------|----------------|--------------------|--------------------|
| variable | Category | Not Vaccinated | Vaccinated | p-value |
| Hospital admission | Admitted | 140 (67.3) | 68 (32.7) | 0.101° |
| Antibiotics | Yes | 224 (62.6) | 134 (37.4) | 0.398^{c} |
| Vitamin A | Yes | 214 (62.8) | 127 (37.2) | 0.487 ^c |

^f Fisher's Exact Test, ^c Chi Square Test

Though not statistically different (p=0.101), the proportion of vaccinated children among those not admitted was high 71 (40.8%) compared to those who required admission 68 (32.7%).

Of those who were given antibiotics, 134 (37.4%) were vaccinated compared to 4 (26.7%) of those who were not given antibiotics that were vaccinated; the difference was not statistically significant (p=0.398).

Table 6: Association between vaccination status and outcome

| Variable | Category | Vaccination status | |
|----------|----------|--------------------|------------|
| | | Not Vaccinated | Vaccinated |
| Outcome | Alive | 242 | 140 |
| | Died | 3 | 0 |

All 3 (100%) the patient who died had not been vaccinated

Measles vaccine effectiveness in Agok

VE(%) = (ARU-ARV)X100

ARU

VE=42.85%

Where: VE- Vaccine effectiveness

ARU- Attack rate in unvaccinated

ARV-Attack rate in vaccinated

The vaccine effectiveness was 42.9% in Agok, this was lower than the expected 85% with initial measles dose vaccination.

The FGD participants reported that there were 3 health facilities in Agok town serving the population with EPI, outpatient and inpatient services. Apart from the cattle camps that were implicated for high measles transmission rate because of overcrowding and non-existent health services as they were temporary sites, Agok primary school with slightly above 2000 children was also a major conduit for transmission. The source of transmission was thought to be mainly from IDPs seeking safe environment from the neighbouring Unity, Warrap and Aweil state due to political conflict and insecurity.

The routine EPI activities were present in Agok compared to Unity and Warrap states where most had been vandalized by the warring communities and military personnel. Strengthening of EPI activities, increase of vaccination outreaches and campaigns were viewed as the ultimate control strategy to the measles epidemic in the region. Agok is a safe place with good road access to Rumbek and Gambella in Ethiopia. The health workers and community leaders in the FGD were not aware of the second measles vaccine dose protocols introduced in different nations.

Conclusion

The children who got infected with measles and had not received the vaccine seemed to have severe presentation, more inpatient admission and fatality. The vaccine effectiveness was at 42.85%, lower than the expected 85%.

5 DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Discussion

This study aimed to determine the proportion, characteristics and transmission patterns of patients who had received a measles-containing vaccine, among children aged 15 years and below diagnosed with measles at Agok Hospital. The results revealed that among the 385 measles patients studied, 36.6% had received measles vaccine. The vaccine effectiveness was 42.9% contrary to the expected 85% after the initial vaccine administration. The measles patients in the study area presented with cough (97.1%), maculopapular rash (95.3%) and conjunctivitis (91.2%). Interventions for measles included hospital admission/isolation, use of antibiotics and vitamin A supplementation whereas measles transmission in Agok was higher in children attending schools and living in the cattle camps during the dry season.

The study results further revealed the association of measles patients to measles vaccination status in the region. Among the 385 patients who presented to Agok Hospital with measles, 36.6% had received measles vaccine. The vaccine effectiveness was 42.9% contrary to the expected 85% after the initial vaccine administration. The results were different compared to a similar study conducted by Khan A, et al in Peshawar district in Pakistan where 7.5% of the vaccinated population contracted measles virus. The findings could present a different dimension to the measles susceptibilities in relation to geographical location and economic status of a population. A vaccine effectiveness study carried out in Bosnia indicated a proportion of 2.1% of fully vaccinated children (measles two doses) contracted the disease, a significant difference from the children who had received only a single dose that stood at 8.1% (Musa et al., 2018). However, measles attack in a closed population such as schools and cattle camps present an intense and prolonged exposure that eventually infects more of the populace including the vaccinated children. This phenomenon was apparent in a study carried out at a high school by Nkowane to establish vaccine failure rate. The results showed a 70 % measles infection in the vaccinated population (single dose), the schools had a vaccination coverage rate of 98% (B. M. Nkowane, Bart, Orenstein, & Baltier, 1987)

The clinical presentation of the measles patients in the study area was cough (97.1%), maculopapular rash (95.3%) and conjunctivitis (91.2%). The results were consistent with the WHO and CDC universal guidelines on the presentation and complications associated with measles infection (Hagan et al., 2017). Furthermore, a measles ophthalmic association and management study (Mihály &

András, 2017) elaborates the association of conjunctivitis following measles infection as was evident in the study population in Agok.

Management interventions for measles in this study included hospital admission/isolation, use of antibiotics and vitamin A supplementation. The findings are consistent with the conventional management strategies of the virus., the findings are also similar to studies carried out in the developing world where access is limited (Zhao et al., 2018). The presentation and management of measles patients in the study is similar to a retrospective study carried out in Colombo North Teaching Hospital, Sri Lanka (Premaratna et al., 2017) and a study publication by Bentley J on the measles pathology and management (Bentley, Rouse, & Pinfield, 2014).

Specimen collection for laboratory confirmation, serum (12.2%) and mouth swabs (4.2%) were minimal due to lack of needed laboratory services at the health facility. The specimens were transported to Juba National Laboratory for analysis. Furthermore, the region has poor road network presenting accessibility challenges as all the samples had to be flown from an airstrip in Agok to Juba.

Patients with measles in Agok were aged 6 months to 15 years with a median age of 2 years had equal distribution in terms of gender. This results are different from the 2017 study conducted in a Belgium measles outbreak (Grammens et al., 2017) where the median age of the patients was 14. Furthermore, a study conducted in a measles outbreak in China (Zheng et al., 2015) had 1.25:1 for male to female respectively. However, the results mirrors a study conducted in Ethiopia (Getahun et al., 2017) on laboratory-confirmed cases of measles where gender distribution was equal.

Measles patients who had previously received a single dose of measles vaccine developed milder symptoms and hence shorter admissions with few complications in relation to the unvaccinated population. The results echo findings in a study carried out in Guinea Bissau (Aaby et al., 1986) where vaccinated children needed more intense exposure to get infected with measles, presented with lower mortality rate and milder clinical manifestations after infection. The study findings on vaccine efficacy was 72% with 33% of the vaccinated population getting infected with measles, the results were close to this study that had 36% of the vaccinated population infected.

In the study location, the vaccines are acquired from the central MOH stores in Juba then delivered straight to the hospitals and primary health care centres with EPI cold chain system. The county cold chain is not operational. Routine vaccination is provided at the facilities with constant outreaches utilizing cool boxes and vaccine carries. The same approach is utilized during campaigns where there is upscaling.

Socio demographic factors and clinical characteristics of measles children were described. The data also provided information on the predisposing factors, disease severity, immunity status, socio demographic factors and medical and supportive care provided that contributed to the sustainability and severity of measles outbreaks. The findings show strong association of severity of measles clinical presentations to the unvaccinated status. Admission and complications were greater in children not vaccinated hence the need for policy makers to institute key protocols that will avail EPI services and ensure that all the children receive the vaccine despite the geographical and access constraints.

The study may inform measures that can curb the transmission and decrease the incidence. Measles transmission in Agok was higher in children attending schools and living in the cattle camps during the dry season. The cattle camps are closer to water sources and all domestic animals are relocated to the camps during the dry season (November to May). Most children are also relocated to take care of the animals and also benefit from the cattle products such as milk for nourishment.

Some primary schools have adapted to the dynamic movement and usually relocate to the cattle camps during the dry season as follow up on the children to continue with education uninterrupted. Following the high population and congestion of the cattle camps, they have been identified as major transmission zones of the measles virus. The second most common zone of transmission is schools then within households.

The study highlighted a key pattern that can be broken to decrease the incidence of measles in this location. It was apparent that the displacements occasioned by the civil war interrupted the routine vaccination activities and increased movement of susceptible population (MSF, 2018). The displacements had a direct association with inadequate vaccination tracing and tracking of the children.

The nutrition services (OTP, TSFP, SC) in Agok hospital together with the support and management

at the health facility improved the outcome of the measles children as evidenced by outbreak association with 3 mortalities among the 385 children studied.

The study has provided the policy makers with data supporting approaches in curbing the rampant measles transmission in an emergency set up. Moreover, the information can be utilized to design vaccination programmes that will increase the coverage, optimum protection and at the same time increase the vaccine effectiveness.

Conclusion

The study objective was to determine the proportion, demographic and clinical characteristics of vaccinated children less than 15 years among those who developed measles. Results analysed showed 36% of the vaccinated children developed measles infection. The vaccine effectiveness rate was at 42.85%, the proportion was lower than the postulated 85% after the initial dose (Diane E. Griffin, 2018). Consequently, clinical presentation was severe in unvaccinated population hence necessitated admission and treatment of complications when compared to vaccinated children whom were treated mostly as outpatients. The results further highlighted the need to improve routine, outreach and campaigns of measles vaccination to increase the coverage and further introduction of the second dose measles vaccine as standard EPI protocol to decrease the failure rate of the vaccine. The approach will further break the measles transmission patterns in Agok and control the infection spread.

Recommendations

- Study findings indicate profound vaccine failure, some of the measures to mitigate and
 control the epidemic will include: introduction of second dose measles vaccine, increase of
 cold chain centers for effective vaccine management, updating health workers on new EPI
 protocols, measles vaccination campaigns and health education to community members on
 transmission and control measures.
- There is need for regular outreaches and campaigns to facilitate high coverage. Cattle camps should be the primary target for isolation and management of measles patients to break the high transmission rates reported.
- 3. It will be beneficial for MOH to work closely with partners such as UNICEF to increase the number of cold-chain centers in the Country for effective vaccine management. The health workers should also be engaged in regular capacity building on vaccination, disease surveillance and control.

4.0 Budget

Table 7 Research Budget

| Item | No. of | Cost | Total cost | Justification |
|----------------------|---------|--------|------------|--|
| | units | (Kshs) | (Kshs) | |
| Ethics approval | 2 | 2000 | 4,000 | Approval by KNH-UON ERC and |
| | | | | SSREC in Juba |
| Stationery | 3 | 10000 | 30,000 | Printing FGD questionnaires, |
| | | | | research proposal and thesis |
| Local and | 2 Trips | 75000 | 150,000 | Flying to Juba then to Agok South |
| international travel | | | | Sudan and accommodation in Agok. |
| Data collection | 1 | 30000 | 30,000 | Payment for 2 data collection officers |
| | | | | and refreshments during the FGD |
| | | | | interview for one week. |
| Contingency (10%) | | | 21,400 | |
| Total | | | 235,400 | |

5.0 Work plan Table 8 Detailed work plan

| Activity | Jun | Jul | Aug-Dec | Jan-Mar | Apr-Jun |
|-----------------------------------|-----|-----|---------|---------|---------|
| Proposal writing | | | | | |
| Proposal submission for approval | | | | | |
| Data collection and analysis | | | | | |
| Report writing, Defence | | | | | |
| Final corrections and binding and | | | | | |
| Dissemination | | | | | |

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Annex 1-Focus Group Discussion Guide:

Health workers and community leaders in Agok on measles transmission patterns in the

County

Total Participant Time Required: 1 hour

OVERALL QUESTION TO ANSWER IN FOCUS GROUP DISCUSSIONS:

The purpose of the study is to evaluate vaccine coverage among children with measles in Agok

Hospital. The purpose of the FGD is to establish the transmission patterns exhibited by measles

disease in Agok.

Introduction [5 min]

Thank you all for taking time to be with us today. My name is Joshua Murule Mukekhe and I am a

master's student at the University of Nairobi. I am conducting a study focusing on vaccine coverage

among children with measles in Agok Hospital. One of the objectives is to establish measles

transmission patterns in Agok. So I am interested in learning about the perspectives of both the

health providers and the local leaders, which is why you have all been asked to participate. I would

like to hear your experiences and perceptions of measles transmission during this interview. At the

end of this study, based on the findings from these focus groups, we will have recommendations for

prevention and control of measles outbreaks in this area.

I will be guiding the discussion today, which will run for about 1 hour. I will like the discussion to

be informal, so there is no need to wait for me to call on you to respond. In fact I encourage you to

respond directly to remarks other people in the group make. I hope you will feel free to speak openly

and honestly, as everything that is said in this room will be held completely confidential. Your

comments will NOT be linked to your name or identity, and NOTHING that you say will affect your

job appraisal.

I would like to introduce my assistants, who may be asking you a few questions. They will also be

taking notes during the discussion.

Does anyone have a question?

Opening remarks [5 min.]

We shall begin by getting to know each other.

36

- **A**. On the paper in front of you, please write your first name. If you would prefer, you can use a nickname, whatever makes you feel more comfortable
- **B**. First, introduce yourself and tell us how long you have been working at this health facility, or residing in this area.

FGD Questions

- Q1. [3 min] What is measles disease and do you know anyone who has suffered or been infected with measles in the past?
- Q2. [5 min]) In your opinion, how often does measles occur in Agok, and who is affected most (Host community, IDPs)?
- Q3. [5 min] Where do measles patients from Agok get treatment from and what is the most common outcome of the disease?
- Q4. [3 min].Do you know of any reported deaths from measles in this region, if yes, which location are they mostly reported from, and what is unique about that location?
- Q5. [3 min] From your perspective, how do you think measles disease spreads in Agok?)
- Q6. [3 min] In Agok, which place will you find many children suffering from measles disease?
- Q7. [3 min] From previous measles outbreaks, which location do you think measles starts from and where does it spread to?
- Q8. [5 min] What preventive measures have you witnessed deployed against measles in Agok?
- Q9. [5 min] How many health facilities in Agok have cold chain system with vaccines and routinely vaccinate children against measles?
- Q10. [5 min] Do you know of any child who has previously been vaccinated against measles but nonetheless got infected? If yes, what do you think was the reason of the measles infection?

Q11. [5 min] What do you think can be done to prevent future measles outbreak in Agok?

Q12. [3 min] Is there anything we have not discussed that seems relevant? (Would anyone like to make any final comments?

THANK YOU VERY MUCH

Annex II-Consent form

VACCINATION COVERAGE AMONG CHILDREN WITH MEASLES AT AGOK HOSPITAL, SOUTH SUDAN

PARTICIPANT INFORMATION AND CONSENT FORM

ADULT CONSENT

FOR ENROLLMENT IN THE STUDY

(To be administered in English or any other appropriate language e.g Arabic translation)

Title of Study: Vaccination Coverage among Children with Measles at Agok Hospital, South Sudan Principal Investigator\and institutional affiliation: Joshua Murule Mukekhe, University of Nairobi Phone: +254724422997

E-mail:MJmurule@gmail.com

Introduction:

I would like to tell you about a study being conducted by the above listed researcher. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal

1. Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. P588/08/2018 and South Sudan Ethics Review Committee Protocol No. MOH/ERB 61/2018

WHAT IS THIS STUDY ABOUT?

The study will determine the proportion of vaccinated children less than 15 years who develop measles and their socio demographic factors. The data will provide in-depth information on the predisposing factors, severity, immunity status, socio demographic factors and medical care spectrum that contributed to the sustainability and severity of measles outbreaks. Since vaccination does not provide 100% immunity. The study will help us understand the different transmission patterns exhibited by vaccinated children in the study area. The study will provide a platform to postulate measures that can curb the transmission and decrease the incidence. The planned activities will encompass collection of hospital data from Agok hospital on all measles patients since 2015 to 2018. Furthermore, to conclusively answer the research question of measles transmission patterns, the researcher would like to engage you in a discussion on the possible sites that measles outbreak started in the recent past, and the spread within the county. Moreover, some questions will include the vaccination exercises conducted in this location.

The researcher listed above is interviewing individuals who work in Agok Hospital and local authority members. The purpose of the interview is to find out **possible sites that measles outbreak started in the recent past, and the spread within the county. Moreover, some questions will include the vaccination exercises conducted in this location.** Participants in this research study will be asked questions about measles outbreak, spread and control in Agok

There will be approximately 24 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

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

If you agree to participate in this study, the following things will happen:

You will participate in a focus group discussion of more than 8 individuals by a trained interviewer in an area where you feel comfortable answering questions. The discussion will last approximately

1 hour. The interview will cover topics such as origin of measles outbreak in Agok, presence of vaccination services in the county and vaccine storage.

After the interview has come to an end, there will be no further tests conducted.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: sharing of the research findings and feedback being part of accountability to research participants.

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

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in this study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the discussion may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the focus group discussion.

It may be embarrassing for you to share your personal experiences with the Focus group discussion members. We will do everything we can to ensure that you do not have to answer a question if you don't feel like. Furthermore, all study staff and interviewers are professionals with special training in these interviews. Also, the discussion might subject you to recall of past unpleasant scenarios and hence may be stressful.

In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free health education on the spread of measles and preventive measures that can be instituted. Also, the information you provide will help us better understand the patterns of measles transmission in Agok. This information is a contribution to science and will inform policy to decrease the measles outbreaks.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Being in the study will cost your 1 hour of your time to discuss and share your views on measles.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

The study will select FGD participants using purposive method hence it will be the duty of the researcher to meet you at location and time of your convenience hence there will be no refund for expenditures incurred during the study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in

this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

KNH-UoN/ERC/FORM/IC01

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

| I agree to participate in this research study: | Yes | No |
|--|------------------|----------------|
| I agree to have (define specimen) preserved for later study: | Yes | No No |
| I agree to provide contact information for follow-up: | Yes | |
| Participant printed name: | | |
| Participant signature / Thumb stamp | Date | |
| | | |
| Researcher's statement | | |
| I, the undersigned, have fully explained the relevant details of this rese | arch study to th | ne participant |
| named above and believe that the participant has understood and has | willingly and | freely given |
| his/her consent. | | |
| Researcher's Name: | Date: | |
| Signature | | |

| Role in the study: | [i.e. study staff who explained informed |
|--|---|
| consent form.] | |
| For more information contact _Joshua Mur +254724422997 from August 2018 onwards | ule Mukekhe at MJmurule@gmail.com, |
| Witness Printed Name (If witness is necessary, A the researcher and participant) | witness is a person mutually acceptable to both |
| Name | Contact information |
| Signature /Thumb stamp: | Date; |

Annex III: KNH-UON ERC research approval



UNIVERSITY OF NAIROBI **COLLEGE OF HEALTH SCIENCES** P O BOX 19676 Code 00202 Telegrams: varsity

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KNH-UON ERC

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KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202

Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

8th November 2018

Ref: KNH-ERC/A/396

Tel:(254-020) 2726300 Ext 44355

Joshua Murule Mukekhe Reg. No.W64/87134/2016 Institute of Tropical and Infectious Diseases (UNITID) College of Health Sciences University of Nairobi

Dear Joshua

1

RESEARCH PROPOSAL - VACCINATION COVERAGE AMONG CHILDEN WITH MEASLES AT AGOK HOSPITAL, SOUTH SUDAN (P588/08/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 8th November 2018 - 7th November 2019.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72
- e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal).
- Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

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For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M.L. CHINDIA

SECRETARY, KNH-UoN ERC

The Principal, College of Health Sciences, UoN The Director, CS, KNH C.C.

The Chairperson, KNH-UoN ERC

The Assistant Director, Health Information, KNH

The Director, UNITID, UoN

Supervisors: Dr. Moses Masika (Dept. of Med. Microbiology, UON), Dr. Duffton Mwaengo (Dept. of Medical Microbiology, UON), Dr. Robert Napoleon (ACROSS South Sudan)

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The Republic of South Sudan



20 /11/2018

MOH/ERB 61/2018

To: Joshua Mueule University of Nairobi

RESEARCH APPROVAL LETTER

Dear Murule

SUBJECT: - Vaccination Coverage among Children with Measles at Agok Hospital

I am writing in response to the request for authorization for the study on "Vaccination Coverage among Children with Measles at Agok Hospital" As a part of your primary data in South Sudan.

After close review on the proposal, I am glad to inform you that the ethical committee at the Ministry of Health, Republic of South Sudan has approved the study. The ministry acknowledges the importance of the study to determine the measles vaccine effectiveness within the country.

Please, keep the Ministry of Health, Republic of South Sudan and State Ministries of Health informed on the implementation progress. I look forward to the report and recommendations that will be generated from the study. Note that the study should not be published without the consent of the MOH-RSS.

Best regards. Explore enhance

Dr. Richard Loku Lino Loro

Director General of Policy, Planning, Budgeting and Research Ministry of Health, Republic of South Sudan, Juba

CC: Under Secretary, MOH-RSS

CC: Director General, Preventive Health Services- MOH-RSS

CC: Director General State Ministries of Health

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