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DEPARTMENT OF COMMUNITY AND PUBLIC HEALTH

FINAL YEAR DISSERTATION

PREVALENCE AND FACTORS ASSOCIATED WITH OXFORD/ ASTRAZENECA VACCINE ADVERSE EFFECTS: A CROSS SECTIONAL STUDY IN TORORO, EASTERN UGANDA

By

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ABSTRACT

Background:

Vaccines are the most effective strategy against COVID-19 pandemic but have faced roll out challenges partly due to fear of potential side effects. Literature review reveals that socio demographic and other personal factors influence side effect experiences. Uganda rolled out COVID -19 vaccination in April 2021 with Oxford /AstraZeneca vaccine targeting Health workers, teachers, and Security personnel, elderly persons above 50 years and adults above 18 with underlying conditions. This study was conducted to determine prevalence, profiles and predictors of Oxford/AstraZeneca vaccine side effects among the vaccine recipients in Tororo district.

Methods:

A cross sectional analytic study was conducted in Tororo using secondary data from the COVID -19 registers from all the five vaccination sites extracted using a data extraction tool. Telephone interviews with 2204 participants using a pretested structured questionnaire were done to collect quantitative data on the side effects of Oxford/AstraZeneca vaccine. Stata version 13 was used for analysis. Bivariate and multivariate analyses were done to infer associations between side effects of Oxford/AstraZeneca vaccine and potential predictor variables. Adjusted odds ratios with their 95% confidence intervals were calculated and interpreted.

Results:

A total of 603/2204(27.4%) of the participants experienced side effects. Of these 102/2204 (4.6%) had only local side effects while 298/2204 (13.5%) experienced only systemic side effects. Therefore 305/603 (50.6%) experienced local side effects while 501/603 (83.1%) experienced systemic side effects. A total of 247/305 (80.9%) of the local side effects were pain at the injection site. More than half 218/305(71.5%) of the participants experienced headache, 203/305 (66.6%) of the participants experienced tiredness and 134/305 (43.9%) experienced fever. A total of 268/424 (63.21 %) participants experienced side effects only after the first vaccine dose, 44/424 (10.38%) experienced side effects only after the second dose and 112/424 (26.42%) experienced side effects after both doses. Six participants declined second dose because of side effects after the first dose. A total of 61/603(10.1%) of the participants sought medical attention from a health facility following side effects of AstraZeneca. Average duration of side effects was 2-3 days. Seven deaths were reported among the 2204 participants called up however they were likely not directly related to the side effects the Oxford/AstraZeneca vaccine.

Previous infection with COVID-19 (AOR: 4.3, 95% CI: 2.7-7.0, p = < 0.001), and being female (AOR: 1.3, 95% CI: 1.1-1.6, p = 0.004) were positively associated with side effects to Oxford/AstraZeneca vaccine while being a security officer (AOR: 0.4, 95% CI: 0.2-0.6, p = <0.001) was a protective factor as it was less associated with side effects of Oxford/AstraZeneca.

Conclusion and recommendations

Following vaccination with Oxford/AstraZeneca vaccine participants reported side effects that were majorly local and systemic. Most of the side effects were minor events that were self - limiting. We recommend massive campaigns to disseminate correct information about potential

side effects of Oxford/ AstraZeneca vaccine and strengthening the passive surveillance for adverse events following vaccination.

DECLARATION

I, **ONYANGO JAGIRE,** declare that the work in this dissertation is original and my own work, and has never been presented for any academic award before either wholly or partially to any other institution.

SIGNATURE: .....

DATE: 06/05/2022

APPROVAL

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DEDICATION

To my wife, Mrs. Anita Jagire, my children; Evana Jagire, Eglah Jagire, Elvina Jagire, Elwin Jagire and Edwin Jagire.

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First and foremost, I am very grateful to the Almighty ever-loving God for the faithfulness, wisdom, Knowledge, and the Gift of Life. Your blessings have enabled me to pursue my life's goals, and I would not have gone an inch further without you. May your Mighty Name be exalted (Psalms 57:5).

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ABBREVIATIONS

AOR	Adjusted Odds Ratio
AEFI	Adverse event Following Immunization
CI	Confidence Interval
COR	Crude Odds Ratio
COVID-19	Corona Virus 2019 Disease
GOU	Government of Uganda
HC	Health Center
HW	Health Worker
MOH	Ministry of Health
SARS	Severe Acute Respiratory Syndrome
UK	United Kingdom
UBOS	Uganda Bureau of Statistics
VHT	Village Health Team
WHO	World Health Organization

DEFINITION OF TERMS

Vaccination	The introduction of a vaccine to stimulate the body's immune response against diseases.
Immunization	The action of making an individual immune to infection, typically by inoculation.
Side effect	A secondary, typically undesirable effect of a drug or medical treatment that comes along with the desired effect of the medication. These were divided into local at the injection site, systemic (general body complaints and allergic (reactions). Mild side effect is one that does not interfere with daily routines. Self- limiting side effect is one that goes away without any intervention typically after one or two days
Mild side effect	A symptom that was not life threatening and may have warranted minor intervention like a few pain killer tablets
Self-limiting side effect	A symptom that resolves by itself after average of 2 days
Comorbidity	A disease or medical condition that is simultaneously present with another or others in a patient. In this study we considered obesity, hypertension, diabetes mellitus, cancer, chronic respiratory disease and arthritis as underlying conditions.
Health worker	Any person whose occupation is within the health system including support staff and community based cadres like VHTs and linkage facilitators
Priority groups	High risk populations prioritized for vaccination with first available batch of vaccines to protect them from the disease and control spread of infection these included health workers, teachers, security personnel, elderly persons above 50years and all adults above 18 with underlying medical conditions
Oxford/AstraZeneca vaccine	The ChAdOx1-s recombinant COVID-19 vaccine is an adenovirus derived vaccine made by getting the spike protein of Corona virus and

	putting it in a harmless virus to make a vaccine. It is recommended for priority groups like health workers and older people as well as other adults with comorbidities who are at an increased risk of infection. During this initial phase of vaccination the Covishield brand was the entirely used.
Case definition of COVID 19	Annex1. Operational case definitions Surveillance case definitions for COVID-19are as follows: Suspect case A Any person with acute respiratory illness (temperature of 37 .5°C and above and at least one sign/symptom of respiratory illness (e.g., cough, shortness of breath), AND with no other cause that fully explains the clinical presentation AND a history of travel in the last 14 days prior to symptom onset from a country/area or territory reporting local transmission of COVID-19 disease OR B. Any person with any acute respiratory illness AND having been in contact with a confirmed or probable COVID-19 case in the last 14 days prior to onset of symptoms OR C. Any person with severe acute respiratory infection (temperature of 37.5°C and above and at least one sign/symptom of respiratory illness (e.g., cough, shortness breath) AND requiring hospitalization AND with no other cause that fully explains the clinical presentation. Probable case: A suspect case for whom testing for COVID-19 is inconclusive. Confirmed case: A person with laboratory confirmation of COVID-19 infection, irrespective of clinical signs and symptoms

CHAPTER ONE: INTRODUCTION

1.1 Background to the study

The world over, countries are grappling with low Coronavirus Disease 2019 (COVID- 19) vaccine acceptance though vaccines are known to save lives (Victoria C. *et al* 2021). The hesitancy in part is caused by the fear of vaccine side effects that in some communities are known to out strip the fear of the COVID- 19 disease itself (Sprent & King, 2021) The World Health Organization (WHO) estimates that immunization programs across the world prevent 2-3 million deaths from vaccine preventable diseases every year (Shrestha *et al*., 2016) and are not only cost effective but a key element of preventative healthcare. Vaccines work with our body's natural defenses to build protection against diseases in a process called immunization. It has successfully reduced the global burden of illness and death. A study done in the United Kingdom that compared infection rates among a subset of vaccinated individuals reported a significant buildup of immunity after 12 days following vaccination with Oxford/AstraZeneca (Indrāvati *et al*., 2021). This interaction and other aspects of vaccines may however cause untoward experiences like swelling, pain, redness at the injection site, fever, headache, dizziness, joint pain, fainting, nausea vomiting, diarrhea, rash, among the vaccine recipients.

Vaccines are also critical to the prevention and control of infectious disease outbreaks and therefore an effective and safe vaccine is vital for controlling the COVID-19 outbreak (Pormohammad *et al*., 2021). Immunization is one of the most cost effective health investments with proven strategies that make it accessible to even the most hard to reach and vulnerable populations (Mehnaz, 2016). However, not only does a vaccine need to be safe and effective, it must be accepted by those people at greatest risk of harm from the disease (Robertson *et al*., 2021). COVID-19 vaccine acceptance by a large proportion of the population would also offer protection to the other people who remain unimmunized, a phenomenon called herd immunity. Reported serious side effects, inconsistent information, conspiracy theories and geo politics seem to be the drivers of poor acceptance at this level.

While evidence on promoting vaccination in general is useful in the context of the current pandemic, the acceptance and uptake of COVID-19 vaccines present an unprecedented challenge. In addition to the sheer magnitude of the ongoing vaccination efforts, the vaccines are

new and are likely to be only partially effective for a yet an unknown period of time. There may be so-called adverse events rightly or incorrectly attributed to the new vaccines, and countries will set different safety thresholds before offering the vaccines to their populations.

Uganda registered its first confirmed case of COVID- 19 on 21 March 2020. The disease quickly progressed from imported cases through sporadic community cases to stage four epidemic, with widespread community transmission (Kadowa, 2020). Government of Uganda (GOU) through the Ministry of Health (MOH) issued guidelines referred to as Standard Operating Procedures (SOPs), like on use of face masks, hand washing and how to conduct meetings, burials and other mass gatherings in addition to other public health measures meant to control infection spread. In fact the success of these public health measures will depend on good adherence (Indrayathi *et a*l., 2021). This however has not been completely successful and number of cases continued increasing hence the need for other novel interventions to control the pandemic.

Uganda initially acquired about 900,000 doses of Oxford/AstraZeneca vaccine (Covishield) manufactured by the serum institute of India as and embarked on vaccination campaign in earnest. These initial quantities by donations and government procurement of COVID-19 vaccines to cover 22 million people by March 2022. However, low vaccine acceptance and hesitancy in Uganda is common (Echoru *et al,* 2021). This could be attributed to fear or potential risks that can be encountered especially where a vaccine has not been well evaluated (Echoru *et al*., 2021). The vaccine dispensing protocol among other things involve informed consent and such other requirements like provision of one's' National Identification Number (NIN). These new practices have caused doubt and apprehension in some people. Civil society organizations have also expressed their concerns in regards to the same and taken actions including dragging government to court as reported in print media.(cite) Misinformation by the widely accessed social media too has not been helpful.

As of 30th April 2021 the vaccination coverage in Uganda was at 330,077/990,000 of the available doses representing about 33% achievements for the country (MOH press statement on COVID-19 updates). However by the same date Tororo District had posted well over 85.9% utilization with 6,865 doses of the available 8,000 dispensed showing a fairly good acceptance. The study conducted in western Uganda concluded that government needs to prioritize vaccine acceptance strategies especially among the risky groups in the community in order to ensure

successful vaccination process (Echoru *et al*., 2021) . The same study found that the level of vaccine acceptance (53.6%) and risk perception (46.7%) was relatively average in western Uganda. High risk groups like health workers are targeted with this vaccine to ensure stability in the system in case an over whelming epidemic threatens to derail service delivery. The surveillance system that is in place may not be relied upon to provide conclusive data on adverse events following immunization. Anecdotal evidence suggests that there has been varying untoward experiences with the vaccine that need to be investigated.

The known adverse side effects are local injection site pain, swelling at injection site and redness. There can also be fever, headache, dizziness, fainting, numbness of the limb, muscle pain, joint pain which are examples of systemic adverse side effects. Rash and red welts around lips are examples of possible allergic reactions. Rare side effects like cardiovascular accidents and blood clots have also been reported.

1.2 Statement of the Problem

Uganda registered her first case of COVID-19 on March 21st 2020. Since then COVID-19 cases steadily increased despite stringent measures instituted by government to contain the COVID-19 pandemic at the population level. Novel interventions like COVID-19 vaccination had to be deployed to try and contain the spread of infection.

On 10th March 2021 the Ministry of Health launched the COVID -19 vaccination campaign using the COVID-19 vaccine (Oxford/AstraZeneca) with a target to vaccinate 49.6% of the population (about 21,936,011 people) in a phased manner. As at 30th April 2021 only about 33% of the targeted population had been reached. This poor uptake of the vaccine (vaccine hesitancy) in part was due to reported and social media accounts of vaccine side effects among those who had taken the vaccine and people are demanding for empirical evidence

Tororo district was allocated 8,000 doses of Oxford/AstraZeneca vaccine to cover priority populations of health workers, teachers, security personnel, all persons who are 50 years and above and all persons above 18 but with underlying chronic conditions. Vaccination campaign was launched in Tororo District on 15th March 2021, in a public function covered by the media

and the first jab taken by the RDC and followed by the other District leaders. As of 30th April 2021 coverage was at 85.8% of the targeted population.

According to the WHO protocol governing vaccination, all patients who experience side effects after vaccination are expected to report and be followed up. However, this is not being done as hardly anyone has reported or called on the available numbers. In a cross sectional online survey on incidence and severity of post vaccination reactions against COVID -19 in Poland, the results are equally un impressive. Only 4.6 % of the vaccinated people reported an adverse event to the sanitary inspection (Jęśkowiak *et al*., 2021). Worth noting, there is only anecdotal evidence of vaccine side effects among the vaccine recipients in Tororo District. Studies on prevalence and predictors of side effects of COVID-19 vaccines are rare. Thus the need for this study.

1.3 Objectives of the study

1.3.1 Main Objective

The main objective of the study was to determine the prevalence of and predictors for Oxford/Astra Zeneca vaccine side effects among the vaccine recipients in Tororo District.

1.3.2 Specific objectives

1) To determine the proportion of Oxford/AstraZeneca vaccine recipients that experienced side effects
2) To establish the side effects profile experienced by Oxford/AstraZeneca vaccine recipients
3) To determine the predictors (personal, socio demographic and systemic) to the side effects of Oxford/AstraZeneca vaccine among the vaccine recipients in Tororo District

1.4 Research Questions

1. What proportion of Oxford/AstraZeneca vaccine recipients experienced side effects?
2. What side effects did the Oxford/AstraZeneca vaccine recipients experience?
3. What were the predictors for experiencing these side effects?

1.5 Hypothesis

1. 13% of the research participants will experience side effects following vaccination with Oxford/AstraZeneca
2. Participants will experience both local and systemic side effects after receiving Oxford/AstraZeneca
3. There is no difference between females and males in experiencing side effects of Oxford/ AstraZeneca

1.6: Justification of the Study

Specific countries are implementing their vaccine deployment mandate in varying fashion. The success of any vaccination program depends on high vaccine acceptance and uptake, and the main challenge that now lies ahead is building public confidence in an emergency-released vaccine. Without such confidence, vaccine hesitancy is imminent (Fabricius *et al*., 2021)

With the recent introduction of Oxford/AstraZeneca vaccine in Uganda, which is a new vaccine that is essentially under study, there is need for ongoing documentation on all its features including side effect profile to facilitate its further roll out for wide spread use as any other vaccine. There is a surveillance system that is tracking adverse events following immunization. This is deemed unreliable as hardly anybody reports those events as expected. This study will provide valuable back up evidence of Oxford/AstraZeneca vaccine side effects that now only exists anecdotally. The findings in this study will be used to gauge projections of COVID-19 vaccine side effects burden in the population and inform on going COVID -19 vaccination implementation programs. The district health office (DHO) and indeed MOH will use the evidence from this study to guide future immunization programing and interventions. There will also be an opportunity to give people assurance in the vaccine and potentially debunking myths with evidence from this study.

1.7 Scope of the study

The study was carried out in Tororo district located in eastern Uganda bordered by Mbale district to the north, Namisindwa District to the north east, Butaleja District to the West, Busia district to the south, Bugiri district to the south west and Kenya to the East. The headquarters are located approximately 210 kilometers (130 miles) by road, to the east of Kampala, the capital of Uganda.

The district covers an area of 1196.4 square kilometers (461.9 sq. miles). The population of Tororo district is estimated at 597,500(2020) projected from the 2014 national census with a growth rate of 2.5% (Uganda BUBOS, 2017)

The District public health system is structured along the local government set up from Health Center (HC) I i.e. Village Health Team (VHT), HCII at parish level, and HC III at sub-county, HCIV at county/constituency level and a District Hospital. The vaccination exercise was launched at public function at the district Headquarters then rolled out to the District hospital and all the three HCIVs. Nagongera, Mukuju and Mulanda and one HCIII (Osukuru). These five facilities that offered the vaccines during the period under review hosted the study.

The study focused on assessing the existing burden of Oxford/AstraZeneca vaccine side effects and the predictors of the same among the recipients of the vaccine in Tororo District. The study target population comprised of all the Oxford/AstraZeneca vaccine recipients as of 30th July 2021 from the five sites. A cross sectional study design was adopted for the research that used quantitative methods. The study was conducted between December 2021 and April 2022 after approval by all relevant authorities. During the study, all COVID- 19 standard operating procedures were observed.

1.8 Conceptual Framework

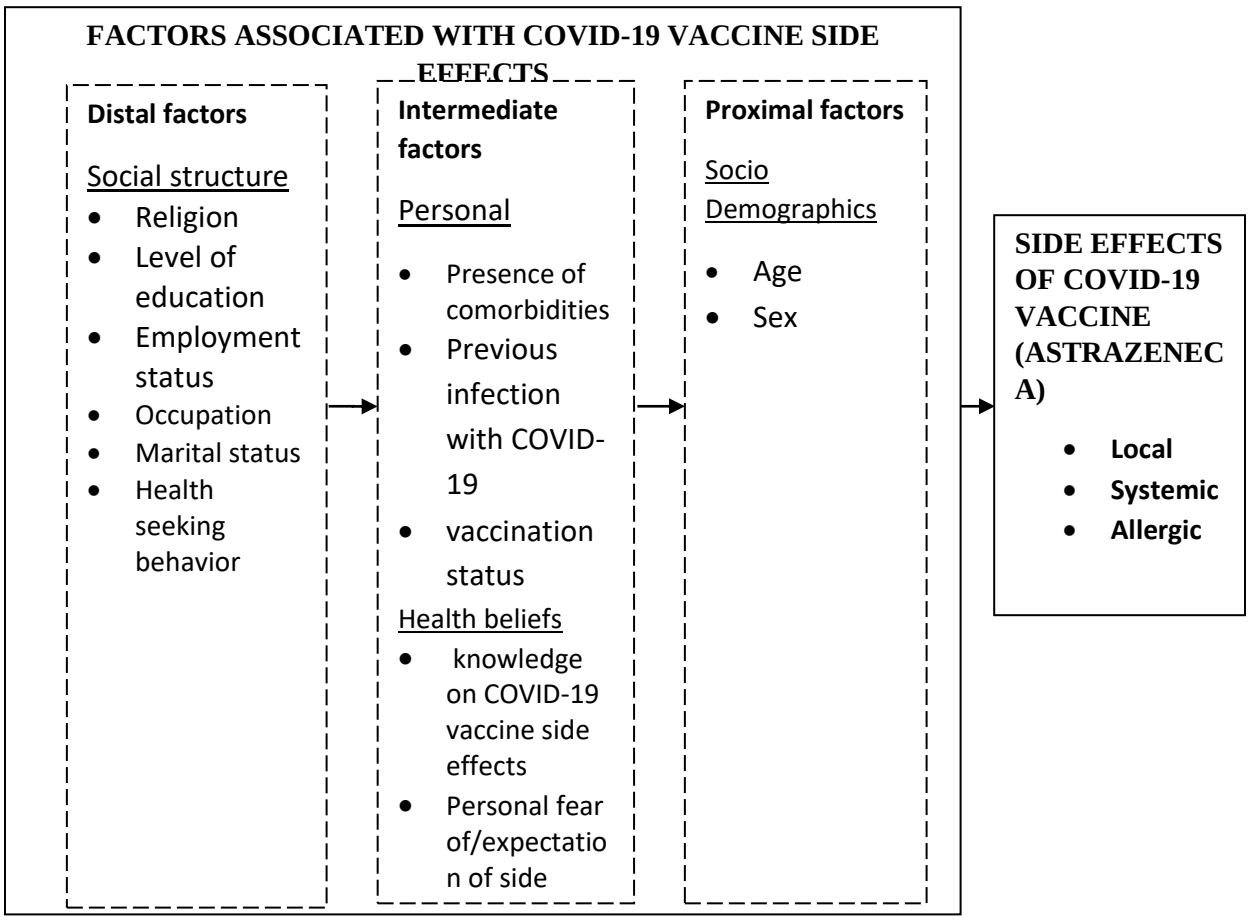

Figure 1- 1. Conceptual frame work of COVID-19 vaccine (Oxford/AstraZeneca) side effects and the associated factors, adopted from UNICEF frame work on malnutrition**.** (UNICEF, November, 2021)

Side effects are expected outcomes following vaccination using Oxford/AstraZeneca vaccine. The side effect can be local (around the injection site), systemic (presenting as general symptoms and signs) or Allergic (reaction like). These side effects may be influenced by such proximal factors like age and sex. These could themselves be influenced by intermediate factors like comorbidities, vaccination status, previous infection with COVID-19, personal fears, duration of symptoms and knowledge of vaccine side effects. Distal factors like; education level, religion, occupation, care seeking behavior, residence and marital status of the vaccine recipient, can also influence vaccine side effect experiences from the periphery.

CHAPTER TWO: LITERATURE REVIEW

2.0 Introduction

This literature review provides the theoretical support for this research by examining the factors associated with Oxford/AstraZeneca vaccine side effects among vaccine recipients globally. It is an attempt to review the existing literature relevant to the study. It is based on the objectives of the study which are listed in chapter one above.

2.1 Vaccine development

Scientists and researchers around the world are racing against time to develop effective vaccines for COVID- 19 control with 21 vaccines now at different stages of roll out in different countries ranging from phase 1 trials to phase 4 (post marketing surveillance) also called pharmacovigilance (WHO 2022). The vaccine's development and deployment is one of the most promising health intervention strategies to mitigate the spread of COVID-19 with messenger ribo-nucleic acid (mRNA) vaccine shown to be the most efficacious. This was reported in a meta- analysis whose objective was to assess the effectiveness and safety of COVID-19 vaccines through analysis of all currently available randomized clinical trials. (Korang *et al*., 2022). This same meta-analysis recommends further trials and longer follow up for better insight into safety profile of these vaccines. Oxford/AstraZeneca is an adenovirus based vaccine that deliver Deoxyribo nucleic acid (DNA) to the nucleus of the cell which is used to make mRNA that serves as a blue print for making proteins. DNA is more stable and lasts longer than mRNA, which is evidenced by strengthening of the immune response for one to two months after vaccination (Fabricius *et al*., 2021). In December 2020 based on advice from joint committee on vaccination and immunization, the UK government decided to delay the administration of second doses of the Oxford- AstraZeneca vaccines over safety concerns (Menni *et al*., 2021). Despite demonstrated safety and efficacy profiles of COVID -19 vaccines there are genuine concerns of possible side effects and therefore post marketing vigilance is still reasonable (Sinha *et al*., 2021). This same study by Sinha *et al* reports that COVID-19 vaccines have shown high reactogenicity with fever, headache and fatigue more common than in other vaccines. The long term effects of these gene therapy based vaccines are practically unknown.

2.2 Vaccine acceptance

The success of any vaccination program depends on high vaccine acceptance and uptake (WHO 2020). However most at risk groups are not receptive to COVID-19 vaccines, referred to as vaccine hesitancy, "delay in acceptance or refusal of vaccination despite availability of vaccination services. It is complex and context specific, varying across time, place and vaccines and influenced by factors such as complacency, convenience and confidence"(MacDonald *et al*., 2015). The resultant poor acceptance is deemed injurious to the fight against COVID -19 pandemic. Vaccine side effects too have been cited as reason for poor acceptance. Poor acceptance of vaccines among specific groups like health workers has been shown to be caused by concerns about serious side effects and lack of trust in information received from public experts (Lucia *et al*., 2021). In this particular study, concern for serious side effects was independently predictive of lower odds of intent to participate in a vaccine trial (AOR =0.4, P= 0.001). An analysis of residents' willingness to vaccinate against COVID -19 in Hubei China showed that the residents mostly paid attention to the side effects of the vaccine rather than its effectiveness (Wan *et al*., 2021)

A study conducted in western Uganda on acceptance and risk perception of COVID-19 vaccine states the need to sensitize the population against their fears early enough before the trials can progress. The government can establish messages and trainings for its people especially the at risk groups regarding vaccination against COVID-19. This can be done through radios, televisions, newspapers, seminars and phone messages (Echoru *et al*., 2021).

2.3 Vaccine prioritization

Given the limited supply in the short to medium term, vaccines are likely to be prioritized for health workers at high risk of acquiring or transmitting infection and older adults based on the framework developed by the WHO Strategic Advisory Group of Experts on Immunization (WHO 2020). A population based cohort study in the metropolitan areas in Milan Italy defines a two level stratification for priorities in vaccination that can be adopted by health authorities (Russo et al., 2021) .Another study conducted in Brody school of medicine Eastern Carolina emphasizes the need for a web mapping tool to aid health workers rationally prioritize vaccines in face of scarcity (Kearney *et al*., n.d.). In Uganda the target groups in the first phase are five: health workers, teachers, security personnel, the elderly (above 50 years of age) and adults

between 18 and 50 with underlying chronic conditions. This later group is more likely to have severe disease and hence the need to prioritize them in vaccine distribution as reported by the International Council on Adult Immunization (ICAI), (Privor-Dumm, 2021)

2.4 Vaccine experiences and side effects.

The quality of the experience of being vaccinated: Do people feel that they are treated with kindness, understanding and respect? Are health workers well informed and able to answer questions about COVID-19 and vaccination? These and related questions may linger in the mind of the vaccine recipient and affect utilization. Furthermore, post vaccination experiences in terms physiological side effects, as well as psychological and social effects may have a bearing on the utilization of vaccination services (Ghiasi *et al*., 2021). Common side effects of Oxford/AstraZeneca vaccine include: pain or swelling at injection site, fatigue, headache, muscle aches, chills, joint pain, fever, redness at injection site and nausea.(Omeish *et al*., 2022). Uncommon side effects include: enlarged lymph nodes, feeling unwell, painful limbs, insomnia, and itching at injection site. Thromboembolism has too been reported as a very rare side effect (Østergaard *et al*., 2021). Localized and systemic side effects have also been shown to be less common in real world community setting than reported in phase 3 trials (Menni *et al*., 2021). In this prospective observational study in the UK, systemic and localized side effects after BTN162b2 and CHAdOx1nCoV-19 vaccination were reported to occur at frequencies lower than reported in phase 3 trials. Both vaccines lower the risk of SARS CoV-2 infection after 12 days. There are also rare effects like temporary one sided facial drooping reported in clinical trials. An analysis of vaccine adverse events reporting system (VAERS) data was done by Dr. Tracy Hoeg at university of California. Data shows healthy boys 12-15 years of age are 4-6 times more likely to be diagnosed with vaccine related myocarditis than with COVID- 19 itself.

According to the reports, local and systemic side effects were reported within 7 days after injection with BNT162b2 (AstraZeneca) or Placebo, by age group. Data on local and systemic reactions and use of medication were collected with electronic diaries from participants in the reactogenicity subset (8,183 participants) for 7 days after each vaccination. Pain at the injection site was assessed according to the following scale: mild, does not interfere with activity; moderate, interferes with activity; severe, prevents daily activity; and grade 4, emergency department visit or hospitalization. Redness and swelling were measured according to the

following scale: mild, 2.0 to 5.0 cm in diameter; moderate, >5.0 to 10.0 cm in diameter; severe, >10.0 cm in diameter; and grade 4, necrosis or exfoliative dermatitis (for redness) and necrosis (for swelling). Systemic events included mostly fever. Additional scales were as follows: fatigue, headache, chills, new or worsened muscle pain, new or worsened joint pain graded as (mild: does not interfere with activity; moderate: some interference with activity; or severe: prevents daily activity). Others include vomiting (mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; or severe: requires intravenous hydration), and diarrhea (mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; or severe: 6 or more loose stools in 24 hours); grade 4 for all events indicated an emergency department visit or hospitalization.

In a negative case-control study of Oxford/AstraZeneca in comparison with Pfizer-BioNTech vaccine results showed that if people get a second dose six weeks after the first one, they have lower immunity than if they get the second dose after 65-84 days, (Amirthalingam *et al*., 2021). This interaction and other aspects of vaccines may however cause untoward experiences like physiological side effects, Psychological trauma as well as social effects among the population.

2.5 Summary of literature review

Most of the available literature identified the profiles of side effects of Oxford/AstraZeneca vaccine and the associated factors. There is however a strong case for further inquiry to build on the available knowledge on the side effects of the vaccines in general. This study therefore inquired about the side effects of Oxford/AstraZeneca vaccine in Tororo district.

CHAPTER THREE: MATERIALS AND METHODS

3.0 Introduction

This chapter involves a discussion of the steps and approaches that were used in the study. This chapter presents the research design, study area, sample size, sampling techniques and procedures, data collection methods, data collection instruments, quality control, , measurement of variables and variable description procedures of data collection and data analysis.

3.1 Study Design

This was a cross sectional analytical study on prevalence and predictors of Oxford/AstraZeneca vaccine side effects among vaccine recipients in Tororo district community members using quantitative methods. The population based survey used secondary data extracted from COVID-19 vaccination registers and a telephone questionnaire interview.

3.2 Study setting

The study was conducted in all the five different vaccination sites allocated COVID-19 vaccination materials for the initial phase of vaccination i.e. Tororo General Hospital, the three Health Center IVs (Mukuju, Mulanda and Nagongera) and Osukuru HCIII. The primary health care system in Uganda is structured along the local government setup. Health Center (HC) I that by cadre is a village heath team (VHT) is a community based entity that offers home visits, health education, community based medicines distribution, registration of patients and referrals. The jurisdiction is for a village or Local Council 1. At a parish level is a HCII that operates an Out Patient Department (OPD). Services offered include management of simple cases of infectious diseases, vaccination (usually as an outreach post) community sensitization and education and referral. They are manned by an enrolled nurse, a nursing assistant and two support staffs. The HCIII is a sub county facility that offers all the HCII services plus maternity services including facility delivery of expectant mothers. The staffing also includes a midwife, health assistant and a records person. It is headed by a senior Clinical Officer assisted by a clinical officer. The HCIV is a county facility that offers all the HCIII services and in addition serving as a referral facility for the lower units in the county and offering emergency obstetric care including caesarean sections. It is headed by a senior Medical officer assisted by medical officer and a senior nursing officer and midwife .The COVID 19 vaccines were allocated to the

Level III, IV health centers and the general Hospital that were seen as having the requisite infrastructure and personnel to take on the vaccination campaign. Allocation was guided by initial registration of health workers and the available teachers as per the district registry records at the District Education Office. The vaccination exercise was under the direct supervision of Immunization focal persons that mobilized and supervised teams of nurses, midwives and data clerks that did the vaccination and data entry into the registers. The in charges of these facilities were the responsible offers doing overall supervision of the exercise among other programs. The exercise was initially facility based but later involved targeted outreaches for organized entities like schools and factories.

Much as 5 five health centers are reflected in the data base, these were merely vaccination points where participants would freely access vaccination regardless of where they came from. So this disputes the notion of naturally occurring clustering in this geographical area.

3.3 Study population

The target population was all persons who accessed COVID-19 vaccination services in the government facilities and whose records were available in the COVID -19 registers of the involved HCs Some 7834 records were accessed of which 5750 had complete data. The study population was all persons who had accessed at least the first dose of the Oxford/AstraZeneca vaccine from the designated sites within Tororo District as of 10th July 2021 and were deemed to have complete information in the registers including a telephone contact. On further review only 2204 had accessible telephone contact in the register and consented to be part of the study.

3.4 Inclusion and exclusion criteria

3.4.1 Inclusion criteria

All the COVID-19 vaccine adult recipients as listed in the COVID-19 vaccination registers of the five participating sites with complete information in Tororo district and consented to participate in the study by answering the telephone interview questions.

3.4.2 Exclusion criteria

All vaccine acceptors with hearing impairment and those with disability in sustaining a telephone interview. Also those that did not provide informed consent were excluded.

3.5 Sampling strategy and sample size

3.5.1 Objective 1. To determine the proportion of oxford/AstraZeneca vaccine recipients that experienced side effects.

For objective one this study utilized a data extraction tool to retrieve socio demographic data from the COVID- 19 vaccine register as a secondary data source. A census of all the 7834 people who received AstraZeneca vaccine from all of the five sites was done. From simple eyeballing of raw data from register and then running a simple query, all those who had presumed viable contacts (5750 participants) were extracted and targeted for call up. However only 2204 were finally accessible and these formed the sample. Data on socio demographics and whether they experienced side effect was collected using a questionnaire telephone interview.

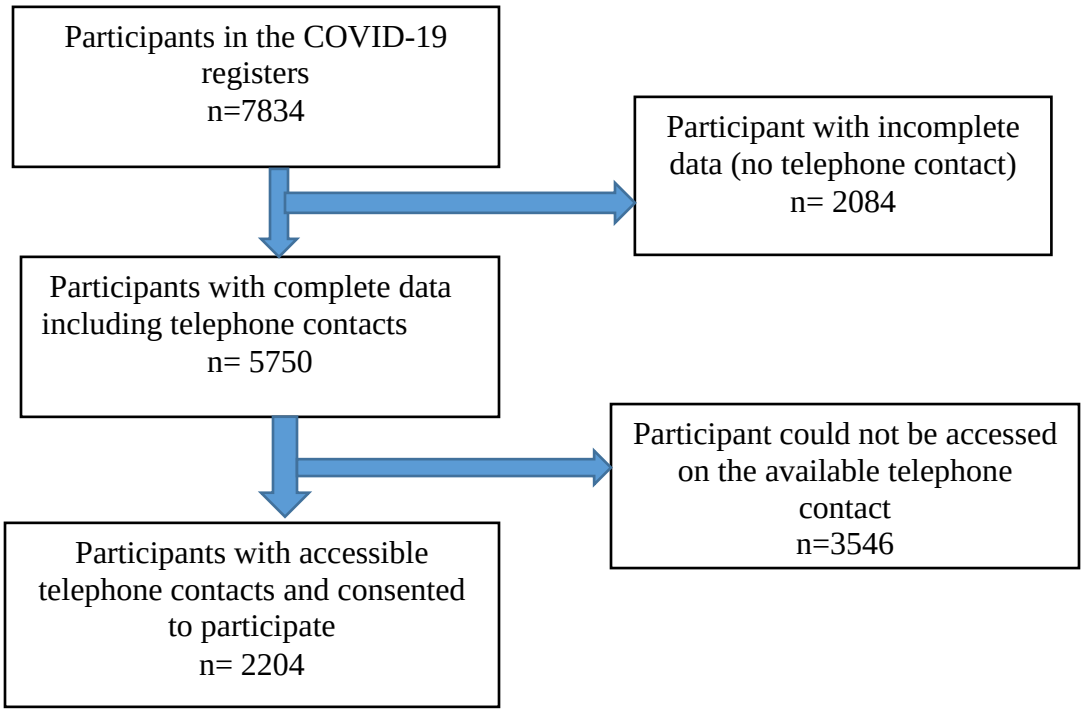

Figure 3- 1.A flow chart showing number of patients at every stage of sampling.

3.5.2 Objective 2. To establish the side effects profile experienced by Oxford/AstraZeneca vaccine.

For objective two the sampling procedure for objective 1 sufficed.

3.5.3 Objective 3. To determine the predictors, socio demographic and systemic to the side effects of Oxford/AstraZeneca vaccine among the vaccine recipients in Tororo district

The sampling procedure done for objective 1 still sufficed. Parameters like age, sex, marital status, previous COVID-19 infection, education level, occupation were considered. Additional data on vaccination status, nature of side effect, duration of symptoms, health care after experiencing side effects and outcome of the side effects were collected using a structured questionnaire through telephone interview. Information was also sought on which dose affected the participant more and whether the side effect influenced their decision to get the second dose.

3.6 Data collection methods

The cross sectional observational study used telephone interviews for data collection. Personal profile data was derived from review of the COVID 19 vaccination registers as secondary data source except for additional information that was included in the questionnaire. A data extraction tool was used to generate this data as already collected in the COVID-19 vaccine registers. A questionnaire interview with those with functional telephone contacts was used to gather data on side effects, related information (like previous infection with COVID -19) and other additional socio demographic data.

3.6.1 Data collection tools

For objective1 a data extraction tool was used to extract data on socio demographics and side effect prevalence. For objective 2 a questionnaire was used to guide a telephone interview and data was filled in the tool. For objective 3 some data on factors associated with AstraZeneca side effects were extracted from the COVID -19 vaccination register as for objective 1. Other information like on vaccination status, health care after experiencing side effects and outcome of side effects were specifically asked and entered into a questionnaire developed in kobo collect.

3.6.2 Data quality control

A questionnaire was adopted from previously validated tools as found in literature.(Alhazmi et al., 2021). As reported in the Khazi and Khalid of Agha khan University, Karachi, Pakistan study, it is extremely important for a researcher to know the importance of a proper questionnaire and whether it measures what it intended to measure (Kazi & Khalid, 2012). We did pre testing of tools among non-participant individuals before actual data collection to

determine understanding of questions. The non- participants were individuals conveniently identified as they came for second doses but were not part of the group in the initial phase under study. This also provided evidence that the tool would provide the necessary information as reported from an earlier study above. We envisaged that this pre testing would provide the most direct evidence of validity of questionnaire data for most items as opined by previous researchers (Hilton, 2017). However this was only crudely done and content validity index was calculated. Training of research assistants ensured that they were familiar with the tool and were able to use it to collect quality data.

3.7 Study variables

3.7.1 Dependent variable

The dependent or outcome variable was a side effect following vaccination with AstraZeneca. It was defined as any untoward feeling experienced by a person after being vaccinated. A question was asked, 'Did you experience any of these listed side effect or untoward feeling after receiving AstraZeneca vaccine?" The list included local side effects (pain at injection site, redness, swelling of lymph nodes, and local swelling, systemic side effects; (tiredness, headache, nausea, diarrhea, vomiting, breathlessness, fainted, fever, muscle pains, joint pains and chills) and allergic side effects (rash, skin burning, and red welts on face and lips). The data from this question directly answered the prevalence question. A study in Nepal on vaccination experiences challenges and solutions following vaccination with Oxford/AstraZeneca listed these as the common side effects of the vaccine (Grey, I., *et al,* 2020)

3.7.2 Independent variables

The independent variables included potential factors associated with Oxford/AstraZeneca vaccine side effects. These were adopted from literature and included socio demographic factors like age, sex, education, religion, marital status, occupation and residence. Others were individual participant characteristics like vaccination status, previous infection with COVID-19, comorbidities and health care seeking behavior. In a study to assess the factors associated with COVID-19 vaccination it was reported that gender and marital status were found to be associated with COVID-19 vaccine side effects (Grey, I., *et.al*, 2020).

3.8 Data management and analysis

Data were captured using a questionnaire designed in kobo tool box. Analysis was done using Stata statistical software version 13. Exploratory data analyses were conducted to check the cleanliness of the data. Analyses involved summarizing data using frequency tables, and measures of central tendency [mean (SD), median (IQR)]. The bi-variable analysis helped to assess any unadjusted statistical associations. Multivariable analysis assessed adjusted statistical associations. Odds ratios were used as a measure of association.

3.9 Ethical consideration

The study was conducted in conformity with the principles of declarations of Helsinki. Approval from the Review and Ethics Committee (REC) of Mbale Regional Referral Hospital was secured with the REC approval number MRRH-2021-91. Informed consent was sought on phone from individual participants at the beginning of the interview. For confidentiality, names of participants were removed from the extracted data set and only serial number alongside the telephone contacts were availed to research assistants. The generated data on questionnaires were pooled together in the secure office of the principle investigator for safety.

3.10. Environmental and gender implications

The telephone interviews was envisaged as compliant with the COVID 19 guidelines of no gathering and maintaining social distance. No gender discrimination was envisaged as we were simply following serial numbers as generated at data extraction.

CHAPTER FOUR: RESULTS OF THE STUDY

4.0 Introduction

This chapter presents the findings of the study in form of table narratives, a pie chart and bar charts. The results are presented chronologically, starting with the socio demographics then side effect prevalence, profile, associated factors, interventions undertaken and outcomes of the side effects. The quantitative findings present how the independent variables predicted Oxford/AstraZeneca vaccine side effects. As indicated in the preceding chapter, three forms of results including the univariate, bivariate and multivariate are presented here. The univariate analysis results present the distribution of the variables used in the study. Differences in side effects by explanatory factors are presented in bivariate analysis results, and the net effects are isolated in multivariate analysis.

4.1 Participant characteristics

A total of 2204 participants were recruited, of whom 68.7% were aged less than 50 years. The study had more males 59.4% compared to females (43.6%). In terms of education, more than half, that is 57.4% had a tertiary education. This is above the education level of the general population and this is not surprising since the original target was among the working population like health workers, teachers among others. However those few ones who had primary education and those mainly from the general population who are also aged more than 50 years regarded as the risk population to the COVID -19. In relation to religion, 88.7% were Christians without dividing them among the common Christian denominations namely the Catholics, Anglicans and Pentecostal. Surprisingly where as there is a small population of Hindu religion in the country, this place had up to 2%. It is also worth noting that a country with near universal nuptialty, only13.8 percent of the population was married. In terms of occupation majority of the population that received the vaccination were teachers (23.2%), accounting for almost one in four, followed by health workers at 17.1% and security, 8.7%. However, half the population their occupation was classified as others because it was difficult to establish it from the medical records. On having had COVID – 19 infection before, only 3.4 % of the population had had COVID- 19.

Table 4. 1. Characteristics of study participants

Characteristic, N= 2204	Frequency(n)	Percentage
Age		
<50	1515	68.7
>50	689	31.3
Sex		
Male	1310	56.4
Female	894	43.6
Education level		
Primary	398	18.1
Secondary	541	24.5
Tertiary	1264	57.4
Other	01	00.0
Religion		
Christian	1953	88.7
Moslem	206	9.3
Hindu	44	2.0
Other	01	00.0
Marital status		
Married	304	13.8
Single	1900	86.2
Occupation		
Teacher	512	23.2
Health worker	377	17.1
Security	191	8.7
Others	1124	51.0
Previous COVID – 19		

Infection		
Yes	75	3.4
No	2129	96.6
Had side effects		
Yes	603	27.3
No	1601	72.7

4.2 Prevalence of side effects to Oxford/AstraZeneca vaccine in Tororo district.

Among the study population of 2204 persons who received the vaccine, 603 experienced side effects representing (27.4%) that is slightly more than one in four participants. Of those who experienced side effects, 102/2204(27.4%) experienced only local side effects and 298/2204(13.5%) experienced only systemic side effects. Therefore, 203 participants experienced both local and systemic side effects. The total number of side effects when disaggregated into local and systemic side effects totals to 806 ((203x2) +102+298) side effects. However, at analysis we used the primary level prevalence (individuals as unit of analysis), 603/2204 as prevalence of side effects in our regression analysis.

On when the side effects occurred only 424/ 603 participants had responses to the question. Of these, 68/424(63.2%) of the participants experienced side effects after the first dose, 44/424 (10.38%) experienced side effects after the second while 112/424 (26.4%) experienced side effects after both doses. Six participants did not get the second dose of the vaccine because of the side effects they experienced after the first dose. Among those that experienced side effects after both doses of the vaccine, 76/112(67.9%) reported to have been affected more in terms of severity of symptoms by the first dose.

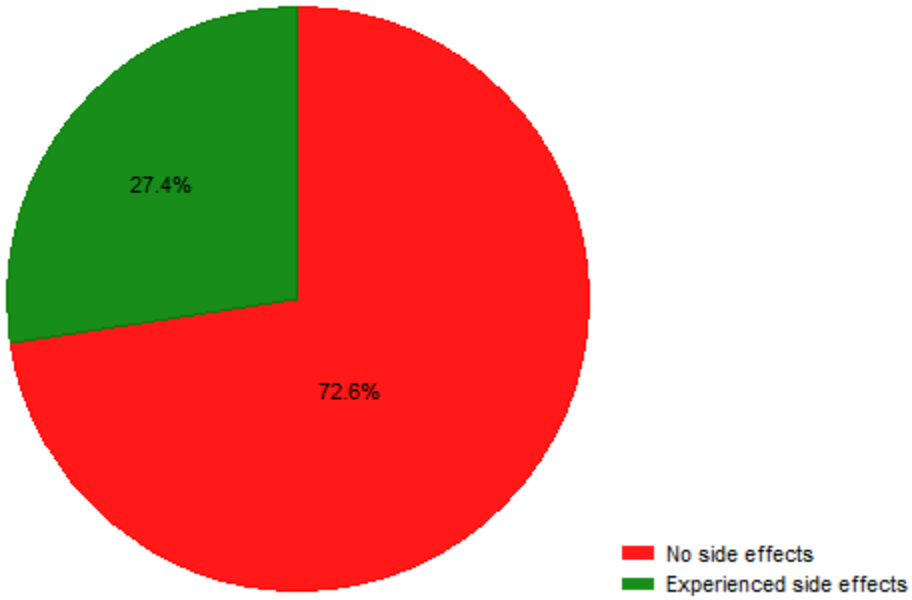

Figure 4- 1. Prevalence of side effects to Oxford/AstraZeneca vaccine in Tororo district.

4.3 Side effect profile (local side effects and systemic side effects of Oxford/AstraZeneca)

The side effects experienced can be divided into two; Local side effects, majority of which, 237/305(77.6%) were pain at the injection site, 16/305(4.7%) swelling at the injection site, 3/253(1.2%), swollen armpit lymph nodes and 1/253(0.4%) had redness at the injection site. As shown in the table below:

Table 4- 2. Shows the type of side effects, local and systemic due to Oxford/AstraZeneca vaccine

Local side effect (N=305)	**Frequency (n)**	**Percentage (%)**
Pain at the injection site	237	97.6
Swelling at the injection site	12	3.9
Swollen armpit lymph nodes	3	0.9
Redness at the injection site	1	0.3

. Systemic side effects of Oxford/AstraZeneca

Side effect (n=501)	**Frequency (n)**	**Percentage (%)**
Tiredness	145	28.9

Headache	102	20.3
Fever	97	19.2
Joint pains	42	8.3
chills	22	4.4
Nausea	21	4.2
Muscle pain	10	2.2
Vomiting	4	1.9
Fainted	3	0.7
Diarrhea	2	0.3
Breathlessness	1	0.1

The majority of the participant who experienced systemic side effects reported tiredness 145/501 (28.9%), followed by headache at 20.3% and fever at 19.2%.

Although they may be few, 3/501 (0.6%) fainted after the jab, these cases can be scary and need to be followed up. Also one person had breathlessness. These type of side effects need to be documented and further studies carried out why to the people who experienced them and remedy made.

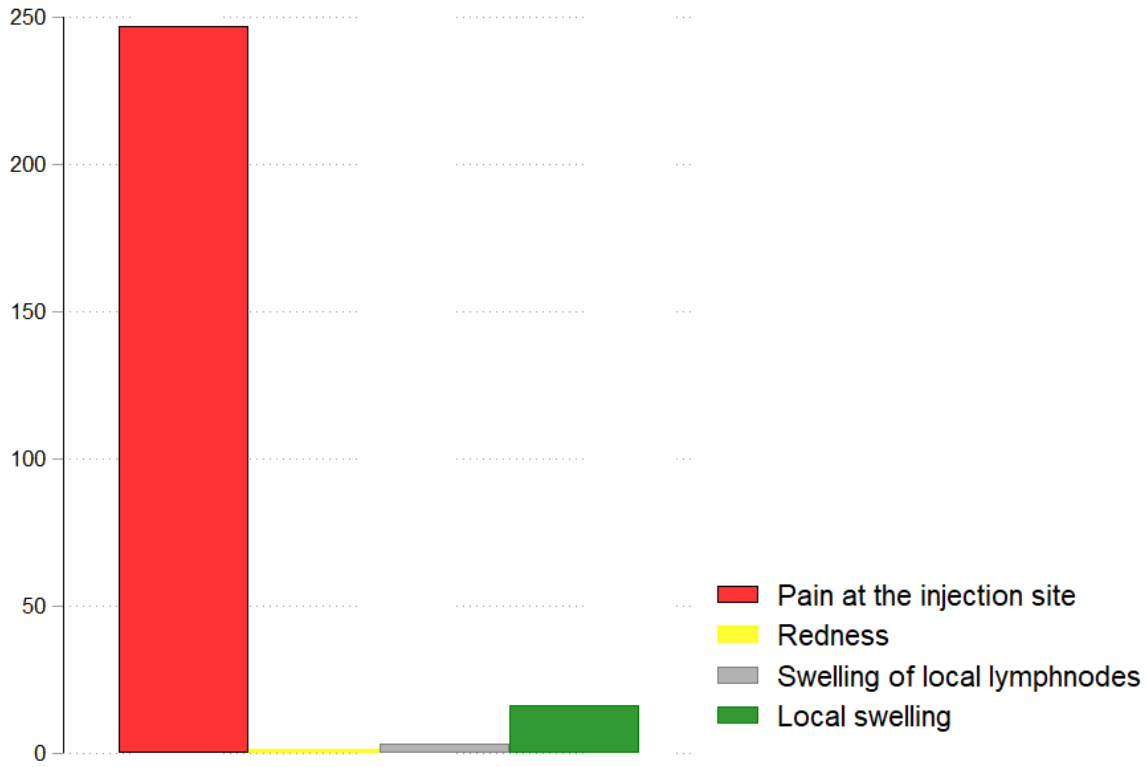

Figure 4-2: local side effects following vaccination with Oxford/AstraZeneca

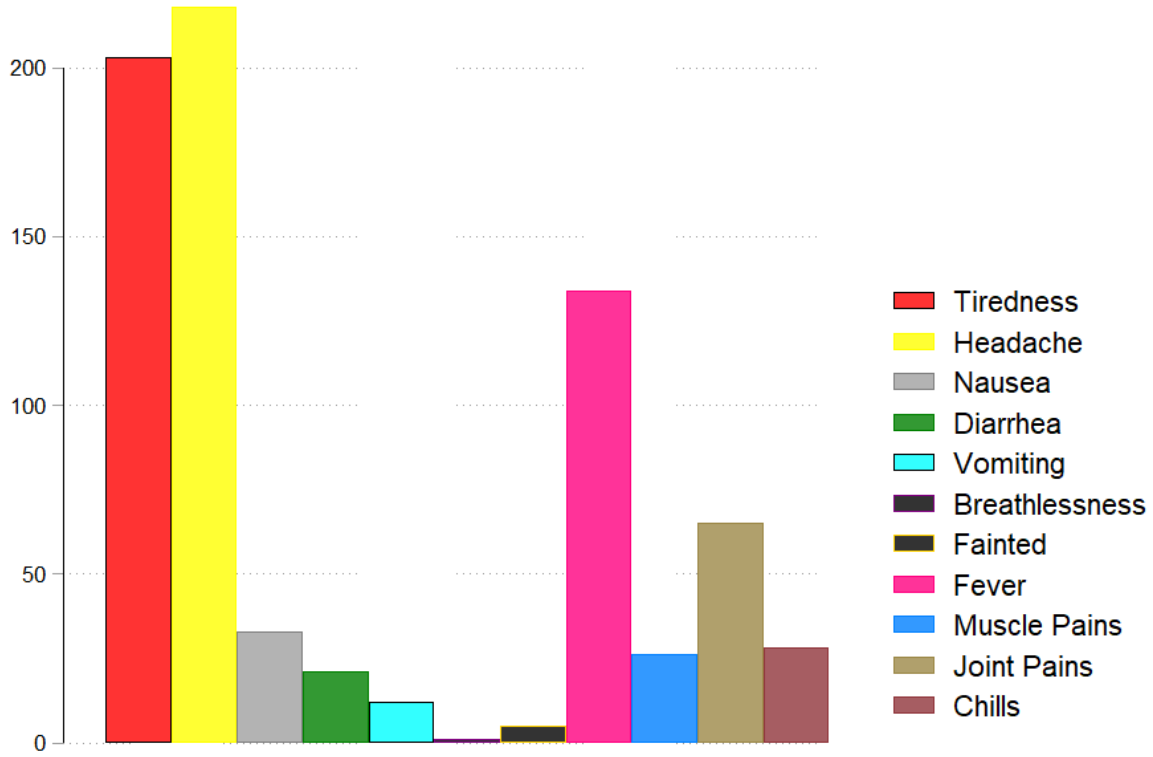

Figure 4- 3: Systemic side effects following vaccination with Oxford,/AstraZeneca

4.4 Duration of symptoms

Overall symptoms experienced lasted a median of 1 day (IQR: 1-2). However variations occurred between the duration of the side effects by the type of side effect whether local or systemic and within the local and systemic side effects.

Table 4- 3. Duration of side effects of Oxford/AstraZeneca vaccine

Side effect	**Number affected**	**Duration**	**Still had symptoms by the time of study, 6 months after vaccination (n)**
		Median (IQR) days	
Local side effect			
Pain at injection site	237	2 (2,3)	3

Swelling at injection site	16	4(3,6)	6
Redness	3	2.5 (2,3)	0
Swollen armpit glands	1	4 (4,4)	0
Systemic side effects			
Tiredness	145	3(2,6)	2
Headache	102	3(2,6)	2
Fever	97	3(2,5)	1
Joint pain	42	6(2,8)	2
Muscle pain	10	5(2,7	1
Nausea	21	5(1,6)	0
Rash	12	4.5(3,6)	0
Chills/shiver	22	5(3,5)	0
Skin burning	9	5(3,6)	0
Diarrhea	2	4(1.5,6)	1
breathlessness	5	2(2,3)	0
Vomiting	4	3.5(1,21)	0
Fainted	3	1(0,1)	0
Red welts on the face and lips	2	19.5(3,36)	0

4.5 Health care seeking following Oxford/AstraZeneca vaccine side effects

Table 4- 4. Health care seeking following AstraZeneca side effects

Place of seeking care (n=603)	Frequency (n)	Percentage (%)
Did not seek health care	265	42.4
Consulted CHW	19	3.1
Consulted traditional healer	3	0.4
Visited Health Center	16	2.6
Visited Hospital	12	1.9
Visited Private Clinic	33	5.4

Self -medication	74	12.2
Other	181	0.5

Almost half of the participants, 265/603 (42.4%) did not seek any health care after experiencing side effects. However a total of 61/603(10.1%) of the participants sought medical attention in a health facility. These probably represented those with serious side effects as a visit to a health facility may be a proxy indicator for a serious medical condition. Among those who visited a health facility, 33 out of 61 visited a private facility. This probably reflects the contribution of private practice to health services in this setting.

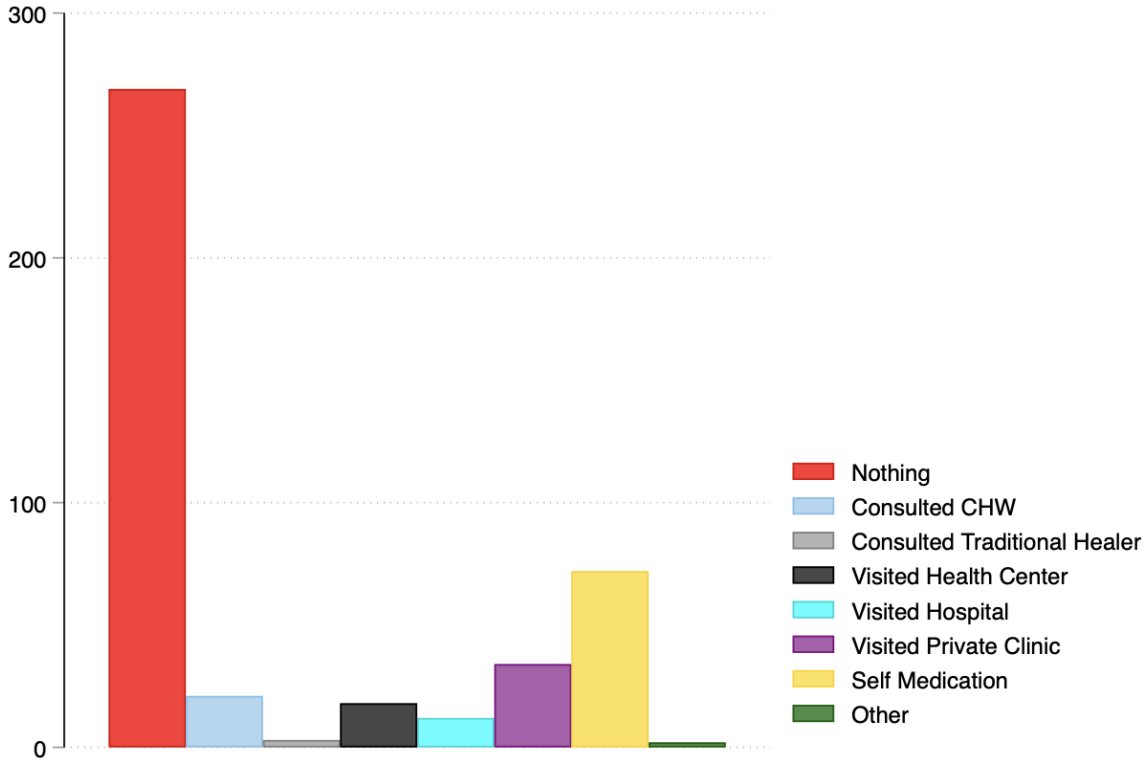

Figure 4- 4: Health care seeking following COVID-19 vaccination Medications following COVID-19 vaccination side effects

4.6 Medications following Oxford/AstraZeneca side effects

Most of the participants [96/155 (61.9%)] used Paracetamol following COVID-19 vaccination side effects. Other medications used are in Table 4-6 and figure 4-5 below.

Table 4- 5. Medications following Oxford/AstraZeneca vaccine side effects

Medication (N=155)	Frequency (n)	Percentage (%)
Herbs	6	3.9
Paracetamol	96	61.9
Diclofenac	32	20.7
Amoxicillin	11	7.1
Azithromycin	3	1.9
Chloroquine	1	0.7
Ciprofloxacin	6	3.9
Vitamin C	4	2.6
Others	10	6.5
Dexamethasone	12	7.7

The vast majority of those who experienced side effects, 448/603 (74.2%) did not use any medication. This is probably due to the mild and transient nature of the majority of the side effects.

4.7 Deaths following Oxford/AstraZeneca vaccination

7/424 participants died after COVID-19 side effects. The causes of death were probably not directly related to the side effects as shown in the table below. However it was not possible to infer association between death and side effect of Oxford/AstraZeneca.

Table 4- 6. Deaths following receipt of Oxford/AstraZeneca vaccine

Participant	Cause of death	Time period from date of second dose of vaccine
1	Diabetes complication	Three weeks

2	Hypertension/Stroke	Three weeks
3	Accident	Two weeks
4	Malaria	One month
5	Sudden death	Three months
6	Accident	Five months
7	Tuberculosis	Two months

4.8 Factors associated with experiencing side effects to Oxford/AstraZeneca vaccine

Previous infection with COVID-19 (AOR: 4.3, 95% CI: 2.7-7.0, p = < 0.001) and being female (AOR: 1.3, 95% CI: 1.1-1.6, p = 0.004) were positively associated with side effects of AstraZeneca. Being a security officer (AOR: 0.4, 95% CI: 0.2-0.6, p = <0.001) was also statistically significant. Participants who were previously infected by COVID-19 were 4.3 times as likely to experience Oxford/AstraZeneca vaccine side effects as those who weren't. Females were 1.3 times as likely to experience side effects as the male. Security officers were 0.4 times less likely to experience side effects to Oxford/AstraZeneca vaccine compared to participants of different occupations therefore being security officer was protective.

Table 4- 7. Factors associated with experiencing side effects to Oxford/AstraZeneca vaccine

Characteristic	COR	95% CI	p-value	AOR	95% CI	p-value
Age						
<50	1			1		
≥50	1.0	0.8-1.2	0.958	1.0	0.8-1.2	0.942
Sex						
Male	1			1		
Female	1.4	1.2-1.7	<0.001	1.3	1.1-1.6	**0.004**
Marital status						
Single	1			1		
Married	1.0	0.7-1.3	0.800	0.9	0.7-1.2	0.595
Previous COVID-19 infection						
No	1			1		
Yes	4.5	2.8-7.2	<0.001	4.3	2.7-7.0	**<0.001**
Education level						
Primary	1			1		
Secondary	1.0	0.8-1.4	0.756	1.1	0.8-1.5	0.423
Tertiary	0.9	0.7-1.1	0.304	0.8	0.6-1.1	0.163
Occupation						

Teacher	1			1		
Health worker	0.9	0.7-1.2	0.549	0.9	0.7-1.2	0.561
Security	0.4	0.3-0.6	<0.001	0.4	0.2-0.6	**<0.001**
Others	1.0	0.7-1.3	0.919	0.8	0.6-1.1	0.152

CHAPTER FIVE: DISCUSSIONS.

5.0 Introduction

This chapter deals with the discussion of the results as presented in the results section above. Specifically, it covers the prevalence of the side effects of Oxford/AstraZeneca vaccine experienced by the vaccine recipients in Tororo. It also covers the factors associated with the side effects, the interventions undertaken, and the outcomes of the side effects as well as the methodological discussion.

5.1 Socio demographic characteristics of participant

A total of 2204 participants were reached during this survey and of these 68.7% were <50 a clear reflection of the target groups that were prioritized i.e. teachers, health workers' security personnel who well within this age bracket. These priority groups were deemed more at risk of contracting the infection hence the need to protect them on the other hand in case of overwhelming epidemic these priority groups would be protected and keep the system stable. That more than half of the respondents were male could also be explained by a higher numbers of men in these priority groups and or having reliable phone contacts. Overwhelming majority being Christian however that only 13% were married was a surprising finding. This could have resulted from the definition of marriage as taken by the interviewers.

5.2 Prevalence of side effects of AstraZeneca vaccine

In this telephone based survey conducted in Tororo in Eastern Uganda, we investigated the side effects and associated factors following COVID -19 vaccination with Oxford/AstraZeneca among priority populations comprising health workers, teachers, security personnel, the elderly above fifty and all adults between 18- 50 with underlying conditions. This was a COVID-19 vaccine naïve population as they were the first beneficiaries of this service in the phased approach the government undertook to vaccinate its eligible citizens. A total of 603/2204(27.4%) of the participants experienced side effects of which about 37% were local while 63% were systemic. A study carried out in Saudi Arabia reported a much higher figure of 68.5% of participants reporting side effects(Adam *et al*., 2021) Another study carried out in Jordan on a vaccine naïve population but comparing AstraZeneca with Pfizer and Sino pharm reported had even much higher figure of 89.9% rate of participants reporting side effects(Omeish *et al*., 2022)

The same study revealed that more side effects were significantly associated with Oxford/AstraZeneca vaccine than other vaccines. In our study, injection site symptoms were reported by 201/501(40.1%) of the participants the majority of which (77.6%) were pain at the injection site while These symptoms were just as common in other vaccines and these results are in tandem with other studies in Ethiopia and Poland (Solomon e*t al*., 2021). 416/619(67%) side effects were of systemic nature majority of which were tiredness (24%) and headache (24%). These were lower than in a study in Ethiopia (Solomon *et al.*, 2021) that reported 54% incidence. The differences here could be explained by differences in populations as some of them could present differing thresh holds for discomfort as well as the nocebo effect in that some populations could be more averse to rumors and misinformation and experience side effects out of expectation reported in a study in Grenoble Hospital in France. Nocebo effect can modulate the outcome of a given therapy in a negative way (Plan es *et al*., 2016). In this case it could be induction or worsening of side effects of Oxford/AstraZeneca vaccine.

5.3 Factors associated with Oxford/Astra Zeneca vaccine side effects

Being female was positively linked to experiencing side effects while being a security personnel was negatively associated after vaccination with AstraZeneca in Tororo. This is contrary to study done in Ethiopia on health workers that found no association(Solomon e*t al*., 2021). However this mixed group could have provided a differing denominator as well as differences in population characteristics. However a cross sectional survey among recipients of COVID-19 vaccine in the general population in Saudi Arabia reported a higher prevalence of side effects among women than men after either doses(Saeed *et al*., 2021). In this study there was particularly significant relationship between being female and fatigue (p=0.0006) but no significant difference by gender for tenderness redness, fever and headache. We cannot rule out nocebo effect in explaining the gender relations as some people could have experienced side effects out of expectation. This is emphasized in a report by Winfried Rief of JAMA health forum that the very fear of side effects can amplify or induce side effects(Rief, 2021).

A total of 64/424 (15.1%) of the participants who had side effect sought medical care from a health facility. We can take these as those with serious side effects as a visit to the health facility could be a proxy indicator for a serious condition in our setting. This was way above the 2%

serious side effects reported by a study in the United states in (Wadman, 2020). The difference could be accounted for by difference in definition of serious side effect. However a study conducted in England concluded that there aren't enough data to draw conclusions on serious adverse events following COVID -19 vaccination as not enough clinical trials and long term follow up has been done (Boekel et al., 2021).

The strong relation with a previous infection could be as result of a primed body with a natural immunity developing from a previous infection reacting more aggressively to the vaccine. A prospective observational study conducted in the United Kingdom showed such strong linkage between a previous COVID-19 infection and side effect experience, a 1.6 times more likelihood of side effects in those with previous infection. (Menni *et al*., 2021). Significant association between side effects following previous infection was quite apparent suggesting the possibility of the vaccine landing on a primed immune system that probably reacted harder.

Among those that experienced side effects after both doses of the vaccine, 76/112(67.9%) reported to have been affected more by the first dose. Similar results were reported by a study in Poland of participants being affected more by the first dose of the vaccine(Andrzejczak-Grządko *et al*., 2021)

Being a security personnel at an AOR 0.4, CI0.2-0.6 P<0.0001 had a statistically significant protective relationship. Perhaps the hardened nature of this group makes them less likely to report minor events as side effects. However these are generally fit people but also 'macho' nature by training and possibly they are more inclined towards not reporting minor events.

5.4 Outcomes of Oxford/AstraZeneca vaccine side effects

The study provides evidence of mild symptoms as the majority of the side effects were managed conservatively (did nothing) followed by self-medication using mainly Paracetamol tablets. This is in agreement with a study done in Ethiopia amongst health workers that reported 64% of the people who got side effects used Paracetamol as remedy.(Solomon *et al*., 2021). Up to 18/424 (4.2%) of those who got side effects had ongoing symptoms at the time of study averagely six months later. Seven participants died of causes that may not necessarily have been related to the

vaccine; two of accidents, one of TB, malaria, stroke, Hypertension and diabetes mellitus respectively on average 3 months post vaccination. Six participants couldn't proceed to get the second dose on account of the side effects.

5.5 Methodological discussion

This population based survey used telephone interviews to gather quantitative data using a structured questionnaire. It purposed to each out to all the 7834 people who had received Oxford/AstraZeneca vaccine from the first 8000 does released to Tororo as of July 2021.By this date the District reported stock out of vaccines and therefore end of that phase of vaccination. This paused a major challenge of selection bias as data could only be collected from those with reliable phone contact. Of the over 7834 targeted population only 5750 were deemed to have complete data to be contacted and of these only 2204 were reached. Some telephone contacts were not available or unreachable. Some contacts were actually duplicated in the register. This could have also resulted in information bias as the participants who could not be accessed could have reported side effects,

Other potential bias in the methodology included information bias as some people could have reported side effects out of anticipation given that there was a lot of unverified information about the vaccines among the population. Some participants were not forthcoming with information insisting that they only be called by the principal investigator. Recall limitations could have also resulted from the retrospective nature of the study that took place more than six months after the vaccination exercise

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

A total of 608 out of 2204 (27.4%) of the participants experienced mild to moderate side effects of which about 32% were local while 67% were systemic. The study provides evidence of mild symptoms as the majority of the side effects were managed conservatively. The majority of the symptoms were self- limiting and resolved within 2-3 days and this is expected with vaccine side effects. Seven deaths within the study period were recorded and it was beyond the capacity of this study to determine association though the two accidents were probably not at all linked. The reported side effects following the first dose could have had some nocebo bearing.

Significant association between side effects following previous infection was quite telling in terms of the vaccine landing on a primed immune system that probably reacted harder. Being female was positively linked to experiencing side effects while being security personnel was negatively associated after vaccination with AstraZeneca.

6.2 Recommendations

We strongly recommend a more aggressive dissemination of correct information on potential vaccine side effects to communities including the need to take a conservative approach to their management as the vast majority are transient.

In event that significant discomfort is experienced simple remedies like Paracetamol would suffice otherwise a visit to the health facility could help.

Participant education to report any untoward events to strengthen the passive surveillance on adverse events following vaccination will help strengthen the system.

6.3 Limitations of the study

The retrospective nature of this study paused a risk of recall limitations as this study took place several months past the events being investigated. Furthermore, COVID 19 considerations are envisaged to have impacted on some practical aspects of this study.

Data collection from only those with functional telephone contacts with potential for many dropped calls that could have led to a low response and information bias.

The variable vaccination status (whether a participant had 1 dose or 2 two doses) is not available in the data set as it was not collected. This was not included as predictor and yet it is a biologically plausible factor.

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APPENDICES

APPENDIX 1: QUESTIONNAIRE

Section 1: Socio demographic data

Date: …….. Research Assistants Number: ……

District: …….. County: …….Sub County: ……

Parish: …… Village: …….

1.1) Respondent's number: ……

1.2) Age: ……

1.3) Education level: a) Primary b) Secondary c) Tertiary

1.3) Religion; a) Catholic b) Anglican c) Muslim d) Pentecostal e) Other

1.4) Marital status; a) Single b) married c) divorced e) others

1.5) Occupation; a) Teacher b) Health worker c) Security d) others, specify: ……..

Section 2: Post vaccination experiences/side effects

2.1): Did you experience any side effects after vaccination? : a) Yes, b) No

2.2): If no go to 4, if yes, which one of these?

2.2.1) Local side effects;

1. Pain at injection site
2. Redness
3. Swollen armpit glands
4. Swelling

2. 2. 2): systemic side effects

5. Tiredness
6. Headache
7. Nausea
8. Diarrhea
9. Vomiting
10. Breathlessness

11. Fainted
12. Fever
13. Muscle pain
14. Joint pain
15. Chills/shiver

2.2.3): Allergic reactions

16. Rash
17. Skin burning
18. Red welts on face and lips
19. Other(s), specify: ……..

3: Symptom time of the side effect

1. <24 hours
2. 24-48 hours
3. >48 hours

4: Previous infection with COVID -19? Yes /No

Supplemental information on the topic prevalence and predictors for COVID-19 vaccine (AstraZeneca) side effectors among vaccine recipients in Tororo.

1) After how long did it take for the symptoms to appear?

……. (Days)

2) Did you get the side effects?

1. after first jab

2. after second jab

3. after both jabs

2b) If after the first jab: have you got your second jab?

1. No 2. Yes

2c) If No, did the side effects influence your decision not to get the second jab?

1. No 2. Yes

2d) If after both: which jab affected you most?

1. First 2. Second

3) How long in days did the symptoms last?

…… (Days) [Write 888 if still ongoing, and 999 if participant does not know)

4) What did you do after the onset of side effects?

0. [ ] Nothing
1. [ ] Consulted TBA
2. [ ] Traditional healer
3. [ ] Taken to health centre
5. [ ] Taken to hospital
6. [ ] Taken to private clinic
7. [ ] Self medication
8. [ ] Other specify

5. What medication did you take?

1. Herbs, 2. Paracetamol, 3. Diclofenac, 4. Other NSAID, 5. Amoxicillin, 6. Aspirin, 7. Azithromycin, 8. Chloroquine, 9. Ciprofloxacin, 10. Vitamin C, 11. Vitamin D, 12. Dexamethasone,

13. Others specify

14. I don't know

6) Has the event resolved

1. No (ongoing)
2. Yes

7) If No, what symptoms are still present?

Local side effects

1. Pain at injection site, 2. Redness, 3. Swollen armpit glands, 4. Swelling

Systemic side effects

5. Tiredness, 6. Headache, 7. Nausea, 8. Diarrhea, 9. Vomiting, 10. Breathlessness, 11. Fainted, 12. Fever, 13. Muscle pain, 14. Joint pain, 15. Chills/shiver

Allergic reactions

16. Rash, 17. Skin burning, 18. Red welts on face and lips

19. Others, specify…….

5) Is the participant alive?

1. Yes

2. No

APPENDIX 2: RESEARCH ETHICS COMMITTEE APPROVAL LETTER

Telephones: General Line: 039-3280584
041-4671162

E-mail: mrrhrec@gmail.com

MINISTRY OF HEALTH
MBALE REGIONAL HOSPITAL
P.O. BOX 921
Mbale – Uganda

THE REPUBLIC OF UGANDA

In any correspondence on this
Subject, please quote: MRRHREC-OUT- 011/2020 Date:

MRHREC ACCREDITED BY THE UNCST, REGISTRATION NUMBER UG-REC-011

19/10/2021

To: Jagire Onyango

Busitema University
+256772358537

OFFICE OF THE CHAIRPERSON
APPROVED
APPROVED DATE EXPIRY DATE
19 OCT 2021 19 OCT 2022
MBALE REGIONAL REFERRAL HOSPITAL
RESEARCH & ETHICS COMMITTEE
(MRRH- REC)

Type: Initial Review

Re: MRRH-2021-91: PREVALENCE AND PREDICTORS OF COVID 19 VACCINE SIDE EFFECTS; A CROSS SECTIONAL STUDY OF TORORO, EASTERN UGANDA, English, 2021-09-28

I am pleased to inform you that the Mbale Regional Referral Hospital REC, through expedited review held on **13/08/2021** approved the above referenced study.
Approval of the research is for the period of **19/10/2021** to **19/10/2022.**

As Principal Investigator of the research, you are responsible for fulfilling the following requirements of approval:

1. All co-investigators must be kept informed of the status of the research.
2. Changes, amendments, and addenda to the protocol or the consent form must be submitted to the REC for re-review and approval **prior** to the activation of the changes.
3. Reports of unanticipated problems involving risks to participants or any new information which could change the risk benefit: ratio must be submitted to the REC.
4. Only approved consent forms are to be used in the enrollment of participants. All consent forms signed by participants and/or witnesses should be retained on file. The REC may conduct audits of all study records, and consent documentation may be part of such audits.
5. Continuing review application must be submitted to the REC **eight weeks** prior to the expiration date of **19/10/2022** in order to continue the study beyond the approved period. Failure to submit a continuing review application in a timely fashion may result in suspension or termination of the study.
6. The REC application number assigned to the research should be cited in any correspondence with the REC of record.
7. You are required to register the research protocol with the Uganda National Council for Science and Technology (UNCST) for final clearance to undertake the study in Uganda.

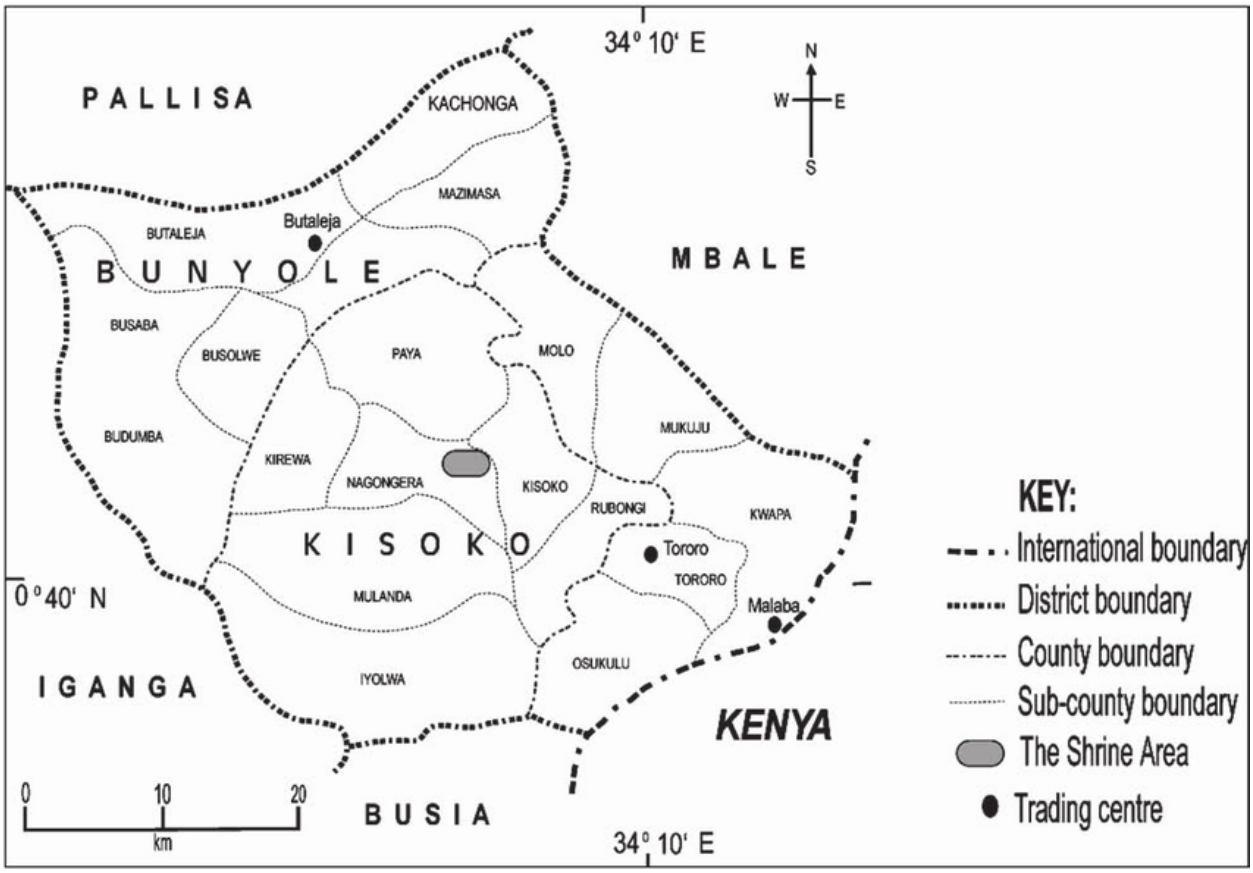
The following is the list of all documents approved in this application by Mbale Regional Referral Hospital REC:

No.	Document Title	Language	Version Number	Version Date
1	Risk management plan	English	00	2021-10-18
2	Informed Consent forms	English	00	2021-09-28
3	Data collection tools	English	00	2021-09-28
4	Protocol	English	English	2021-09-28

Yours Sincerely,

Fred Bulamba
For: Mbale Regional Referral Hospital REC

APPENDIX 3: MAP OF TORORO DISTRICT SHOWING SUB COUNTIES



APPENDIX 4: DATA EXTRACTION TEMPLATE

S/N	NIN:	NAME:	AGE	SEX	ADDRESS (sub County)	OCCUPATION	CONTACT	CLIENT CATEGORY (NATIONAL(N)= 1, REFUGEE(R) =2, FOREIGNER(F) =3	PRIORITY POPULATION GROUPS	HAS UNDERLYING CONDITION	UNDERLYING CONDITION	FIRST DOSE DATE	SECOND DOSE DATE	OTHER DOSE (SPECIFY)	FOLLOW UP	REMARKS