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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.

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APPROVAL

This dissertation with our approval as academic supervisors:

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

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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

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