IJID Regions 4 (2022) 47–52

Contents lists available at ScienceDirect

IJID Regions

journal homepage: www.elsevier.com/locate/ijregi

Adverse events following introduction of the ChAdOx1 nCoV-19 vaccine in Somalia in 2021: findings from a fragile setting and implications for the future

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WHO Somalia

ARTICLE INFO

Keywords:
Vaccine
COVID-19
AEFI
Somalia
Covishield
ChAdOx1 nCoV-19

ABSTRACT

Background: Vaccination against coronavirus disease 2019 (COVID-19) began in Somalia on 16 March 2021 with the Covishield (ChAdOx1 nCoV-19) vaccine. However, by the end of 2021, only a small percentage of the population had been fully vaccinated. As side effects play an important role in determining public confidence in vaccines and their uptake, this study aimed to examine reported adverse events following immunization (AEFIs) of vaccine recipients.

Methods: This cross-sectional-survey-based study was conducted between March and October 2021 in Somalia. Vaccine recipients who were eligible to receive the first dose of the Covishield vaccine in the first phase of COVID-19 vaccination were eligible for study inclusion. $P<0.05$ was considered to indicate significance.

Results: Of the 149,985 respondents who had received the first dose of the Covishield vaccine, 378 reported side effects. This represented a reported AEFI rate of 2.5 per 1000 population. Amongst those who reported adverse events, males (2.8 per 1000; $P<0.001$), respondents aged 35–49 years (3.3 per 1000; $P=0.001$) and teachers (3.5 per 1000; $P=0.000$) had higher rates of adverse events compared with females, other age groups and other occupations. Amongst population settlement types, a higher rate of AEFIs was observed amongst refugees (23.9 per 1000; $P=0.000$) and internally displaced populations (19 per 1000; $P=0.000$). Nearly half of the vaccine recipients who reported side effects (48%) reported one local symptom, and most symptoms were mild in nature. The probability of having acute and severe side effects was found to be 66% lower among males compared with females [odds ratio (OR) 0.44, 95% confidence interval (CI) 0.26–0.73; $P=0.002$]. Respondents aged >60 years (OR 1.52, 95% CI 0.64–3.62; $P=0.34$) were more likely to develop acute and severe AEFIs. None of the study population reported any severe life-threatening symptoms or death.

Conclusion: Some variables (sex, profession, age) put recipients at higher odds of acute and severe AEFIs, but the Covishield vaccine generally produced mild side effects in a small proportion of the vaccinated population in Somalia. This study confirms that COVID-19 vaccines are safe, and their benefits clearly outweigh any associated risk.

Background

The first laboratory-confirmed case of coronavirus disease 2019 (COVID-19) in Somalia was reported on 16 March 2020 (Ali et al., 2022). Since then and as of 5 March 2022, the country has reported a total of 26,431 cases and 1348 deaths (WHO, 2022a). The Federal Ministry of Health and Human Services of Somalia introduced the Covishield (ChAdOx1 nCoV-19) vaccine on 16 March 2021 in the country, received through the COVAX facility (WHO, 2022b). The Covishield vaccine is a version of the Oxford-AstraZeneca (CHADOX1 nCOV-19 or ChAdOx1 nCoV-19) vaccine that has been found to have average efficacy of 70.4% in randomized controlled trials across the UK, Brazil and South Africa (Voysey et al., 2021). Somalia faced unpredictable supply issues during the first half of 2021, and national progress in reaching optimal uptake was slow compared with neighbouring countries in Eastern Africa. By the end of 2021, only 5.5% of Somalia's population were reported to be fully vaccinated against COVID-19 (WHO, 2022b).

A vaccine has always been one of the best public health interventions to stop human-to-human transmission of a viral disease that causes widespread public health, economic and social consequences, especially in situations when no effective medical countermeasures are available.

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https://doi.org/10.1016/j.ijregi.2022.06.001
Received 14 April 2022; Received in revised form 31 May 2022; Accepted 3 June 2022

The development of a safe and effective vaccine against COVID-19 was a milestone achievement for the international community, and offered high hopes to end the pandemic, despite not knowing what percentage of population immunity was required through vaccines or through natural infection to lead to herd immunity. As of 6 April 2022, a total of 11,242,252,352 vaccine doses had been given worldwide (WHO, 2022a). Specific severe and infrequent adverse events following immunization (AEFIs) were observed when a global mass vaccination effort was rolled out (Lo Re et al., 2021; Shrestha et al., 2021). Following the initial dosage of the Covishield vaccine, the incidence of at least one adverse event varied between countries; for example, 57–69% in India (Kamal et al., 2021), 71.6% in Togo (Konu et al., 2021), 65.2% in Thailand (Watcharananan et al., 2021) and 90% in the Republic of Korea (Bae et al., 2021). According to data reported to the European Medicines Agency, approximately 50% of participants complained of injection site pain, headache or fatigue after receiving the Oxford-AstraZeneca vaccine (Remmel, 2021).

When the first dose of the Covishield vaccine was administered in Somalia, the country had no formal system for recording and reporting AEFIs for routine childhood vaccinations. As such, the country could not rapidly deploy an active and standardized system for reporting adverse events following introduction of the COVID-19 vaccine. However, the Federal Ministry of Health decided to use the newly introduced electronic registration platform – Demagi's CommCare (Feroz et al., 2021; WHO, 2013) – when the Covishield vaccine was rolled out to record official data of COVID-19 vaccine recipients and for self-reporting of adverse events. The idea was driven by the fact that data gleaned from this self-reporting event, and leveraged on the support received from international partners to roll out the COVID-19 vaccine in a fragile health system setting, could eventually lead to establishment of a pharmacovigilance system for monitoring, detecting, investigating and reporting AEFIs in Somalia for all childhood and adult vaccinations.

The introduction of self-reporting AEFIs was guided by the Somalian Government's aim to communicate transparently with its people about the safety of the Oxford-AstraZeneca COVID-19 vaccine in order to achieve greater vaccine acceptance, as studies conducted in Somalia when the vaccines were being rolled out showed that the main reason for vaccine hesitancy among high-risk groups in the country was uncertainty about side effects surrounding the deployed vaccines (Ahmed et al., 2021). As this was a new vaccine that had not been used previously in Somalia, and there were reports of adverse events and even deaths during the early roll out of COVID-19 vaccines elsewhere (Kuter, 2021; MacNeil et al., 2021; Wolf et al., 2021), it was important to study the safety of the Covishield vaccine introduced in Somalia in order to raise public confidence regarding vaccine safety and effectiveness.

In order to allay any public distrust and improve public acceptance of COVID-19 vaccines, the Federal Ministry of Health and Human Services of Somalia introduced post-vaccination self-reporting of adverse events following receipt of the Covishield vaccine using the Demagi's CommCare system.

This study aimed to examine the types and rates of AEFIs for the Covishield vaccine administered in Somalia, which were self-reported during the first phase of vaccination in the country.

Methods

Study design and setting

This study on AEFIs of the Covishield vaccine was a cross-sectional-survey-based study conducted between March and October 2021 in Somalia to investigate the magnitude of COVID-19 vaccine side effects in the population following receipt of the first dose of vaccine.

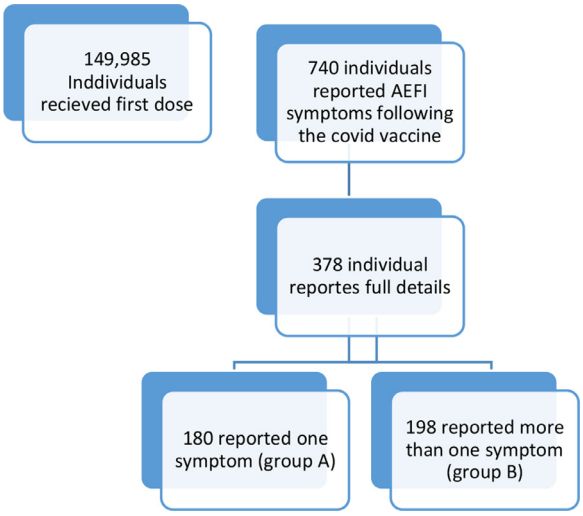

Figure 1. Study flow chart. AEFI, adverse events following immunization; COVID-19, coronavirus disease 2019.

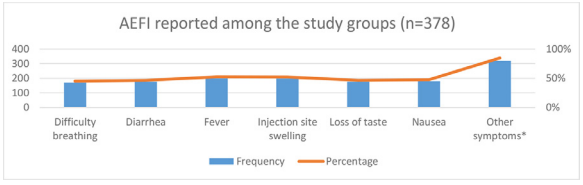

Figure 2. Distribution of adverse events following immunization reported by the study group (n=378)

Study population

All vaccine recipients who were eligible to receive the first dose of the Covishield vaccine during the first phase of COVID-19 vaccination in the country were eligible for inclusion in this study. This group, according to the national COVID-19 vaccine deployment plan, comprised 3% of the population and represented people aged >50 years, healthcare workers, elderly people, people with chronic medical conditions and frontline workers. Using these eligibility criteria for receipt of the COVID-19 vaccine, the total number of individuals aged >18 years who received the first dose of the Covishield vaccine in Somalia between March and October 2021 was 149,985. In total, 740 individuals who received the first dose of the Covishield vaccine reported adverse events; of these, 378 vaccine recipients were included in the study sample after removing duplicates and results with missing values (Figure 1). Data for the remaining individuals were either missing, duplicated or did not match with the case definition of AEFIs.

Data collection

The national database for COVID-19 vaccination, including the demographic profile of all vaccine recipients, was established using Dimagi's CommCare application, which is an offline-first, open source mobile data collection and service delivery platform (Dimagi, Inc., Cambridge, MA, USA). The CommCare application was also used to extract relevant information, such as demographics (age, gender, state and profession), history of COVID and reported AEFIs for this study. Data for adverse events were self-reported by the vaccine recipients, and the events were registered in the application by authorized data entry operators using a structured format.

Statistical analysis

Demographic variables (gender, age, profession and state), medical history (comorbidities and history of COVID-19), and vaccine side effects (difficulty breathing, fever, diarrhoea, loss of taste, nausea and others) have been represented as frequency, percentage and rate per 1000 population. Inferential statistics were performed to assess the association between side effects and age, gender, state and profession using Chi-squared test with a confidence level of 95%; $P \leq 0.05$ was taken to indicate significance. Univariate and multivariate logistic model regression analyses were performed to study and assess the sociodemographic variables that were associated with acute and severe events after the first dose of the Covishield vaccine. Crude and adjusted odds ratios (OR) were calculated to study associations of acute and severe events, and to identify the predictor variables for acute and severe events following immunization with the Covishield vaccine. All data analyses and statistical tests were performed using Statistical Package for the Social Sciences Version 27 (IBM Corp., Armonk, NY, USA).

Results

Demographic data and acute adverse events

This study was conducted between March and October 2021. The total number of individuals aged >18 years who received the first dose of the Covishield vaccine in Somalia during this period was 149,985. The mean age was 43 years (standard deviation 14.4) and the median age was 40 years [interquartile range (IQR) 21.3]. Of these, 378 vaccine recipients reported at least one side effect, representing an overall rate of 2.5 per 1000 population. These 378 vaccine recipients were included in the bivariate and multivariate analyses in this study after cleaning the dataset (i.e. removing duplicate/irrelevant observations) and avoiding data with missing values.

Among those who reported adverse reactions, the rate of events was higher among males compared with females; this difference was significant (2.8 per 1000 vs 2.1 per 1000; $P<0.001$). Comparing side effects between vaccine recipients, the highest rate (9.3 per 1000 population) was found in the state of Galmudug. Teachers reported higher rates of adverse events compared with healthcare workers (3.5 per 1000 population vs 2.2 per 1000 population) and other occupation groups. Compared with other age groups, the rate of adverse events was highest among vaccine recipients aged 35–49 years, and this difference was significant (3.3 per 1000; $P=0.001$). Refugees (23.9 per 1000) and internally displaced populations (19.0 per 1000) had the highest rates of adverse events amongst population settlements.

AEFIs reported among the study groups

Among the recipients of the first dose of the Covishield vaccine who reported adverse events ($n=378$), 180 (180/378;47.6%) reported one side effect. The remaining 198 vaccine recipients (198/378; 52.38%) reported more than one side effect (Table 2). In this study, the commonly self-reported adverse events of the COVID-19 vaccine included fever (52.60%), injection site swelling (52.40%), diarrhoea (46.60%), loss of taste (46.60%) and difficulty breathing (45.20%). Symptoms identified as 'other' represented 85% of the AEFIs in the study sample, and included malaise and headache (Figure 1). However, except for 'other' symptoms, all reported side events, such as injection site swelling (93.9%, 95% CI 90.0–96.6), fever (92.4%, 95% CI 88.1–95.5) and loss of taste (88.9%; 84.0–92.7), were predominantly reported by those with more than one side effect (Table 2).

Factors associated with occurrence of adverse events

Bivariate and multivariate analyses were conducted to look for sociodemographic predictors for acute and severe adverse events following receipt of the first dose of the Covishield vaccine. On univariate analysis, associations between sociodemographic factors and acute and severe adverse events were not significant, except for occupation. On bivariate analysis, females reported more acute and severe adverse events compared with males (71.8% vs 55.9 %; $P=0.004$), although the difference was not significant. Within different age groups, people aged >60 years (69.6%) were more likely to report acute and severe adverse events compared with other age groups.

However, multivariate logistic regression analysis (Table 3) found that gender and occupation were significant predictors of acute and severe adverse events following receipt of the first dose of COVID-19 vaccines in Somalia. The probability of acute and severe adverse events was 66% lower among males compared with females (OR 0.44; 95% CI 0.26–0.73), while police (OR 5.99, 95% CI 2.75–13.07), teachers (OR 1.75, 95% CI 0.95–3.20) and healthcare workers were at higher risk of adverse and severe adverse events compared with point of entry staff and municipality workers. Both bivariate and multivariate analyses showed that acute and severe adverse events were more likely among participants aged >60 years (OR 1.52; 95% CI 0.64–3.62) compared with other age groups (30–39 years, OR 1.19, 95% CI 0.62–2.29; 40–49 years, OR 0.89, 95% CI 0.46–1.74; 50–59 years, OR 0.72, 95% CI 0.36–1.43). These results (Table 3) show that women, elderly people (age >60 years), and police and teachers were more likely to experience acute and severe adverse events compared with men, younger age groups, and other occupations following receipt of the first dose of the Covishield vaccine.

Discussion

To the authors' knowledge, this is the first study in Somalia to report the type, number and rate of adverse events among the Somali population who received the first dose of the Covishield vaccine during the first phase of the COVID-19 vaccination programme in Somalia. This study also investigated the predictive factors associated with the occurrence of acute and severe adverse events among the eligible population who received the first dose of the Covishield vaccine between March and October 2021 in Somalia. The authors believe that this study represents the first data from Somalia, which did not have a system for monitoring and reporting AEFIs, even for childhood immunization programmes, until the COVID-19 pandemic. To the authors' knowledge, few studies have been published from similar fragile settings or from other African countries looking at associations between the occurrence of adverse events and sociodemographic factors in order to determine predictive factors for acute and severe AEFIs against COVID-19 vaccines. Similar to the present study, a report from Togo by Konu et al. (2021) is the only other study from Africa to investigate the association between the occurrence of adverse events and other sociodemographic factors.

According to the study findings, the rate of AEFIs against the COVID-19 vaccine was 2.5 per 1000 population. In this study, less than half of the participants (47.6%) reported one side effect, and the remaining participants (52.38%) reported more than one side effect. Most of the side effects were mild in nature, as found in other studies conducted elsewhere (Konu et al., 2021; Shrestha et al., 2021; Sultana et al., 2021; Watcharananan et al., 2022), including in some African settings (Konu et al., 2021). The present finding that women were more likely to experience acute and severe AEFIs from the Covishield vaccine compared with males was also observed in Thailand (Watcharananan et al., 2021), Nepal (Shrestha et al., 2021) and Bangladesh (Sultana et al., 2021). This finding is also consistent with other data published on the COVID-19 vaccine (Gee et al., 2021; Blumenthal et al., 2021). In Thailand, Bangladesh and Togo, the odds of experiencing side effects following immunization were higher in younger age groups. The present study found that the odds of experiencing acute and severe side effects after vaccination against COVID-19 were higher in vaccine recipients aged >60 years. This could be because, at the time of conducting this study, the population eligible to receive the Covishield vaccine in Somalia was aged >50 years and the median age of the study population was

Table 1
Demographic characteristics of recipients of the first dose of the Covishield (ChAdOx1 nCoV-19) vaccine and self-reported rates of adverse events

Characteristics/variable	Number who received the vaccine*n*=149,985	Frequency of self-reported adverse events *n*=378 (%)	Rate of adverse events/1000 population	*P*-value[a]
Gender				0.014
Male	94,491	261 (69)	2.8	
Female	55,494	117 (31)	2.1	
Total	149,985	378	2.5	
State				0.000
Banadir	66,914	16 (4.2)	0.2	
Galmudug	17,144	160 (42.3)	9.3	
Jubaland	15,538	37 (9.8)	2.4	
South West State	14,165	1 (0.3)	0.1	
Hirshabelle	17,013	1 (0.3)	0.1	
Puntland	19,211	163 (43.1)	8.5	
Occupation				0.000
Health worker	49,495	110 (29.1)	2.2	
Municipality worker	29,997	82 (21.7)	2.7	
Teacher	26,997	95 (25.1)	3.5	
Police	23,998	82 (21.7)	3.4	
Point of entry staff	19,498	9 (2.3)	0.5	
Age (years)				0.001
Median (IQR)	40 (29.5-50.5)			
20-29	35,796	61 (16.1)	1.7	
30-39	34,498	102 (27)	3.0	
40-49	22,697	88 (23.3)	3.9	
50-59	34,496	74 (19.58)	2.1	
>60	22,498	53 (14.2%	2.4	
Settlement				0.000
Urban	138,736	334 (88.3)	2.4	
Rural	8,934	10 (2.6)	1.1	
IDP	1,054	20 (5.3)	19.0	
Nomadic	926	6 (1.6)	6.5	
Refugee	335	8 (2.1)	23.9	

IDP, internally displaced population; IQR, interquartile range.
[a] *t*-test for continuous variables and Chi-squared test for binary/categorical variables.

Table 2
Distribution of adverse events following immunization (AEFIs) self-reported by vaccine recipients

AEFIs	Group A (*n*=180) Frequency	% (95% CI)	Group B (*n*=198) Frequency	% (95% CI)
Difficulty breathing	0	0	171	86.4(81.1–90.6)
Diarrhoea	1	0.6 (0.1–2.6)	175	88.4 (83.4–92.3)
Fever	16	8.9 (5.4–13.7)	183	92.4 (88.1–95.5)
Injection site swelling	12	6.7 (3.7–11.0)	186	93.9 (90.0–96.6)
Loss of taste	0	0	176	88.9 (84.9–92.7)
Nausea	3	1.7 (0.5–4.4)	177	89.4 (84.5–93.1)
Other symptoms	148	82.2 (76.1–87.3)	172	86.9 (81.6–91.0)

Group A, reported one symptom; Group B, reported more than one symptom; CI, confidence interval.

40 years (IQR 29.5-50.5), while in Togo, the median age of the study population was 32 years (IQR 27–40) (Konu et al., 2021) and the odds of experiencing side effects following vaccination against COVID-19 in Togo were higher in a younger age group. Nevertheless, although only 14% of the present study population was aged >60 years, the percentage of people experiencing side effects in this age group was the highest seen in this study (69.6%). No life-threatening symptoms or death were reported in the present study.

The finding that police and teachers were more likely to experience acute and severe side effects compared with other occupational groups was unique; to the authors' knowledge, no other contemporary studies from Africa have looked at this association among frontline workers following vaccination against COVID-19. Most of the study participants came from urban settings (88.4%), but the majority of side effects were seen among rural populations; this remains unexplained.

In light of the rumours and uncertainty surrounding the long-term consequences of COVID-19 vaccines, many people were reluctant to be vaccinated. This study focused on the identification of all self-reported side effects among Somali vaccine recipients using clear and transparent communication strategies. The study findings can be disseminated to the general population to alleviate their concerns and drive optimal vaccine uptake.

The rollout of any new vaccine requires a robust pharmacovigilance system and post-licensure surveillance that allows real-time information sharing. This study should pave the way towards establishing a surveillance and monitoring system for AEFIs in Somalia using either sentinel surveillance or e-health platforms. As Somalia does not have a pharmacovigilance surveillance system for any type of vaccine at present, this experience can be useful to build and develop a sustainable AEFI surveillance system, not only for COVID-19 vaccines but for childhood

Table 3
Univariate and multivariate analysis of sociodemographic parameters/correlates associated with side effects following the first dose of the Covishield vaccine

Sociodemographic characteristics	Number and percent of vaccine recipients reporting side effects(*n*=378)	Had acute and severe complications/side effects (60.85%)	Bivariate analysis		Multivariate analysis	
			Unadjusted OR with 95% CI	*P*-value	Adjusted OR with 95% CI	*P*-value
Gender						
Female	261 (69%)	71.8%	0.00	0.004	0.00	0.002
Male	117 (31%)	55.9%	0.50 (0.31–0.80)		0.44 (0.26–0.73)	
Age (years)						
Mean = 42.99						
SD = 14.27						
Median = 40						
IQR = 29.5-50.5						
20–29	61 (16.1%)	60.7%	1.00 (Reference)	0.60	1.00 (reference)	0.46
30–39	102 (27.0%)	64.7%	1.19 (0.62–2.29)	0.89	1.30 (0.64–2.60)	0.58
40–49	88 (23.3%)	58.0%	0.89 (0.46–1.74)	0.35	0.82 (0.39–1.69)	0.34
50–59	74 (19.9%)	52.7%	0.72 (0.36–1.43)	0.99	0.69 (0.33–1.48)	0.34
>60 years	53 (14.0%)	69.6%	1.5 (0.69–3.29)		1.52 (0.64–3.62)	
Occupation						
Health worker	110 (20.1%)	57.3%	1.00 (Reference)		1.00	
Municipality and point of entry worker	91 (24.1%)	37.4%	0.45 (0.25–0.79)	0.005	0.53 (0.29–0.98)	0.042
Police	82 (21.7%)	86.6%	4.82 (2.30–10.08)	0.0001	5.99 (2.75–13.07)	0.001
Teacher	95 (25,1%)	60.8%	1.40 (0.80–2.50)	0.24	1.75 (0.95–3.20)	0.07
Area of residence						
Rural and other	44 (11.6%)	100%				
Urban	334 (88.4%)	55.7%				

CI, confidence interval; OR, odds ratio; SD, standard deviation; IQR, interquartile range.

vaccination programmes and any other new vaccines which could be introduced in the future.

Limitations of the study

The study had a few limitations. Side effects were self-reported by the vaccine recipients, and the events were not verified or investigated by any trained healthcare providers. As such, it is not possible to exclude selection bias due to the inherent limitations of studies based on self-reporting of events. The lack of follow-up on the duration of side effects meant that it was not possible to identify how long the side effects persisted post-vaccination, and whether the events were self-limiting or required medical intervention.

Conclusion

The Oxford/AstraZeneca COVID-19 (Covishield; ChAdOx1 nCoV-19) vaccine led to mild side effects in the vaccinated population in Somalia during the first phase of the COVID-19 vaccination programme. Nearly half of the vaccine recipients who reported side effects only reported one symptom, and more than half reported more than one symptom. Females, subjects aged >60 years, police and teachers were at higher odds of experiencing acute and severe side effects following vaccination against COVID-19 in Somalia. This study confirms that COVID-19 vaccines are safe, their benefits clearly outweigh any associated risk, and they should be rolled out rapidly in Somalia to help end the pandemic.

Conflict of interest statement

The authors declare that they have no known competing financial interests or personal relationships that could appear to influence the work reported in this paper.

Funding

None. Data analysis support was provided by the WHO Country Office, Somalia.

Ethical approval

This study obtained ethical clearance, and all ethical considerations were made before study commencement.

Box 1. Variables and definitions

Adverse event following immunization	Any untoward medical occurrence following immunization, which does not necessarily have a causal relationship with vaccine usage
Comorbidities	Chronic illnesses such as diabetes, asthma, hypertension, renal disease, liver disease and cancer
Other symptoms	For example, joint pain, malaise, headache, general body pain

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