Review Article

Preparedness in Combating the New COVID-19 Variant, Omicron in Saudi Arabia: A Review of Existing Strategies, Findings, and Implications for the Future

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ABSTRACT

The SARS-CoV-2 is mutating persistently with the newer variant, Omicron infecting many countries including Saudi Arabia. There are concerns regarding the efficacy of the existing treatment and vaccinations in this context. Although the Saudi ministry has issued selected exemptions, public awareness about the need for social distancing, masks, and personal hygiene is key to prevention. COVID-19 booster doses are freely available and easily accessible in Saudi Arabia, and the Ministry of Health (MOH) has underlined the importance of the booster dose vaccine to maintain active immune status in the Tawalkana App, the Saudi Arabian government's frontline application for managing and combating the pandemic. Moreover, their official website has established forty distinct guidelines for tackling COVID-19. The MOH of Saudi Arabia has also implemented an effective COVID-19 treatment protocol with strict governmental surveillance enabling them to be among the first to lift COVID-19 preventive measures and serve as a role model for others. Nevertheless, considering limited research data, further studies are necessary for the in-depth evaluation of new variants, including Omicron, and their potential implications.

Keywords: Coronavirus, COVID- 19, SARS-CoV-2, Omicron, Countermeasures, Outbreak, Pandemic, Preparedness, Response.

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INTRODUCTION

SARS-CoV-2 , a single-strand RNA virus that emerged in China, has now spread to 221 countries and has killed over six million people across the world and over 9000 in Saudi Arabia.[1,2] In addition to the public health crisis, the pandemic has significantly impacted the world economy, financial markets, education, travel, and transportation.[3] Despite nations implementing precautionary measures, including face masks, social distancing, quarantine, and curfews, the evolution of newer variants by continuous mutation proceeds to confront all.[4] Among the multiple variants of SARS-CoV-2, a few are listed as variants of concern, because of their public health impact from either high transmissibility rates or compromised vaccine efficacy. So far, five mutants have been identified as variants of

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concern. The Alpha (B.1.1.7 Lineage) variant, identified in September 2020 in the United Kingdom caused a fast-growing outbreak and increased active cases by four-fold within a few months.[5] The Beta (B.1.351 Lineage) sub-type of SARS CoV-2 that emerged in South Africa towards the end of 2020 exacerbated the crisis. The World Health Organization (WHO) declared, the beta variant to be strongly associated with greater transmissibility, increased hospitalization, and mortality.[6] Subsequently, the Gamma (P.1 Lineage or B.1.1.28.1) variant sprouted in Brazil and caused massive hospitalization despite immunization.[7] The most dominant Delta (B.1.617.2 Lineage) variant detected in India was more infectious than previous variants, devastating the subcontinent and in the United States. Furthermore, the newer concern, the Omicron variant (B.1.1.529) from South Africa marks an epidemiological shift in COVID-19 spread.[8] The evolution of COVID-19 needs to be studied extensively to ensure that newer variants would not compromise prevailing preventive strategies and enable early detection of possible future variants of concern. This narrative review aims to comprehensively understand how the Kingdom of Saudi Arabia (KSA) combatted the COVID-19 variant, Omicron, and visualizes their preventive measures through augmented public awareness and massive nationwide vaccination programs.

CHARACTERISTICS OF OMICRON VARIANT

In the course of a flurry of mutations that followed the first reported case of the SARS-CoV-2 genome, its Receptor Binding Domain (RBD) has undergone more than 150 structural changes. Although most of the mutated strains were less virulent, the L452R, T478K, E484K, E484Q, and N501Y strains were highly transmissible. Moreover, the delta variant with RBD mutation has shocked the world with conspicuous symptoms and mortality. Moreover, the transformed SARS-CoV-2 has a double mutation and is expected to aggravate the global catastrophe. Omicron, the new variant, struck when the world was just recovering. It carries many novel mutations in structural and non-structural proteins, out of the 32 mutations which have reported in the viral spike protein, 15 are in the RBD, which in turn leads to serious concerns over increased transmissibility, vaccine failure and immune escape.[9] The multiple mutations in the spike protein are associated with increased antibody evasion and infectivity. Studies have been reported the ability of omicron to infect triple-vaccinated individuals.[10]

TRANSMISSIBILITY AND SEVERITY

Studies from South Africa indicated the infection reached 90 % within a month of Omicron's arrival, while previous variants were less prone. The higher affinity of Omicron towards Angiotensin-Converting Enzyme-2 receptors and greater potential for transmission had further intensified the spread leading to the rise in prevalence throughout UK and gulf countries.[11,12] WHO is still uncertain about Omicron's transmissibility and infection severity compared to other variants.[13] The massive surge of COVID-19 in many countries is possibly the result of the BA.2 subvariant of Omicron, also defined as stealth Omicron.[14] Although Omicron symptoms are less intense than the delta variant, it cannot be labeled as 'Mild'.[15] Meanwhile, the five prominent symptoms were similar to those imparted by other SARS-CoV-2 mutants (i.e., runny nose, headache, fatigue, sneezing, and sore throat), making it challenging to identify Delta from Omicron without laboratory confirmation.[16] The Polymerase chase reaction (PCR) can confirm the variant, whereas the antigen test would not produce accurate results.[17] Nevertheless, the fact that all strains of COVID-19, including Delta, do persist worldwide and should not be forgotten owing to its potential for exacerbating complications and mortality. In this context, prevention is the best option in the face of the pandemic and suboptimal treatment.[13] However, more data are required concerning Omicron, especially with regards to its re-infection potential and breakthrough infections of fully vaccinated people.[18]

Vaccine effectiveness against Omicron

Most vaccines act on the spike protein of SARS-CoV-2; concerns on "How well each vaccine can shield the new variant?" generate a public health dilemma.[19] Few post-vaccination infections were reported, but were not severe, as claimed by Paudel *et al*., had aggravated the apprehension.[20] Lesser effectiveness of the vaccine during the Omicron era and such or more intensive decline may occur in the future that require early detection and rectification. However, the preliminary laboratory data showed that the booster dose following the double doses of the COVID-19 vaccine would neutralize the Omicron variant better than the two-dose regimen. Because the SARS-CoV-2 evolution has not simulated 80% of epitopes in the spike protein identified by CD8+ T-cells in the Omicron variant, led to the availability of booster dose during March 2022.[21] Moreover, Johnson Johnson from the South African Phase 3b Sisonke study demonstrated the booster dose of the Ad26.COV2.S vaccine prevented 85% of victims from COVID-19-related complications.[22] Meanwhile,

the United States medical wing recommends vaccination to all above 5 years of age and booster doses for those above 16 years old who completed 2 months after the Janssen shot or 6 months after Pfizer or Moderna's 2nd shot.[23] Thus, getting a booster dose would shield people from Omicron and other variants. However, vaccine hesitancy is a prime obstacle. Research at the molecular level alone won't do. People's views should also be reviewed. Negative attitudes or misleading statements towards immunization need immediate correction.

COVID-19 SPREAD AND VACCINATION STATUS IN SAUDI ARABIA

KSA, the largest middle east country, witnessed 78,7212 confirmed cases of COVID-19 by 23rd June 2022, with 9191 deaths.[2] The Saudi Food and Drug Authority (SFDA) authorized the first COVID-19 vaccine Pfizer/BioNTech on December 10, 2020, for limited populations, i.e., frontline healthcare workers and the elderly. In December 2020, KSA launched the vaccination program as a discretionary service to all citizens, residents, and eligible persons, including ex-pats. Within 48 hr of submitting an application through the government portal Sehhaty, one can get vaccinated for free at the nearest location. Likewise, vaccinated individuals receive a notification on the next dose schedule.[24] The government ruled that only those vaccinated and verified by the Tawakkalna mobile application could host or participate in all commercial, economic, cultural, and entertainment programs. In December 2021, the Ministry of Health, Saudi Arabia, announced the eligibility for booster doses to be three months after their second dose, underlining the essentiality of the next shot from the beginning of February 2022. The Tawakkalna update would grant "immune" status only to the vaccinated, demonstrating Saudi Arabia's rigor in enforcing the vaccine mandate. 65,837,671 vaccine doses have been administered until 14th June 2022, constituting 40.4% of the population with at least a dose and 37.9% completely immunized.[2] However, a study conducted in Saudi Arabia by Temsah *et al*. found that only 1/3rd believed the vaccines would be an effective prophylactic solution.

TREATMENT FOR SARS COV-2 (B.1.1.529/ OMICRON VARIANT)

From the beginning of the COVID-19 era, it was established that asymptomatic patients with confirmed COVID-19 infection do not need treatment. Instead, their symptoms should be monitored for worsening, requires nutritional supplements, and ensured isolation from the public.[25] Meanwhile, healthcare providers and family members should care for the patient's mental and physical well-being. However, to ensure optimal treatment for those with symptoms in COVID-19 patients, the KSA's MOH has updated COVID-19 treatment guidelines and recommendations that are readily accessible through their official online portal. These guidelines were streamlined with scientific and evidence-based COVID-19 data. Moreover, the healthcare providers are also served with adequate training manuals (around forty are currently available) and instructions, retrievable from the ministry website (Figure 1).

When we analyzed the COVID-19 treatment protocol, it was observed that those patients with mild to moderate symptoms that do not require oxygenation are recommended inhaled budesonide with new onset of cough and fever, anosmia, or both.[26] The high-risk and non-hospitalized patients above 12 years could be on a single dose of intravenous Sotrovimab.[27] *In vitro* studies have shown it's effectiveness against the Omicron variant. The US Food and Drug Administration recently issued emergency use authorization for two new oral antivirals, i.e. Ritonavir boosted Nirmatrelvir and Molnupiravir for treating mild to moderate COVID-19 infection which has a high risk of progression to severe illness (without hospitalization). Nirmaltrelvir is a protease inhibitor that blocks viral replication [28,29] and Ritonavir is a pharmacokinetic enhancer that inhibits the CYP3A-mediated metabolism of Nirmaltrelvir thereby increasing it's plasma concentration. While, Molnupiravir is a prodrug with potent antiviral activity against SARS Cov-2, upon metabolism enters the virus and cumulatively adds errors in the viral genome and eventually inhibits viral replication.[30] This was also included in the latest COVID-19 treatment protocol by the Saudi Ministry of Health (Version 3.4, Jan 6th 2022). Also, Remdesivir that was widely utilized for COVID-19 confined to other variants is also effective against Omicron.[31]

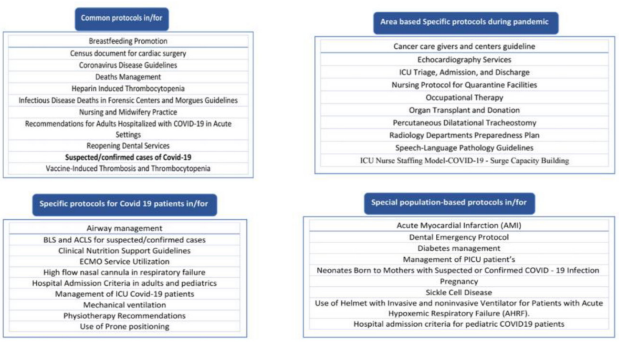

Figure 1: Different categories of COVID-19 guidelines published by the Saudi Ministry of Health.

The WHO recommends corticosteroid and Interleukin-6 inhibitors to critical and severe COVID-19 patients infected with Omicron. It was Toda *et al.* who suggested pulse steroid therapy in such patients and those on hemodialysis.[32,33] Moreover, Remdisivir can be added along with steroid or Baricitinib when corticosteroids are contraindicated. The susceptibility to drug interactions, the need for dose modifications in hepatic and renal impairment, and their potential to induce serious infections, malignancies, and thrombosis can restrict the use of Baricitnib. On the other hand, a combination of Tocilizumab with Dexamethasone is suitable for those who are liable to rapid respiratory decompensation.

Tocilizumab is in the KSA's MOH formulary but is not indicated for COVID-19 because many randomized clinical trials did not affirm it's efficacy and hence considered off-label. However, Mady *et al.* 's study in KSA claimed that Tocilizumab could free severely ill patients from ventilation within 28 days.[34] Even though Remdesivir has been found safe with good clinical outcomes, it is not currently used in Saudi Arabia. Similarly, Favipiravir has appreciable viral clearance and the potential to minimize hospitalization in mild to moderate COVID-19.[35] Nevertheless ,its low benefits in severe circumstances caught the Favipiravir to be off SFDA's list to treat COVID-19.[36] However, the exclusions of these drugs would require further research in the context of the emergence of new variants.

HOW TO COUNTER DIFFERENT STRAINS WITH MONOCLONAL ANTIBODY

International travel has led to the mix-up of SARS-CoV-2 strains and necessitated the best treatment protocol to counter the latest strain. In these circumstances, the Monoclonal antibodies are recommended and proved effective for those with comorbidities such as chronic liver, kidney, respiratory and cardiac diseases, immunocompromising conditions, Diabetes Mellitus, Malignancies, and those with comorbidities such as chronic liver, kidney, respiratory and cardiac body mass index $\geq 35 Kg/m^2$ and age $\geq$ 65 years.[37] Table 1 shows the key points on the currently available monoclonal antibodies for various strains of SARS-CoV-2.

Laboratory studies depicted reduced susceptibility of the authorized monoclonal antibodies for countering the Omicron variant. Numerous mutations in the spike protein of the Omicron is predicted to have diminished the activity of Balmanivimab plus Etesevimab and Caserivimab plus Indevimab in the new era.[38] However, Sotrovimab has retained its effectiveness and gained provisional marketing authorization in KSA.[39] Convalescent sera also have severely reduced neutralizing efficiency against the Omicron variant, while Tixagevimab and Cilagavimab administration is favorable. However, Tixagevimab with Cilgavimab is not registered under SFDA owing to risk in patients with thrombocytopenia or blood disorders. Moreover, this

Table 1: Monoclonal antibody treatment approach for various strains of SARS-CoV-2.

Variant of concern	Effectiveness of Current treatment
Alpha (~50% increased transmission)	Balmanivimab plus Etesevimab is effective. Caserivimab plus Indevimab is effective. Sotrovimab is active against the variant. Minimum effect of neutralizing by convalescent and post-vaccination sera.
Beta (~50% increased transmission)	Balmanivimab plus Etesevimab is unlikely to be effective. Caserivimab plus Indevimab is effective. Sotrovimab is effective. Moderately reduced neutralization by convalescent and post-vaccination sera.
Gamma	Balmanivimab plus Etesevimab is unlikely to be effective. Caserivimab plus Indevimab is effective. Sotrovimab is effective. Reduction in neutralization by convalescent and post-vaccination sera.
Delta	Increased transmission when compared to the Alpha variant. Minimal reduction in neutralization by monoclonal antibodies. Potent/moderate decrease in vaccine effectiveness against mild to moderate COVID-19(without impact on the severe disease).
Omicron	Preliminary data shows: Replication advantage over delta variant. Balmanivimab plus Etesevimab is unlikely to be effective. Caserivimab plus Indevimab is unlikely to be effective. Sotrovimab is effective. Significant reduction in vaccine effectiveness. A booster dose is likely to give higher protection against mild to severe disease.

combination has a high probability of cardiovascular severe events, especially myocardial infarction there.

SAUDI ARABIA'S STRATEGICAL APPROACH AGAINST COVID-19 CRISIS

Currently, Saudi Arabia is positioned 75th in the table of global COVID-19 cases.[40] The preparedness and quick response to counter the pandemic crisis has made the country remarkable. This was accomplished through the collaborative work of many disciplines with defined roles and responsibilities. The country-level planning, administration, and monitoring by a national emergency response committee, chaired by the Minister of Health has the credit for the outcome. Moreover, the National Command and Control Center, Ministry of Health, was initiated to keep track of the global and KSA's local operations confined to COVID19 and suggest remedies. In response to the pandemic, the digital health surveillance network by the Ministry of Health was also proven to be an effective solution. The development of a comprehensive and easily accessible database to a single server aided in overcoming the hurdles towards linking various healthcare sectors within the nation. There was effective utilization of systematic scientific tools for hosting mass gatherings placing the country high in controlling the pandemic. Moreover, the Ministry of Health provides regular, updated, reliable information for the people regarding procedures and plans with regard to COVID-19 in the country. This has controlled the risks of rumors and misinformation in the community.

OMICRON PREVENTIVE MEASURES

The outbreak of Omicron persuaded the Ministry of Interior, Saudi Arabia, to focus on preventive measures such as wearing masks (in open and closed spaces) and social distancing, in all places, including the two Holy Mosques, from 7 AM to 30 December 2021.[41] The Public Health Authority (Weqaya) updated health protocols for commercial centers, markets, restaurants, and malls. Individual violators were liable to pay a penalty of a minimum of 1000 SAR, which will be doubled on repeating the offense, up to 100,000 SAR.[42] This proactive step effectively restricted the COVID-19 spread, including new variants of Omicron, reported to be more contagious than its predecessors. The impact of these strategies is now evident in the country. Government authorities also recommend avoiding unnecessary travel inside and outside Saudi Arabia.[43] Moreover, Weqaya also insisted that outside travelers avoid social contact for five days and undergo a PCR test if they suffer from any respiratory symptoms, regardless of their immune status. The booster shot was mandatory for all residents and citizens (above 18 years) to enter shopping malls, restaurants, and public places. As public awareness about COVID-19 improved over the last year, controlling the spread of COVID-19 in the pandemic was eased. If cases rise exponentially, border measures and travel restrictions may be reimposed. A country-wide strategic plan needs to be implemented along with existing preparedness and coordination programs. Furthermore, highlighting the importance of public health measures against COVID-19 and canceling or controlling public events/mass gatherings are being considered to counteract the omicron spread. The KSA successfully minimized the restrictions of the COVID-19 pandemic and later lifted all COVID-19 preventive measures, including using a facemask and gathering minor exceptions in sensitive areas such as healthcare premises.[44]

CONCLUSION

As the spike proteins of SARS-CoV-2 mutate continuously, experts caution us about the possibility of multiple variants shortly. The severity and spread may not be predicted accurately at this point. Therefore, it is essential to enhance public awareness about COVID-19, the importance of vaccination and booster doses to maintain immunity levels, and the need to avoid unnecessary travel and public gatherings. Rigorous implementation of proper protocol and strict governmental surveillance has helped Saudi Arabia to be among the first countries to lift all the COVID-19 restrictions and serve as a role model. However, treatment protocols need to be updated periodically because existing treatment options may not be effective against new variants. For example, monoclonal antibodies were considered the mainstay for delta variants, but CDC has warned that they are less effective against the Omicron variant. Likewise, the effectiveness of existing vaccinations against Omicron is debatable too. Continuous research is needed to update the status of existing remedies for new variants.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ACLS: Advanced cardiac life support; **AHRF:** Acute hypoxemic respiratory failure; **AM:** Ante meridiem (before noon); **BLS:** Basic life support; **CDC:** Centers for disease control and prevention; **COVID-19:** Coronavirus disease 2019; **ECMO:** Extracorporeal membrane oxygenation; **ICU:** Intensive care unit; **KSA:** Kingdom of Saudi Arabia; **MOH:** Ministry of health; **PICU:** Pediatric intensive care unit; **RBD:** Receptor binding domain; **SAR:** Saudi Arabian riyal; **SARS-COV-2:** Severe acute respiratory syndrome coronavirus 2; **SFDA:** Saudi food and drug authority; **WHO:** World health organization.

SUMMARY

- Since the inception COVID-19 in China, 221 countries were affected and more than 6 million people were killed across the globe including Saudi Arabia.
- Although vaccines are effective against spreading the COVID-19, many countries unable to vaccinate the citizens due to varying reasons. However, Saudi Arabia managed the spreading of COVID-19 to some extend by implementing strict preventive measures including penalty to the violators.
- Saudi Arabia followed a strategical approach against COVID-19 crisis by incorporating WHO protocol and CDC measures. Moreover, MOH provides regular, updated information about the preventive strategies against COVID-19.
- Public awareness about new variants of SARS-CoV-2 including Omicron have been implemented through government authorized websites and by sending personal messages to individual residents. A country-wide approach was followed to control the spread of new variants in Saudi Arabia.

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