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Implementation of Covid 19 vaccine: Acceptance, Success and Challenges: Prospective observational design from tertiary referral hospital, Kerala, India

Ardra Rose Thomas[1], Aysha Nesni[1], Raseel Omar Ahmed[1], Shahir Ahmed, K.V. Ahamedunni[1], Dilip Chandrasekhar*[1], Mohammed Salim KT[1], Linu Mohan Panakkal[1], Shinu Cholamugath[1]

Department of Pharmacy Practice, Al Shifa College of Pharmacy, Perinthalmanna, Kerala, India .

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***Corresponding author:**

Email : dilipc@alshifacollegeofpharmacy.ac.in

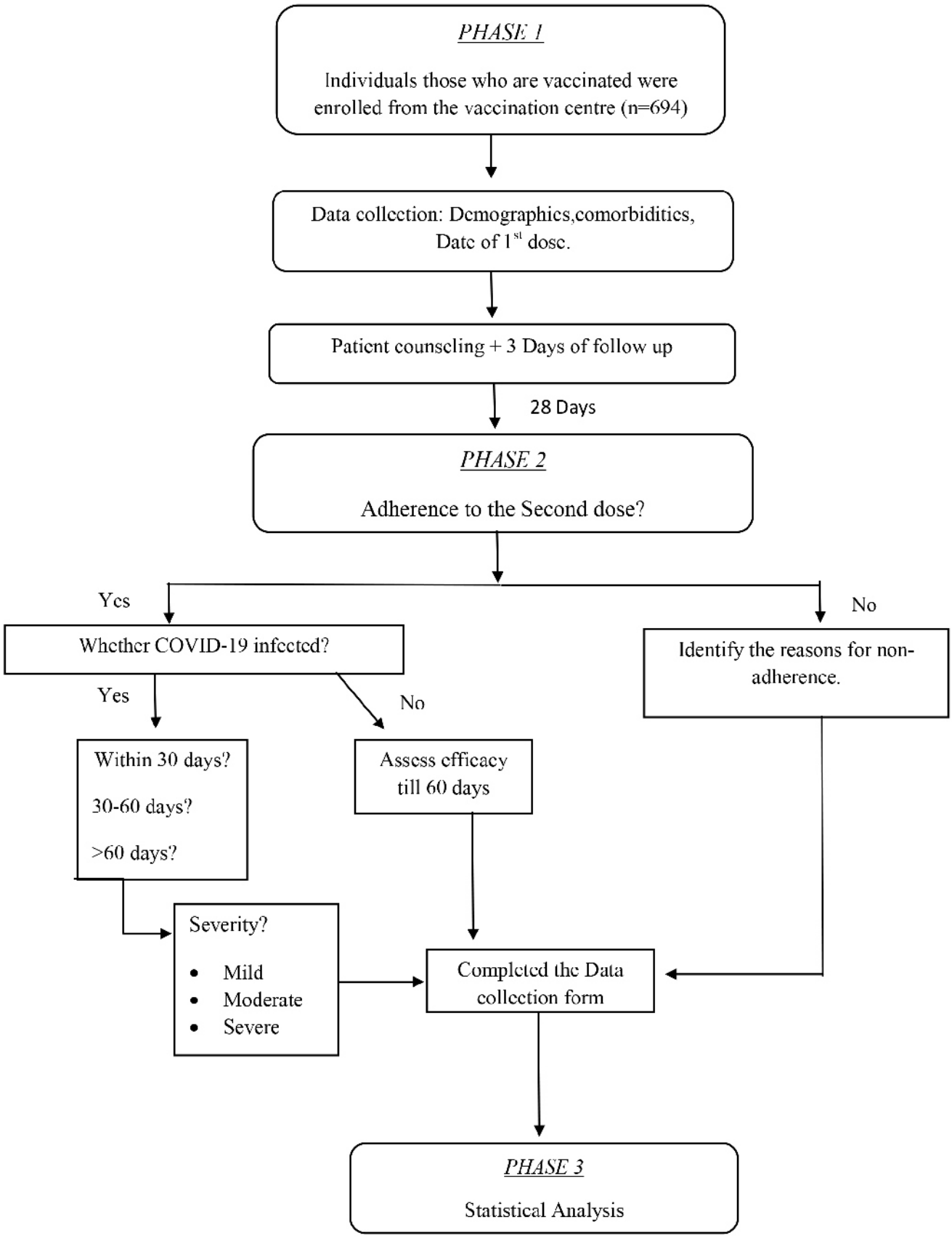
ABSTRACT

To assess the adherence to the second dose of ChAdOx1 nCov-19 vaccine (Covishield) among the registered beneficiaries during Phase 1 of vaccination, to determine its efficacy as to the incidence of infection post vaccination and to evaluate the severity of the infection and its association with the onset time of infection. A prospective single centered observational design was conducted 5 months among the healthcare providers and front line workers registered for vaccination. All the partially vaccinated participants were provided counseling for their second dose, and follow up was done on the due date and 60 days post vaccination to assess their compliance towards next shot and occurrence of COVID 19 infection correspondingly. Out of total 694 participants enrolled in the study, majority of participants (n= 425, 61.2 %) fall into 18-45 category followed by 45-59 category (n= 217, 31.2 %).Female participants were predominant (n= 404, 58.2%) over males (n= 290, 41.8%). Participants with normal exposure (n =338, 48%) were more than close contacts to susceptible individuals (n=325, 46.8%).Greater number of participants (n= 686, 98.8%) adhered to second dose on time according to the guidelines and as per instructed compared to those showed non adherence (n=8, 1.2%).11 (1.6 %) stated confirmation for COVID 19 infection while majority of participants' (n= 683, 98.4%) reported neither infection nor symptoms on follow up. Assessment of severity of symptoms among the infected participants revealed that considerable portion had moderate symptoms (n=6, 1.5%) of infection while 4 (0.6%) had mild symptoms. Implementation of COVID 19 vaccination opens a new window for the development of herd community. A coordinated and harmonized mass vaccination program elevates the development of a complete herd community.

INTRODUCTION

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered severe acute respiratory syndrome corona virus-2 (SARS-CoV-2), spread rapidly worldwide. In March 2020, the World Health Organization (WHO) announced the COVID-19 outbreak as pandemic that has severely ravaged health systems, the economy and society [1].The development of safe and effective vaccines has been widely considered an essential tool to control any pandemic. Vaccine efficacy encompasses both transmission effects i.e., the ability of the vaccine to prevent the spread of SARS-CoV2 from an infected person to a susceptible person and disease-modifying effects i.e., the ability of the vaccine to slow or prevent progression of illness, to speed recovery, to decrease the use of critical care resources, or to reduce mortality among people who have been vaccinated but who nonetheless becomes infected [2].Vaccine efficacy can be determined in different ways depending upon the mechanism it employs. The preventive vaccines decrease susceptibility towards infection, while the disease-modifying ones improve the disease progression among infected, decrease transmission and help in reducing mortality. A

OUTLINE OF THE STUDY



broader category of vaccines comprises of the two groups, called the composite vaccine [2].Generally, vaccine development takes around 10-15 years, much similar to the process of drug development. Assessment of safety and efficacy of the vaccine is initiated within animal models and then trials are conducted in humans as phases 1-3 followed by post marketing studies. However, considering the on-going contagious virus pandemic and increased mortality unprecedented number of COVID 19 vaccines have been developed and deployed at a speed never before.[3] As of February 2021,at least seventeen vaccines were available for human population. Two vaccines were initially available in India in the best interest of WHO for a disease-free population, namely Covishield and Covaxin. Covisheild was developed by AstraZeneca in collaboration with serum institute Pune, a viral vector vaccine that makes use of a harmless virus carrying a foreign gene representing the antigen of interest and thus incorporates into the host cell. Covaxin, India's first indigenous live attenuated vaccine contains less infective but live form of the virus. They possess all the components of their original pathogen and are evolved not to replicate and cause natural infection. Both the vaccines are administered as two shots at defined time intervals recommended by authorized centers.

The CDC has recommended vaccinating the high-risk population first and a priority list was phased out accordingly in different countries. The government of India categorized the vaccination priority group based on the potential availability of vaccines and risk to infection[1]. The first group included health care providers and frontline workers as they are more susceptible to the prevailing disease and give way for transmission. Moreover, their voluntary attitude towards inoculation could make a difference to the common man's preconceived notion on controversial effects of vaccine. And hence the second group to be vaccinated was people over 60 years of age and persons above 45 years with comorbid conditions. Accelerated vaccine development on COVID 19 necessitates the need to overcome vaccine hesitancy and counter the populations' stigma and misconceptions. Or instead, the general public could be expecting striking reductions in COVID-19 transmission after mass vaccination. A vaccine that mitigates the disease but does not prevent infection may be baffling, making things worse. Immunization programs can be considered successful once if they meet high rates of acceptance and coverage. In view of the continuing painful toll of havoc in the Indian population with the arrival of the new double mutant strain, B.1.617.2, the super spreader, and its intensity, the effect of vaccines over participants warrants research. We had investigated the adherence of participants to the second dose of Covishield vaccine and its efficacy on transmission and prevention of infection that could aid future references.

METHODOLOGY

The mass vaccination drive on COVID 19 initiated on January 16th 2021 in India marked a milestone achievement in medical history. The study aims to evaluate the adherence to 2 doses of Covishield vaccine on participants registered for vaccination using the Government authorized online platform “CoWin portal” or www.cowin.gov.in/ .and the follow up of 60 days designed post vaccination intends to evaluate the effectiveness of Covishield vaccine in reducing hospitalizations from the COVID-19 infection in the Malabar region of Kerala.The prospective observational study was conducted at KIMS Al Shifa Super Specialty Hospital, Perinthalmanna, Malappuram, a well-established vaccination center authorized by the Government of Kerala. Al Shifa College of Pharmacy, a sister institution of the hospital, being recognized as the Adverse drug reaction Monitoring Centre with an Indian Pharmacopeia commission assigned pharmacovigilance associate, collaboratively collected participants' data for a period of 4 months (from 16th January 2021 to May 2021). The inclusion as well as exclusion criteria, were outlined as per the vaccination roll-out phase published in ICMR guidelines due to lack of supportive studies. The study included all registered health care workers and frontline workers partially vaccinated i.e. participants who completed their first dose of vaccine from phase 1.While pregnant as well as lactating and those who had an anaphylactic reaction to any form of injectable, pharmaceutical products or even to first dose of the vaccine was excluded from the study. The detailed study protocol was presented to the Institution's Ethics committee and approval was obtained for initiating the study as per KAS: ADM: IEC: 0203: 21.Literatures pertaining to the study were gathered and reliable data were taken into account for the constructing an appropriate data collection form and a questionnaire was designed for an aggregating response from the participants after vaccination. These tools were verified and validated by a working panel of experts, including the Vaccination Nodal Officer, Pharmacy practice faculty, and finally bythe IEC. The demographics, comorbidities and exposure status of the participants enrolled in the study was filled and documented into the data collection form befor vaccination. The information on the second dose and its immune response and proper use of masks and social distancing were well communicated to the participants through direct patient counseling. Consequent AEFI's for the first and second dose were also reported through follow up.The success of the COVID-19 vaccine and its effective were evaluated based on 2 parameters: Participant's adherence to the second dose of vaccine and Coverage of vaccine i.e., prevention of COVID-19. The due dates of all participants' second dose as recommended by the guidelines were informed and reasons for non-compliance were noted, during follow up on the participant's vaccine scheduled date. The vaccine coverage was assessed by obtaining their feedback through telephonic conversation after 60 days from their second dose of vaccinations so that the subjects gain enough immune response to evaluate for further infections.[1] The incidence of infection since completely vaccinated and the severity were also noted to find any associations. And thereby, challenges involved in the implementation of vaccine were analyzed from the period of immunization.

Statistical Analysis:

The sample size required for the estimation of prevalence of COVID-19 incidence after vaccination was computed as 694. The data analyses of all subjects were performed using the SPSS version 26 and the information collected was summarized by using the frequency and percentage. The Inferential Statistics such as Chi square test, Likelihood Ratio test was used to find the association between the variables. The p value < 0.05 was considered as significant.

RESULTS

The prospective observational study on the adherence and coverage of vaccine conducted for 4 months enrolled a total of 694 subjects during the first phase of vaccination. Demographic details such as age, gender, comorbidities of the subjects are as given in *Table 1*. Majority of participants (n= 425, 61.2 %) fall into 18-45 category followed by 45-59 category (n= 217, 31.2 %).

Table 1 : Patient Demographics (Age, Gender and Co morbidities)

Total subjects (n= 694)		Frequency	%
Age	18-45	425	61.2
	45-59	217	31.2
	60 & above	52	7.64
Gender	Male	290	41.8
	Female	404	58.2
Co morbidities	Yes	104	15
	No	590	85

Table 2 : Reasons for non-adherence to second dose of vaccine

(n = 694)		Frequency	%
Adherence to second dose on time according to guidelines	Yes	686	98.8
	No	8	1.2
Reason for non -adherence	Allergic	1	0.14
	COVID positive on second dose	1	0.14
	Disease on second dose	2	0.29
	Inadequate information	2	0.29
	Out of town	2	0.29

Table 3 : Reasons for COVID 19 Testing

(n == 694)		Frequency	%
Reason for COVID 19 testing	Hospital safety rules	2	0.3
	Asymptomatic primary contacts	8	1.2
	Symptomatic unknown exposure	5	0.7
	Travel purposes	2	0.2

Least participants (n=52, 7.64%) belonged to 60 and above *(Table 1).*Female participants were predominant (n= 404, 58.2%) over males (n= 290, 41.8%). Only a minimal fraction of subjects vaccinated were presented with comorbidities (n=103, 15%).*(Table 1).* Health care providers constituting to different occupational realms were included during the study period whose exposure status to COVID 19 infection and degree of transmission varied accordingly. Participants with normal exposure(n =338, 48%) were more than close contacts to susceptible individuals (n=325, 46.8%).Healthy volunteers with no risk of infection constituted a lower proportion (n= 32, 4.6%), while those recovered from COVID 19 was the least among the vaccinated (n=4,0.6%) *(Figure 1).* Among the infected individuals who had convalesced, the results disclosed that there were more number of infected subjects (n =3, 0.4%) who had recovered from COVID19 above 3 months compared to the incidence of infection before 2 months before vaccination (n =1,0.1%)(Figure 2).Out of total vaccinated participants followed up after 60 days, 17 subjects had done COVID 19 test based on several grounds that mandated it. Asymptomatic primary contacts to susceptible infection (n =8 1.2%) was the major cause that led to testing followed by participants manifested with symptoms with unknown exposure (n=5, 0.7%). Subsequently few participants(n=2, 0.2%) were enforced for testing as a part of hospital safety rules and travel purposes (*Table 3).* A greater number of participants (n= 686, 98.8%) adhered to the second dose on time according to the guidelines and as per instructed compared to those who showed non adherence (n=8, 1.2%).The reasons for non-adherence among those partially vaccinated inferred that subjects were either diseased or out of town(n=2,0.29%) on the date of second dose while subjects who received inadequate information (n=2, 0.29%) regarding next jab. Allergic participants to the first dose and COVID 19 infected contributed similar and lower rates(n=1, 0.14 %) to non-

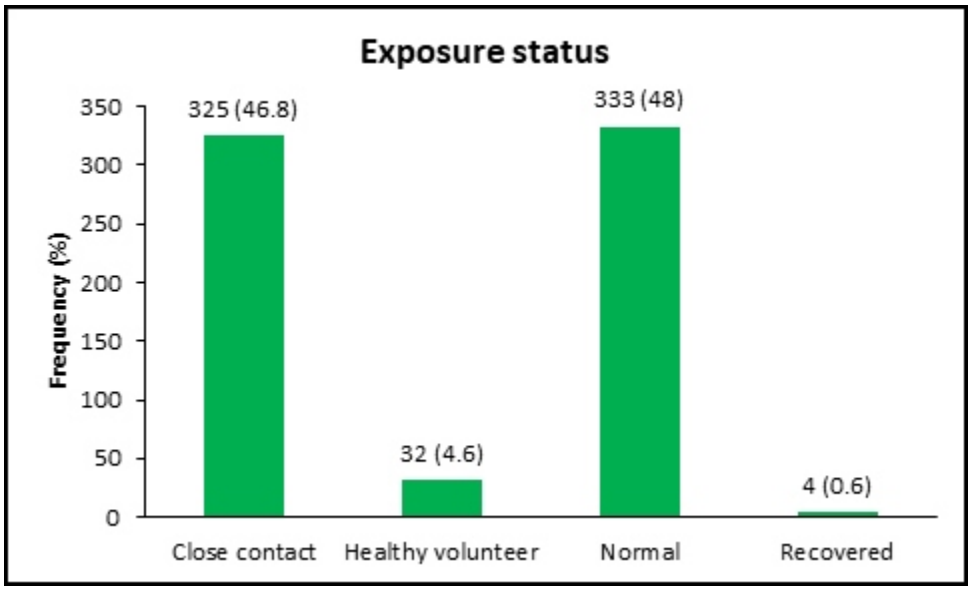


Fig 1: Distribution of exposure status to COVID19

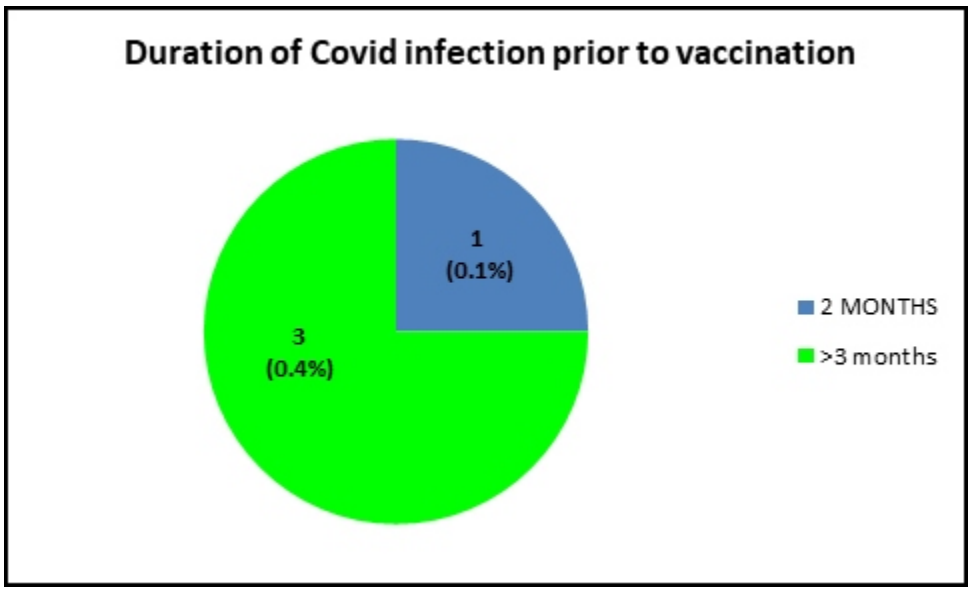


Fig 2: Duration of COVID 19 infection prior to vaccination

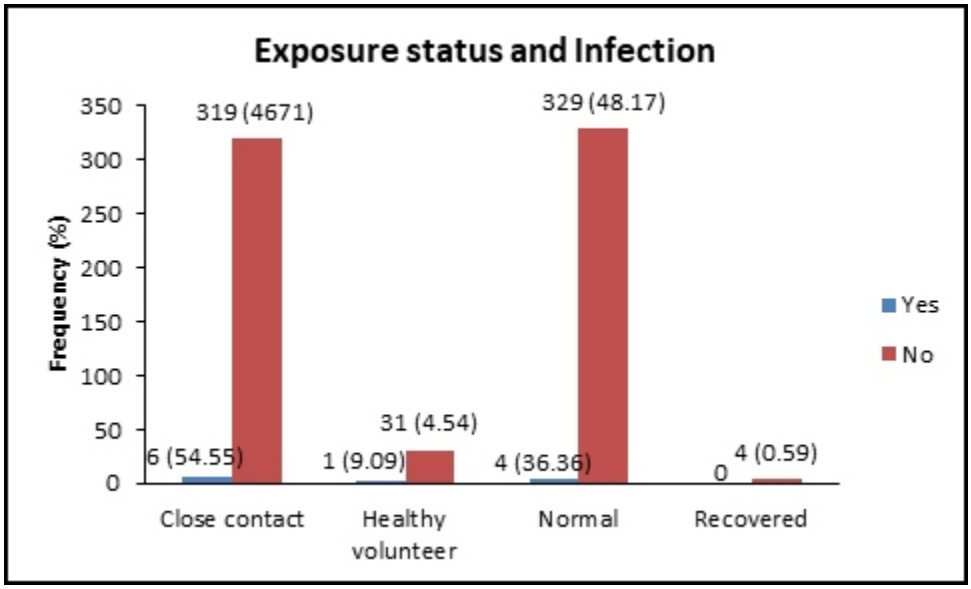


Fig 3: Association between exposure status and Infection

Table 4 : COVID 19 Incidence after vaccination and onset of infection

(n = 694)		Frequency	%
Incidence of COVID 19	Yes	11	1.6
	No	683	98.4
Duration between vaccination and incidence of infection	< 30 days	1	0.1
	30-60 days	9	1.13
	> 60 days	1	0.1

adherence*(Table 2)*.Out of 694 subjects who completed vaccination and 17 subjects tested, 11 (1.6 %) stated confirmation for COVID 19 infection while the majority of participants' (n= 683, 98.4%) reported neither infection nor symptoms on follow up (*Table 4)*.On evaluating the onset of infection post vaccination, the maximum number (n=9, 1.13%) of participants were infected within 45-60 days post vaccination, and only (n=1,0.1%) participant showed disease incidence within 30 days and after 60 days they completed their two shots *(Table 4)*.The severity of symptoms among the infected participants revealed that considerable portion had moderate symptoms (n=6, 1.5%) of infection while 4 (0.6%) had mild symptoms. Severe symptoms requiring hospitalization was manifested only in a (0.1%) patient.*(Table 5)*The Likelihood Ratio test was used to find the association between the incidence of infection and severity of COVID 19. The obtained p value was statistically significant (< 0.05) and hence there was an association between incidence of infection and severity of COVID 19*(Table 5).* After vaccination, the incidence of infection was seen maximum among the close and susceptible contacts (n=6, 54.55 %) to COVID 19 followed by workers who remain in normal exposure (n=4, 36.36%). Healthy volunteers with no risk of infection in the health care sector who reported infection included minimal count (n=1, 9.09 %) Since the p value obtained was above 0.05, there is no significant association between exposure status and infection.(*Figure 3).*

DISCUSSION

The ongoing global pandemic has instigated hasty and steadfast advancements, emergency use authorization, and synergistic efforts from various collaborators. Evenhanded access to safe and effective vaccines is crucial to curtailing down the positivity rate, and hence multiple vaccines have been manufactured and made available. Getting vaccinated provides protection, particularly for people at increased risk for severe illness from COVID-19.The demand for vaccinating the dense population in India has led to the in-house development of vaccines and paid distributions from international manufacturers. This single-centered prospective observational study on vaccines highlights the adherence and coverage of vaccine (Covisheild) among health care and frontline workers dealing with the disease in the Indian population. The age wise distribution of the study population is estimated and it showed that the majority were aged between 18-45 years (n=425, 61.2%) followed by the age group

Table 5 : Severity of COVID 19 among vaccinated and its association between incidence of infection (Likelihood ratio:116.304; p value <0.0001)

(n = 694)		Frequency	%
Severity of COVID19 among vaccinated	Mild	4	0.6
	Moderate	10	1.5
	severe	1	0.1

		Severity of COVID19							
		Mild		Moderate		Severe		Not COVID Positive	
		Frequency	%	Frequency	%	Frequency	%	Frequency	%
Incidence of infection	< 30 days	1	25	0	0	0	0	0	0
	30-60 days	3	75	5	83.33	1	100	0	0
	> 60 days	0	0	1	16.67	0	0	0	0
	No Infection	0	0	0	0	0	0	683	100

of 45-60 (n=217, 31.2%). Those aged above 60 years recruited the least (n=52, 7.64%). This was due to criteria released by government to vaccinate only the healthcare workers and front line workers, as a part of the phase 1 vaccination program in India. This was identical to the study conducted by MerrynVoysey, Sue Ann Costa Clemens et al. on the Safety and efficacy of ChAdOx1 nCOV19 vaccine (AZD1222) against SARS-COV-2 in Brazil, South Africa, and UK[4].Gender distribution shows females have the higher acceptance (n=404, 58.2%) than males (n= 290, 41.8%), as the majority of the female participants were nurses who opted for vaccination, as there were more exposed to the COVID 19 patients, this is comparable with the study conducted by Jeffrey V.Lazarus , Scott C.Ratzan in a global survey of potential acceptance of a COVID 19 vaccine[5]. Health care providers stating to different occupational realms were included during the study period and their exposure status to COVID 19 infection or transmission varied accordingly. Participants with normal exposure were maximum of 338 (48%) followed by close contacts to susceptible individuals 325 (46.8%) and healthy volunteering staff were 32 (4.6%). Only 4 participants (0.6%) recovered from COVID 19 infection were vaccinated. This can be compared with the study conducted by Rahul Shekhar, Abu Baker Sheikh et al in COVID 19 vaccine acceptance in healthcare workers of U.S[6]. Among the participants of the vaccination program, 104 (15%) of the beneficiaries were presented with comorbidities. Out of 4 health line workers 1(0.1%) had been infected 2 months prior to the date of vaccination which violates the recommendation by the Health ministry that COVID 19 patients will have to wait for three months after recovery to get vaccinated while 3 of them are following the recommendations. The importance of adherence to the 2nd dose of vaccination is inconstable element that may affect the success of the vaccination program. It is undoubtful that non adherence can lowers the efficacy. Among those 694 partially vaccinated participants, 686 (98.8%) adhered to the second dose within the time interval as per instructed (counseled), while 8 (1.2 %) showed non adherence, in which 2 (0.29%) subjects were diseased on the second dose, 2 (0.29%) were out of town and other 2 (0.29%) received inadequate information regarding next dose. Allergic patient and the COVID positive patient was 1 (0.14 %) each. This shows a positive result where majority of the participants adhered to the second dose and showed the acceptance of Covisheild vaccine among the healthcare sector and those who weren't able to take both doses were the least. This can be comparable with the online survey conducted by Mohammed A.M Ahmed, Robert Colebunders in COVID 19 vaccine acceptability and adherence to preventive measures in Somalia [7].Healthcare workers are at high risk of exposure to COVID 19, both in community and in the workplace when providing patient care; hence, a study for emergence of infection after vaccination is necessary. Out of 694 subjects vaccinated against COVID 19, 11 (1.6 %) showed seropositivity for COVID 19 infection. In contrast, the majority of paticpants', 683 (98.4%) were not infected after 60 days of vaccination follow up, in which maximum number 9 (1.13%) of participants were infected after 45days of vaccination completion. Only one (0.1%) participant showed disease incidence with 30 days and one after 60 days they completed their two doses. Although few of the vaccine participants become COVID warriors, the severity of symptoms was much less than normal people. Out of 11 infected participants', 10 (1.5%) had moderate symptoms of infection while 4 (0.6%) had mild symptoms. Severe symptoms requiring hospitalization was manifested only in 1 (0.1%) patient. This was contradictory to the correspondence submitted by Jocelyn Keehner, Lucy E Horton et al on SARS-CoV2 infection after vaccination in health care workers in California[8]. They confirmed high rate of positivity among vaccinated participants and underscore the critical importance of maintaining public health mitigation measures until herd immunity is developed world wide.Seropositivity of COVID 19 infection confirmed with polymerase chain reaction

assay or antigen test, and the reason for conducting the test varied among participants. A total of 17 subjects tested for COVID 19, majority of the participants', 8 (1.2%) were found to be primary contacts to susceptible infection followed by 5 (0.7%) who were presented with symptoms. 2 participants had to test due to hospital safety and travel purposes. Association between incidence and severity of COVID 19 was reviewed and the Likely hood ratio test suggests that the obtained P value is <0.05; hence the association between incidence and severity of COVID 19 infections was statistically significant. Incidence of COVID 19 infections in vaccination group was compared with the pre vaccinated individuals to identify the positivity rate and success of the vaccination program. None of the 4 participants recovered from COVID 19 were re-infected after complete vaccination within the time period. The Likelihood Ratio test was used to find the association, and it shows the obtained p value is > 0.05 and hence there was no association between COVID Positive and Infection.COVID positive patients after vaccination were categorized in to close contact, healthy volunteers, normal and recovered and the incidence of infection in these were assayed which shows positivity was seen maximum among the close and susceptible contacts to COVID 19 followed by workers who remain in normal exposure. Since the p value obtained was above 0.05 with the likely hood ratio test, therefore there is no significant association between exposure status and infection.This study has few limitations, such as the sample size; the fact that the majority of participants resided in the Malabar region of Kerala makes it difficult to generalize our observations to the entire state of Kerala. During the first phase of vaccination, the study was conducted where only the healthcare workers and front-line worker were prioritized; vaccination to the public data was not observed from this study. Large sample studies are required to improve knowledge as well as to validate the overall result. The success of covisheild vaccine in Kerala implies the various measures and strategies used by the government and healthcare systems. During the beginning of the vaccination, all the doctors, nurses and other health care participants, those eligible for the vaccination, showed up on time for the jab. This was the major reason there was no wastage of any vial with vaccine daily, with zero wastage due to strict implementation of storage, transportation and usage protocols. The guideline released by government to vaccinate the healthcare workers could be leveraged as a means of sensitization as the general public will trust the advice from the doctors. Key actions at district level by identifying online and in-person training platforms, workshops, organizing sensitization workshops/meeting for the officers from line departments, private doctors, and leading physicians, also conducting refresher trainings for front line workers. The strategies to increase vaccine acceptance were the education to the public by pharmacist; thus, they have a significant role in promoting and supporting the use of vaccination. We conducted webinars, presentations online on the available vaccines during this pandemic crisis. By implementing communication strategies released by government, pharmacist can reduce the vaccine hesitancy by building public confidence in the safety and efficacy of the new vaccine, and ensure understanding and acceptance of the phased and prioritized approach to overcome concerns of the population waiting for vaccination and also managing any misinformation and rumors around it. Today, the entire pharmacist worldwide has involved in the vaccination drive to get the public to get vaccinated and reduce the mortality in every country. As front-line workers, Pharmacist are ideal for this role in providing counseling, managing medication history, and managing adverse effects following immunization, documentation, and administrative measures.

CHALLENGES INVOLVED IN VACCINATION

Once the vaccination drive launched in the country, the phased roll out campaign was in accord with the availability of vaccines, but the national vaccination drive faced vaccine supply, distribution, and pricing hurdles and vaccine skepticism before much time passed. The first priority was the health care workers and other essential, public-serving officials dealing with the pandemic and then it was the turn of those above 60 years whose mortality rates were highest for the virus. The ready availability of vaccine stocks was bountiful to meet the Indian population and export demand to needy nations. Things started to unravel in recent times when Government lowered vaccination eligibility to 18 years and above from April 1st and stipulated for a transcending supply. Since different vaccines requires different temperatures and handling techniques that determines its stability, “Cold chain facilities” are crucial before they are eventually delivered to the public. Covishield vaccines require refrigeration around 2-8ºC, and each 5 ml vial could deliver 0.5 ml of vaccine dose to possibly maximum of 10 participants. Without an appropriate storage facility, vaccines, exposed to excessive light and heat above recommended, results in wastage and reduce potency. India, well-known for its dense population and tropical climate, maintaining a temperature-condoled cold supply chain remains an issue in delivering the vaccines. Besides, several hospitals which serves as initial sites for vaccination, lack these ultra-cold freezers for the proper storage and administration of vaccines. Efforts are required to supply additional Cold chain equipment and regular inspection to confirm maintenance at vaccination centers as well.

The overall essence of vaccine development and vaccination strategies relies on the participants that are benefitted from it. Many surveys conducted so far on the willingness to be vaccinated, and the results varied from certainty to denial as the hasty and multiple introductions of vaccines worldwide was the most discussed topic. Pharmacy professionals do have a role in helping to subdue vaccine hesitancy, hindering stigma involved among the public through proper awareness and education to improve vaccine acceptance. All the above stated key challenges have plagued India's plight on COVID 19.What more matters was when the country was hit with a second wave. An unsatisfactory situation was in place given the recoil of the pandemic and consecutive peaks of infection it leads to. There were fixing the vaccine crunch and vexation quests improved strategies and declarations to boost vaccine production, delivery and patient confidence to allay any concerns related to the same.

CONCLUSION

Implementation of COVID 19 vaccination opens a new window for the development of herd community, which paves a path for eradicating this harmful infection; Novel Corona Virus (SARS Cov 2). This study was performed in accordance with the guideline, which suggested the prioritization of vaccine administration to the front-line health care workers. The participants received the vaccine in interest of their own. The incidence rate in vaccinated individual is lower when compared with the individuals not vaccinated; this result is acquired because of the adherence of participants to the second dose and preserving other public health mitigation measures. Though this is a shaft of light to the world, there are demanding challenges in every step of the way that needs to be vanquished. This accelerated vaccine development necessitates the need to overcome vaccine hesitancy

and counter the patients' stigma and misconceptions. Even though pregnant and lactating women and children under 18 years of age are high risk population, there is no evidence on reasons for exclusion from the study. A coordinated and harmonized mass vaccination program elevates the development of a complete herd community.

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CONFLICT OF INTEREST

Authors declare no conflict of interest

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