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A Study On Side Effects Experienced By Health Care Workers Vaccinated With Covishield Vaccine In Selected Hospital Of Navi Mumbai

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ABSTRACT

BACKGROUND: Aim of the study is to evaluate adverse events following immunization (AEFI) amongst the HCW after first dose of Covishield vaccine. We also evaluated association of AEFI according to sex, and age groups.

METHODS: We performed cross-sectional study on side effects experienced by health care workers. The 200 recipients receiving first dose of 'COVISHIELD' vaccine at selected hospital of Navi Mumbai were approached through phone calls to collect data on occurrence of side effects. Incidence of side effects in different age groups, gender, and those with previous history of COVID-19 were analyzed. Presence of any side effects was evaluated.

RESULT: Among the health care workers visiting vaccination OPD at selected hospital, 84% of them developed side effects after getting vaccinated whereas 16% did not developed side effects. 60.8% of health care workers developed Injection site pain, the most common side effects among the recipients.

CONCLUSION: Most side effects following the first dose of COVISHIELD vaccine. HCWs experienced minor, self-limiting AEFI with the first dose of ChAdOx1nCoV-19

KEYWORDS: ChAdOx1 nCoV- 19, Covishield vaccine, side effects, adverse events.

Introduction

Health is the body's functional and metabolic efficiency, and its ability to adapt to the physical, mental and social changes that it is exposed to. Health is the factor that helps a person to perform his daily life task in a correct and right way.[1]

The sudden outbreak of 2019 novel coronavirus (2019-nCoV, later named SARS-CoV-2) in Wuhan, China, originated in bats which rapidly grew into a global pandemic, marked the third introduction of a virulent coronavirus into the human society, affecting not only the healthcare system, but also the global economy.[2]

The disease is transmitted by inhalation or contact with infected droplets and the incubation period ranges from 2-14days.The symptoms are usually fever, cough, sore throat, breathlessness, fatigue, malaise among others.[3]

Total number of cases recorded in an Indian's are 10.7million till 24 Jan 2021. Among that 2.01million cases were found in Maharashtra. Around 85% of covid-19 cases were confirmed from the Mumbai Metropolitan Region (MMR) and Pune district. The total death rate till now is 155,137.[4]

A covid 19 vaccine is a vaccine intended to provide acquired immunity against covid 19.By January 2021, 69 vaccine candidates were in clinical research, including 43 in Phase I–II trials and 26 in Phase II–III trials. In Phase III trials, several COVID 19 vaccines demonstrated efficacy as high as 95% in preventing symptomatic COVID 19 infections. As of 14 January 2021, 32.64 million doses of COVID 19 vaccine had been administered worldwide based on official reports from national health agencies.[5]

India's drugs regulator DCGI gave final emergency-use approval for two corona virus vaccines: Covishield and Caovaxin. The vaccine received DCGI approval for Phase I & II Human Clinical Trials and the trials commenced across India from July, 2020. After successful completion phase I&II, DCGI approval for III phase clinical trials.[5]

As on February 5,6pm, a total of 52,90,474 beneficiaries vaccinated during 1,04,781 sessions, as said by the Health Ministry.[6] Psychological impact of Covid -19 may vary from immediate effects, like irritability, fear of contracting and spreading infection to family members, anger, confusion, frustration, loneliness, denial, anxiety, depression, insomnia, despair, to extremes of consequences, including suicide . Another very important aspect is stigmatization and societal rejection regarding the quarantined cordon in forms of discrimination, suspicion and avoidance by neighbourhood, insecurity regarding properties, workplace prejudice, and withdrawal fromsocial events even after containment of epidemics.[7]

Nurses are on the front lines of health care delivery, and many of them routinely administer immunizations. The authors describe the Centers for Disease Control and Preventions (CDC)vaccine safety monitoring system, explaining how nurses can access inquiry channels and other immunization information resources. Nurses often are the ones administering vaccines and therefore play a central role in teaching parents and patients about the lifesaving function of vaccines and about vaccine safety. According to a 2005 study, parents main source of information about vaccines is health care professionals, Nurses might also

treat patients when vaccine adverse events required medical attention. The CDC has many resources available to nurses and other health care professionals on vaccine safety.

BACKGROUND

In India two vaccines are currently being administered to prevent the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). India launched its COVID-19 vaccination drive starting with healthcare workers (HCW). Aim of the study is to evaluate adverse events following immunization (AEFI) amongst the HCW after first dose of Covishield vaccine. We also evaluated association of AEFI according to sex, and agegroups.

Nepal started the first phase of Covid-19 vaccination for frontline healthcare workers in January 2021 with the ChAdOx1 nCov-19(Covishield vaccine) and conducted active surveillance of adverse effects following immunization (AEFI) Total 5591 people received vaccine who were approached through phone calls to collect data on a AEFI and Incidence of common AEFI in different age groups gender and those with previous history of COVID- 19 were analysed. Presence of any adverse events of special interest (AESI) were evaluated. Out of 5591 vaccine recipients 3991(71.3%) responded to the phone call and AEFI was noted in 3394(85.04%) of them. Minor a AEFI was seen in 3391(84.9%) Severe Minor AEFI in 1(0.02%) and serious AEFI in 2(0.05%) Out of 807 vaccine recipient with previous history of COVID-19, 709(87.9%) had AEFI while of the 3184 with no history of COVID- 19, 2685 (84.3%) had AEFI. Most AEFI following the first dose of Covishield vaccine were mild and resolved within a few days except for one case of anaphylaxis no other AESI were encountered.[9]

NEED OF THE STUDY

Generally, after vaccination there are sort of side effects which may or may not occur. Research studies have found that after administration of Covishield and Covaxin vaccineside effects were observed in few people.

The study emphasizes on the symptoms that occur after administration of vaccine such as redness, itching, swelling or bruises where the injection is given, fatigue, feeling feverish, headache, nausea etc. These findings revealed that they have implications for future design and research practice in medical healthcare settings.[10]

Bharat Biotech has stated that side effects that have been reported with Covaxin are – injection site pain, injection site swelling, injection site redness, injection site itching, stiffness in the upper arm, weakness in the injection arm, body ache, headache, fever, malaise, weakness, rashes, nausea.[10]

REVIEW OF LITERATURE

1. Deep Kamal, Vaidehi Thakur, Navneet Nath, 16 January to 15 April 2021, conducted a study in Southern India, regards Adverse events following ChAdOx1 nCoV-19 Vaccine

(COVISHIELD) amongst health care workers: A prospective observational study. The aim of the study is to evaluate the occurrence of adverse events following immunization (AEFI) amongst HCW with two doses of Covishield. A prospective observational study was conducted in a tertiary care COVID dedicated hospital of Southern India. Nine hundred an eighty-one HCW who received 2 doses (4 weeks apart) were enrolled. Active and passive surveillance was conducted after 48 hours, and at days 8, 15, 22 and 28 for both doses. The rate of AEFI for each dose was determined. Incidence and association of AEFI with various demographic variables was determined. A total of 1020 non-serious adverse events were reported within 48 h of the first dose of vaccination. Common adverse events included feeling unwell (N-186, 19%), headache (N-171, 17.4%), fever (N-123, 12.5%), fatigue (N- 121, 12.3%) and muscle ache (N- 110, 11.2%). 123 non-serious AEFI were reported between
3 and 7 days (day 8). 66 non - serious adverse events were reported between 8 and 14 days (day15). No adverse events were reported in the last two weeks. Two serious adverse events (altered sensorium) were noted in the first 48 h of vaccination which can be considered negligible. No serious adverse events were reported after 48 h. A total of 220 nonserious adverse events were reported within 48 h of the second dose of vaccination. Common adverse events included feeling unwell (N-50, 5.1%), headache (N-48, 4.9%), muscle ache (N22, 2.2%), decreased appetite (N-22, 2.2%), and fever (N-19, 1.9%). 68 non-serious AEFI were reported between 3 and 7 days (day 8). 61 non - serious AEFI were reported between 8 and 14 days (day15). No AEFI (non-serious/serious) were reported in last two weeks after thesecond dose. Adverse events (non-serious and serious) according to sex, profession, and age were developed. We found no association of AEFI with sex and profession ($p > 0.5$).

Significant association of AEFI was found with age ($p < 0.01$), with the incidence of adverse events being higher in the older age group (>50 years).[11]

2. Sourya Sourabh Mohakuda 1 , Ankur Nigam 2 , K Rajesh 1 , VK Sashindran 1,in India February 2021 regards covishield covid Vaccine in India Demystifying myths- early multicentric study. This multi-centric study was conducted in tertiary care centres in Northern & Eastern India to document the adverse and systemic reactions following exposureto the COVISHIELD vaccine and to study the factors there of. All the participants who consented to the study were included. The participants were administered the first dose of theCOVISHIELD vaccine. All the vaccines were detained at immunization centres for 30 minutes post administration of the vaccine. They were followed up for adverse and systemic effects over a period of 07 days. The vaccine was administered by a trained vaccinator through an auto disposable syringe into the deltoid muscle and the onset of adverse and systemic effects was monitored by a supervisor through participant

administered questionnaire. Individuals complaining of any symptoms post-vaccination were cross- checked by the supervisor for coherence in reporting of symptoms. Data of all the beneficiaries from various centres were compiled and collated in an excel sheet and was analyzed after data cleaning using SPSS v-23. Beneficiaries who did not fill the questionnaire were contacted on the telephone by the supervisor and were asked for their wellness and reactions, thus minimizing loss to follow up. There were 268 participants in the study whose mean age was 33.75(+- 8.86) years. There were no admissions or serious side effects observed over 7 days. Systemic effects post-vaccination was seen in 118(44.02%) study participants. The study population comprised of 200(74.6%) males against 68(25.4%) females. The study population was divided into 04 subgroups based on their age profile. Comorbid conditions were present in 3% (n=8) of the study population.[12]

3. Leeberk Raja Inbaraj, Carolin Elizabeth George, Nirupama Navamani Franklyn conducted a study to determine the incidence of adverse event following immunization (AFFI) among HCWs after their first dose of ChAdOx1nCoV-19 vaccine. They conducted a cross - sectional study among 218 staff of a tertiary care hospital they circulated a google form with informed consent on the hospital WhatsApp platform and asked them to self - report their vaccination experience. They had minor AEFI, and none had severe AEFI. Body ache 46.8% was the most common symptom followed by headache 30.3% and fever 22% most of them 39.4% experienced symptoms within 4- 24hours after taking the vaccine while 22.3% experienced it after a day. Majority of the HCWs 78.9% were anxious before the vaccination. Younger age group and female gender were significantly associated with AFFI compared to their counterparts.[13]

4. Awadhesh Kumar Singh, Sanjeev Ratnakar Phatak, Regards Antibody Response afterFirst-dose of ChAdOx1-nCOV (Covishield™®) and BBV-152 (Covaxin™ ®) amongst Health Care Workers in India: Preliminary Results of Cross-sectional CoronavirusVaccine induced Antibody Titre (COVAT) study. This ongoing, Pan-India, Cross-sectional,Coronavirus Vaccine-induced Antibody Titre (COVAT) study is being conducted amongstHCW, with or without past-history of SARS-CoV-2 infection. SARS-CoV-2 anti-spike binding antibody is being assessed quantitatively at four time points between 21 days or more after the first dose to 6 months after the second dose. Primary aim is to analyse antibody response following each dose of both vaccines and its correlation to age, sex, body mass index (BMI) and comorbidities. Here we report the preliminary results of anti-spike antibody response after the first dose. Amongst the 552 HCW (325 Male, 227 Female), 456 and 96 received first dose of Covishield and Covaxin respectively. Overall, 79.3% showed seropositivity after the first dose. Responder rate and median (IQR) rise in anti-spike antibody was significantly higher in Covishield vs. Covaxin recipient (86.8 vs. 43.8%;

61.5 vs. 6 AU/ml; both p<0.001). This difference persisted in propensity-matched (age, sex and BMI) analysis in 172 subjects. No difference was observed with age, gender and BMI. History of hypertension had lower responder rate (65.7 vs. 82.3%, p=0.001). Covishield recipient had more adverse event vs. Covaxin arm (46.7 vs. 31.2%, p=0.006). Presence of comorbidities, past SARS-CoV-2 infection and vaccine types used were independent predictors for seropositivity after the first dose, in multiple logistic regression analysis.[14]

5. In New Delhi on dated April 28, 2021, regards. One in four people experience mild side effects from Covishield vaccine: Lancet study the researchers from King's College London in the U.K. also found that most systemic side effects — meaning side effects excluding where the injection took place — peaked within the first 24 hours following vaccination and usually lasted 1-2 days. Systemic effects included headache, fatigue, chills and shiver, diarrhoea, fever, arthralgia, myalgia, and nausea. Local side effects — meaning side effects where the injection took place in the arm — included pain at the site of injection, swelling, tenderness, redness, itch, warmth, and swollen armpit glands. The analysis of data from the ZOE COVID Symptom Study app found much fewer side effects in the general population with both the Pfizer and AstraZeneca vaccines than reported in trials. The data comes from 627,383 users of the ZOE COVID Symptom Study app who self-reported systemic and local effects within eight days of receiving one or two doses of the Pfizer vaccine or one dose of the AstraZeneca vaccine between December 8 and March 10. Participants who had a confirmed case of prior COVID-19 were three times more likely to have side effects that affect the whole body after receiving doses of the Pfizer vaccine than those without known infection. Those with a confirmed case of prior COVID-19 number were almost twice more likely to have side effects that affect the whole body after the first dose of the AstraZeneca vaccine. The researchers noted that in Phase III clinical trials of the Pfizer vaccine, the most common side effects were pain at the injection site (71-83%), fatigue (34-47%) and headache (25-42%). However, the real-world analysis found less than 30% of users complained of injection site pain and less than 10% of fatigue and headache after the first dose, they said. Similarly, in Phase III trials for the AstraZeneca vaccine, systemic side effects were found in 88% of younger participants (18-55 years) after the first dose but the study found a significantly lower rate of 46.2% after the first dose. The results support the aftereffects safety of both vaccines with fewer side effects in the general population than reported in the Pfizer and AstraZeneca experimental trials and should help allay safety concerns of people willing to get vaccinated.[15]

6. Seongman Bae, Yun Woo Lee, So Yun Lim, Ji-Hyang Lee, 5 March to 26 March 2021, conducted a study in South Korea regards Adverse Reactions Following the First Dose of ChAdOx1 nCoV-19 Vaccine and BNT162b2 Vaccine for Healthcare Workers in South Korea. To investigate the occurrence of adverse reactions after vaccination in different regions and

populations. HCWs at a tertiary referral hospital in Seoul, South Korea, received a chimpanzee adenovirus-vectored vaccine (ChAdOx1 nCoV-19) or an mRNA-based vaccine (BNT162b2) between March 5 and March 26, 2021. The HCWs were asked to report adverse reactions through a mobile self-report questionnaire for three days after vaccination. A total of 7,625 HCWs received the first dose of ChAdOx1 or BNT162b2 vaccine during the study period. Of them, 5,866 (76.9%) HCWs (ChAdOx1, n = 5,589 [95.3%]; BNT162b2, n = 277 [4.7%]) participated at least once in the survey, of whom 77% were female and 86% were younger than 50 years. The overall adverse reaction rate was 93% in the ChAdOx1 group and 80% in the BNT162b2 group ($P < 0.001$). Both local and systemic reactions were more commonly reported in the ChAdOx1 group, and the difference was larger in systemic reactions such as fever and fatigue. In the ChAdOx1 group, the incidence of adverse reactions was significantly higher in females and those in the younger age groups, while the BNT162b2 group showed such difference according to age.[16]

7. Ranjit Sah, Sunil Shrestha, [...], and Alfonso J. Rodriguez-Morales in Nepal Jan 27th, 2021, regards In Nepal, the COVID-19 vaccination program was initiated on Jan 27th, 2021. The government of Nepal decided to start mass vaccination, starting by immunizing health and security workers. The authors share their experience regarding Oxford/AztraZeneca COVID- 19 AZD1222 (Covishield) vaccination in Nepal. After vaccination, people were asked to wait in the observation room for 30 min to check whether they may experience mild transient headaches, light-headedness, and dizziness. After four hours of vaccination, some health workers complained about irritability in mood, six hours after vaccines, some complained of myalgia, nausea, tenderness at the injection site and feverish feeling. After 12 hours, fever with chills developed which required paracetamol to resolve. By the second day of vaccination, fever and headache were resolved, however myalgia and tenderness at the injection site persisted. Therefore, the study concluded that general people should be aware of these minor side effects which are manageable with some symptomatic treatment like paracetamol to resolve the symptoms timely or such medicine should be taken as prophylaxis to avoid developing the post-vaccination symptoms and increase the acceptance of the COVID-19 vaccine among the mass population.[17]

8.B.V.M., P.K., A.A.S. and H.S.M conducted study on Guillain-Barré Syndrome following ChAdOx1-S/nCoV-19 Vaccine. On April 22, 2021, more than 727 million doses of SARS/nCoV2 vaccines have been administered worldwide. ChAdOx1-S vaccine (Covishield™/Vaxzevria, Astrazeneca) has been administered in 116 countries, BNT-162b1 (Pfizer-BioNTech) in 83, mRNA-1273 (Moderna) in 36 and Ad26.COV2. S (Janssen) in two countries. In India, over 104 million doses of the SARS-CoV-2 vaccine have been administered and 13.5 million people have been fully vaccinated (1% of the population). The ChAdOx1-S vaccine (Astra Zeneca) has been used in >80% of the recipients. In three

districts of Kerala state (Ernakulam, Kottayam & Kannur) in India, approximately 1.2 million
individuals had received the ChAdOx1-S vaccine as of April 22, 2021.Neurological complications such as cerebral venous sinus thrombosis (CSVT) due to vaccine-induced immune thrombotic thrombocytopenia (now termed thrombosis with thrombocytopenia syndrome [TTS]) following adenovector-based COVID-19 vaccines have recently been reported. To date, one case of Guillain Barre Syndrome (GBS) has also been reported after Pfizer BNT-162b1 vaccination in the US. The study reported seven patients who developed GBS in very proximate temporal relationship to the first dose of ChAdOx1-S vaccination in a 4week period (mid-March to mid-April 2021).[18]

9. Miloslav Klugar, Mohamed Mekhemar, Abanoud Riad, February and April 2021 conducted a study in Federal Republic regards side effects of mRNA- Based and viral vector- based covid-19 vaccines among German Healthcare workers. This study aimed to evaluate the postvaccination side effects of the different vaccines approved in Germany. A cross- sectional survey-based study was carried out using an online questionnaire validated and tested for a priori reliability. The questionnaire inquired about demographic data, medical and COVID-19related anamneses, and local, systemic, oral, and skin-related side effects following COVID19 vaccination. Out of the 599 participating healthcare workers, 72.3% were females, and 79.1% received mRNA-based vaccines, while 20.9% received a viral vector-based vaccine. 88.1% of the participants reported at least one side effect. Injection site pain (75.6%) was the most common local side effect, and headache/fatigue (53.6%), muscle pain (33.2%), malaise (25%), chills (23%), and joint pain (21.2%) were the most common systemic side effects. The vast majority (84.9%) of side effects resolved within 1–3 days post-vaccination.[19]

10.H. M Khaleduzzaman and Nafisa Mishu conducted a study in Bangladesh regarding Frequency of side effects after first dose of vaccination against covid-19 among the people ofBangladesh. To assess the side effects after vaccination against covid-19. A cross sectional observational study was carried out with a sample of 1160. Where the individual has been observed for two months. For this purpose, a google form was generated and the link of structured questioner was given to everyone along with researchers contact number to inform any side effects. The sample was collected randomly who were attended at different vaccination centre. Data were collected by purposive simple random sampling method with a structured questionnaire. Total 1160 individuals who were vaccinated against COVID19 participate voluntarily in this study. Participants were from 26 to 60 years age group and 95% of them were male while only 5% were female. Most of the participants were married (96%) though 4% were unmarried. Most of participants (81.9%) did not notice any side effects but 18.1% had been suffering from side effects of various

modalities following COVID-19 vaccination. They noticed side effects mostly (45%) on first and second day. In this study most of the side effects are mild like fever (16.8%), headache (16.8%), sore arm (11.1%), joint pain (10.3%), fatigue 7.2%, chills (6.3%) and transient skin rash (0.9%) but some serious side effects were also found like seizure (1.6%) and unconsciousness (1.6%) whose required hospitalization though they regain consciousness without any neurological deficit. They return to home after 24 hours of hospital supervision. No anaphylactic shock was noticed among the participants.
Following chronic diseases were noticed among COVID-19 vaccinated participants like diabetes mellitus (7.4%), Hypertension (2.6%), chronic liver disease (1.7%), chronic obstructive pulmonary disease (0.5%), Ischemic heart disease with hypertension (0.3%) and Asthma(0.1%).[20]

11. Abanoub Riad, Andera Pokorna, Miloslav Klugar conducted study on 27 January 2021 to 27 February 2021 regards prevalence of covid-19 vaccine side effects among healthcare workers in the Czech Republic. To identify potential risk factors of pfizer-BioNTech covid-
19 vaccine side effects. This cross-sectional survey-based study was to estimate the prevalence of COVID-19 vaccine side effects among randomly selected health care workers in the Czech Republic. The study utilized a self-administered questionnaires of multiple -choice items which had been designed digitally using koBoToolbox version 2.021.03. The most common side effects of covid-19 vaccine among Czech healthcare workers were injection site pain, fatigue, headache, muscle pain, chills, joint pain.[21]

12. Serum Institute of India (SII), the manufacturer of Covishield developed by OxfordAstraZeneca, has stated that there are side effects that have been reported with Covishield. The SII has stated that “very common” side effects that may affect more than 1 in10 people are tenderness, pain, warmth, redness, itching, swelling, or bruises where the injection is given, generally feeling unwell, fatigue, chills, or feeling feverish, headache, nausea, and joint pain.Therefore researcher felt the need to identify common side effects related to Covishield vaccine to do vaccine monitoring.[21]

13. Steffen Mickenautsch (review center for health science research) and Vance W Berger
(National Institute of Health) 2021 regards to Efficacy reporting of the BNT162b2 mRNA Covid -19 vaccine trials. It reported a 95% COVID-19 preventive effect (95% credible interval, 90.3-97.6). Trial using inadequate allocation concealment is associated with 37% increased average estimate of benefit.[22]

14. Centers for disease control and prevention (2021) regarding Allergic reactions including Anaphylaxis after receipt of the first dose of PfizerBioNTech COVID-19 Vaccine. It was reported by Vaccine Adverse Event Reporting System (VAERS). In December 23, 2020 1,893,360 first doses of Pfizer-BioNTech COVID-19 vaccine was administered in the United States, (1,177,527 doses in females and 648,327 doses in males) and reports of 4,393 (0.2%) had adverse events after receipt of Pfizer BioNTech COVID-19 vaccine reported to(VAERS). 21 cases were determined to be anaphylaxis (a rate of 11.1 per million doses administered), including 17 having history of allergies or allergic reactions, 7 of whom had a history of anaphylaxis. The remaining were non anaphylaxis. The median age of persons with anaphylaxis was 40 years (range =27-60 years). The median interval from vaccine receipt to symptom onset was 13 minutes (range = 2–150 minutes); 15 (71%) patients had onset within 15 minutes, 3(14%) within 15 to 30 minutes, and 3 (14%) after 30 minutes. Among 83 non anaphylactic cases, the median age was 43 years (range = 18–65 years), and 75 (90%)
reported reactions occurred in women. The median interval from vaccine receipt to symptom onset was 12 minutes (range = <1 minute–20 hours); in 61 (85%) cases, onset occurred within 30 minutes, in 11 cases, onset occurred after 30 minutes, and for 11 cases, time of onset was missing. For 56 (67%) case reports, a past history of allergies or allergic reactions was documented. Common reported symptoms included pruritus, rash, itchy and scratchy sensations in the throat, and mild respiratory symptoms.[23]

15. United States, 21 December 2020 -10 January 2021 Conducted a study on Allergic reaction including anaphylaxis after receipt of the first dose of Moderna Covid19 vaccine. To assess the adverse side effects of Moderna Covid-19 vaccine. Total cases 4,041,396 were administered Moderna Covid-19 vaccine in that 2,465,411 female (61%), 1,450,966 male (36%) and 125,019 to person whose sex is not recorded (3%). 1,266(0.03%) reported adverse events. Among these, 108 cases reports were identified for further review. 10 cases were determined to be anaphylaxis including 9 in persons with a documented history of allergies or allergic reaction. 5 of whom had a previous history of anaphylaxis. The median interval fromvaccine receipt to symptoms onset was 7.5 minutes. Among the 43 cases of non-anaphylaxisallergic reaction after receipt of Moderna covid-19 vaccination with symptoms onset within 01day, 26(60%) were classified as nonserious. Commonly reported symptoms include pruritus, rash, itchy sensation in the mouth and throat, respiratory symptoms. Median patientsage is 43 years and 39(91%) of the reported reaction occurred in women.[24]

16. Maheshi N Ramasamy, Emma Plested conducted research in 2020, To assess the safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002) using It includes single-blinded

randomised, controlled, phase 2/3 trial done across the UK. Participants were eligible if they did not have severe or uncontrolled medical comorbidities. Between May30 and Aug8, 2020.560 participants were enrolled (160 aged between 18-55 years) from which (100 were assigned to ChAOx1 nCoV19 vaccine and 60 assigned to Men ACWY), 160 aged between 56-69 years from which (120 assigned to ChAOx1 nCoV-19 vaccine and 40 assigned to Men ACWY) and 240 aged 70 years and older from which (200 assigned to ChAOx1 nCoV-19 vaccine and 40 assigned to Men ACWY). ChAOx1 nCoV-19 was administered as a single dose or two dose regimen (28 days a part) as a single IM Inj into deltoid. Doses for ChAOx1 nCoV-19 was 0.22ml and 0.5ml for Men ACWY. After administration participants were observed for 15 mins and to note systemic adverse reaction for 7 days after each dose. Common symptoms observed were injection site pain and tenderness after 48hrs of vaccination. Local and systematic reactions were most common in participants given first dose of ChAdOx-ncov-19 than those given the control vaccine and reported side effects such as injection site pain, feeling feverish, and muscle ache, headache but were less common in older adults than younger adults.[25]

17. Pedro M Folegatti, Katie J Ewer, Parvinder K Aley et al. They assessed the safety, reactogenicity, immunogenicity of a viral vectored Coronavirus vaccine that express the spike protein of SARS-COV2. They did a phase 1/2 with randomized controlled trial in the UK.1077 participants from aged 18-55 who did not had symptoms of covid-19. Between
April 23 and May 21, 2020, 1077 participants were into the study and assigned to vaccination with either (ChAdOx1 nCoV-19) (n-543) or (MenACWY) (n-534); 10 of those participants were in group 3, the prime boost group, and these were not randomly assigned. 88 participants in group 1 coming for follow-up for safety and immunogenicity purpose.42 participants in group 2 blood drawn for cellular and humoral immunogenicity assessment. Group 3- prime booster of ChAdOx1 nCoV-19 administered 28 days after 1st dose.567 participants in group 4 - blood drawn humoral immunology. The median age of participants was 35 years, 536 participants were female and 541 were male. Who did not received paracetamol those participants reported pain after vaccination, which was mostly mild to moderate. In {ChAdOx1 nCoV-19} =328(67%) of 487. In {MenACWY}= 180(38%) of 477. with paracetamol pain reported in few people In ChAdOx1 nCoV-19= 28 (50%), In MenACWY =18 (32%) participants. Tenderness without paracetamol In ChAdOx1 nCoV-19= 403(83%), In MenACWY=276(58%). Tenderness with paracetamol ChAdOx1 nCoV-19= 43(77%) MenACWY= 26 (46%). fatigue and headache were the mostly reported systematic reaction. Fatigue without paracetamol ChAdOx1 nCoV-19 =340(70%) MenACWY=227(48%). Fatigue with paracetamol ChAdOx1 nCoV-19 =40 (71%) MenACWY=26 (46%). Headache without paracetamol ChAdOx1 nCoV-19= 331(68%) MenACWY=195(41%). with paracetamol ChAdOx1 nCoV-19= 34, MenACWY=21. Other

systemic adverse reaction was seen in both vaccines like muscle ache, malaise, feeling feverish. Due to paracetamol local and systemic reaction showed significant reduction. 10 participants of group 3 received prime and booster dose on day 28. The reactogenicity after the 2nd dose was less severe.[26]

18. Ohanna Chapin-Bardales, PhD, MPH; Julianne Gee, MPH; Tanya Myers, PhD, MSc Reactogenicity Following Receipt of mRNA-Based COVID-19 Vaccines. In clinical trials ofMRNA based 2 dose vaccines participate reported local and systemic reaction. A total of 3 643 918persons were enrolled in v-safe and completed at least 1 health survey within 7 days following their first vaccine dose; 1 920 872 v-safe participants reported receiving a second vaccine dose and completed at least 1 daily health survey within 7 days following the second dose. Solicited local and systemic reactions during days 0 to 7after each dose was assessed. during days 0 to 7 after vaccination The most frequently reported solicited local and systemic reactions after the first dose of COVID-19 vaccine were injection site pain(67.8%), fatigue (30.9%), headache (25.9%), and myalgia (19.4%). Reactogenicity was substantially greater after the second dose for both vaccines, particularly for systemic reactions, including fatigue(53.9%), headache (46.7%), myalgia (44.0%), chills (31.3%), fever(29.5%), and joint pain (25.6%).A greater percentage of participants who received the Moderna vaccine, compared with the Pfizer-BioNTech vaccine, reported reactogenicity; this pattern was more pronounced after the second dose. The percentage of v-safe participants who reported local and systemic reactions was highest on day 1 after vaccination and declined markedly through day 7. V-safe participants indicate that injection site pain is common after both the first and second doses of either mRNA-based vaccine. Systemic reactions, including fatigue, headache, myalgia, chills, fever, and joint pain, occurred in participants after the first dose, although they were more frequently reported after the second dose among both Pfizer-BioNTech and Moderna vaccine recipients. Persons 65 years and older reported lessreactogenicity than younger persons.[27]

PROBLEMSTATEMENT

A study on side effects experienced by health care workers vaccinated with covishield vaccine in selected hospital of Navi Mumbai.

Purpose

- To identify side effects of Covishield vaccine.

OBJECTIVES

- **Primary objectives:** To analyze the side effects experienced by health care workers vaccinated with covishield vaccine at OPD of selected hospital of Navi Mumbai.

- **Secondary objectives:** To find out association of side effects of covishield vaccine with demographic variable.

HYPOTHESIS

- H_0:- There are no side effects of covishield Vaccine.
- H_1:- There will be side effects of covishield Vaccine.
- H_2:- There will be association of side effects of Covishield vaccine with demographic variable.

OPERATIONAL DEFINATION

The way by which a researcher clarifies and defines the variables under investigation.

Health care workers

In my study Health care workers are the people receiving Covishield vaccine.

Side effects: -

In this study to recognize symptoms like injection site pain, injection site swelling, injection site redness, injection site itching, stiffness in the upper arm, weakness in the injection arm, body ache, headache, fever, malaise, weakness, rashes, nausea, abdominal pain to the patients in the Covid-19 vaccination OPD of selected hospital of Navi Mumbai.

Vaccination: -

In my study vaccination refers to treatment with a Covishield vaccine to produce immunity against a covid-19 in the selected hospital of Navi Mumbai.

ASSUMPTIONS

- Assumptions are statements that are taken for granted or are considerate true, even though they have not been scientifically tested.
- Health care workers receiving covishield vaccine will develop common side effects.

DELIMITATION

- Delimitations are boundaries that are set by the researcher in order to control the range of study.
- Health care workers receiving covishield vaccine in selected hospital of Navi Mumbai.

CONCEPTUAL FRAMEWORK

Ludwig Von Bertalanffy

A theory is a group of related concepts that propose action that guide practice. General system theory describes “how to break whole things into parts and then to learn how the parts work together in systems”. General system theory is known by different names - systems theory, theory of open systems, systems model, and family systems theory.

The author of General system theory was Ludwig Von Bertalanffy in 1950’s, A system is a complex of elements in interaction, which on first appearance does not seem interconnected or interrelated.

Organizations that exist in dynamic environments must be open systems in order to maintain homeostasis. Because dynamic environments are constantly changing, they create a lot of uncertainty about what an organization must do in order to survive and grow. The key to dealing with uncertainty is information. An open organization monitors its environment and collects information about environmental deviations that is labelled as input.

Other organizations may change their processes in order to adhere to new environmental laws. Processing positive and negative input to adjust to environmental change is called throughput.

After an organizational adapts to environmental changes, its action and messages represents its output.[30]

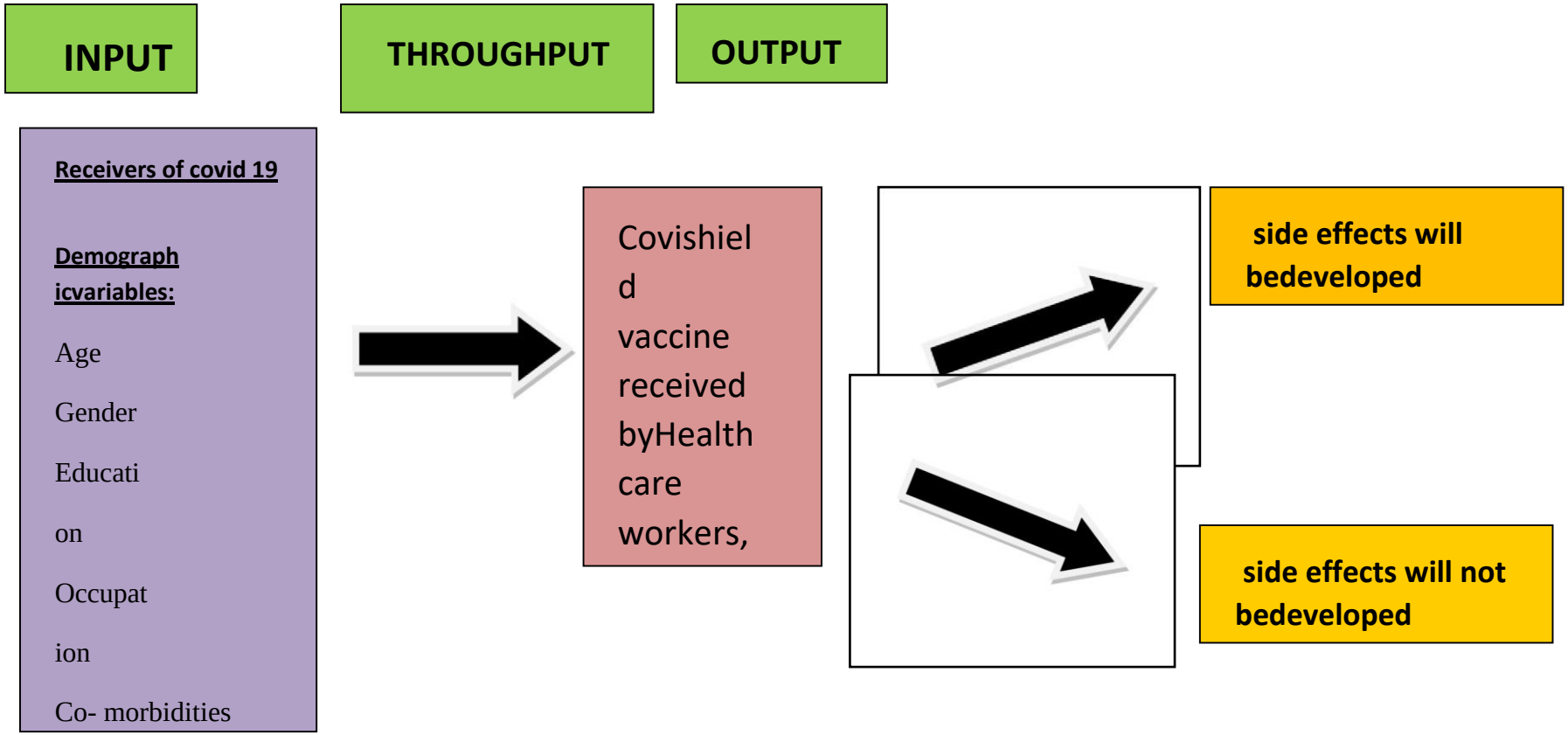


Fig.1 Conceptual Framework Based on General System Theory OF "Ludwig Von Bertalanffy"[30]

VARIABLES

Attributes of characteristics can have more than one value, such as height or weight. In other words, variables are qualities, quantities, properties or characteristics of people, things, or situations that change or vary.[28]

UNIVARIANT

Univariate analysis is the simplest form of analysing data.[31]In my study univariate is side effects.

DEMOGRAPHIC VARIABLE

The characteristics and attributes of the study subjects are considered demographic variables.[28]

In my study the demographic variables are age, gender, education, occupation, allergies, comorbidities, History of Covid-19.

RESEARCH METHODOLOGY

Research methodology is the overall plan for addressing the research problem. It covers multiples aspects of the study structure. It acts as a guide for planning, implementation and analysis of the study. It includes the descriptions of the research approaches, research design, variables, sampling design, descriptions of the tool, pilot study and planned format for data collection and a plan for data analysis.[28]

RESEARCH APPROACH:

"Research approach refers to researcher overall plans for obtaining answers to the research questions or for testing research hypothesis.[28]

Research approach used in this study is Quantitative approach.

STUDY DESIGN

It is the overall plan for obtaining answers to the questions being studied. It constitutes the blueprint for collection, measurement, and analysis of data.[28]

CROSS SECTIONAL DESIGN

Cross sectional research design is the one in which researcher collects data at a particular point of time.[28]

SETTING OF THE STUDY

Covid 19 vaccination OPD of selected hospital of Navi Mumbai.

POPULATION:

Population denotes the entire group of subjects under study.[28]

The population selected for the present study are health care workers receiving Covishield vaccine.

TARGET POPULATION –

According to Sharma S.K (2011) the entire population in which the researchers were interested and in which they would like to generalize the research findings. The term target population refers to any clearly definable group of individuals who are experiencing aproblem or need.[28]
Health care workers receiving covishield vaccine.

ACCESSIBLE POPULATION-

According to Sharma. S. K (2011) the aggregate of the case that conform to designated inclusion or exclusion criteria and that are accessible as subjects of the study.[28]

Health care workers receiving Covishield vaccine at OPD of selected hospital of Navi Mumbai.

SAMPLE

Sample is the proportion or subset of population. An element is the most basic unit about which the information is collected.[28]
Health care workers receiving Covishield vaccine.

Inclusion

- Health care workers receiving covishield vaccine at OPD of selected hospital of Navi Mumbai.
- Health care workers knowing Hindi, Marathi, and English.

Exclusion

- New onset of fever, cough or shortness of breath in month of February.
- Pregnancy and lactation or willingness to become pregnant.
- Those had high risk exposure before enrollment (close contact with covid 19 confirmed cases).
- History of anaphylaxis.

SAMPLING TECHNIQUE

Sampling is the process of selecting samples from the target population to represent the entire population.[28]
The sampling technique used in this study was the Nonprobability purposive sampling technique.

TOOL FOR DATA COLLECTION

A tool is an instrument or equipment used for collection of data.[28]In my study tool for analysis is structured questionnaire.
Section A: - Demographic data
Section B: - Analyse side effects of covishield.

TOOL FOR ANALYSIS

The data was decided to be analysed, by using descriptive and inferential statistics based on objectives and hypothesis of the study. To compute the data, a master data sheet was prepared by the investigator.[28]

Demographic data containing sample characteristics like age, gender, comorbidities, allergies, covid 19 history will be analysed by using frequency and percentage.

Descriptive statistics and inferential statistics will be used.

- Analysis will be presented in frequency and percentage.
- Chi square test will be used
- Presented in graph and table form.

DATA COLLECTION TECHNIQUE:

In this study the data is collected through telephonic interview.

SAMPLE SIZE

It is the number of samples being selected in the study[28].Sample size being selected in the study is 200.

ANALYSIS AND INTERPRETATION OF DATA

SECTION-I

Table No.1- Distribution of Health care workers according to their demographic dataand age group.

Age Group	Frequency	Percentage %
17-26 years	138	69
27-36 years	33	16.5
37-46 years	19	9.5
47-56 years	7	3.5
57-66 years	2	1
67-76 years	1	0.5
Total	200	100

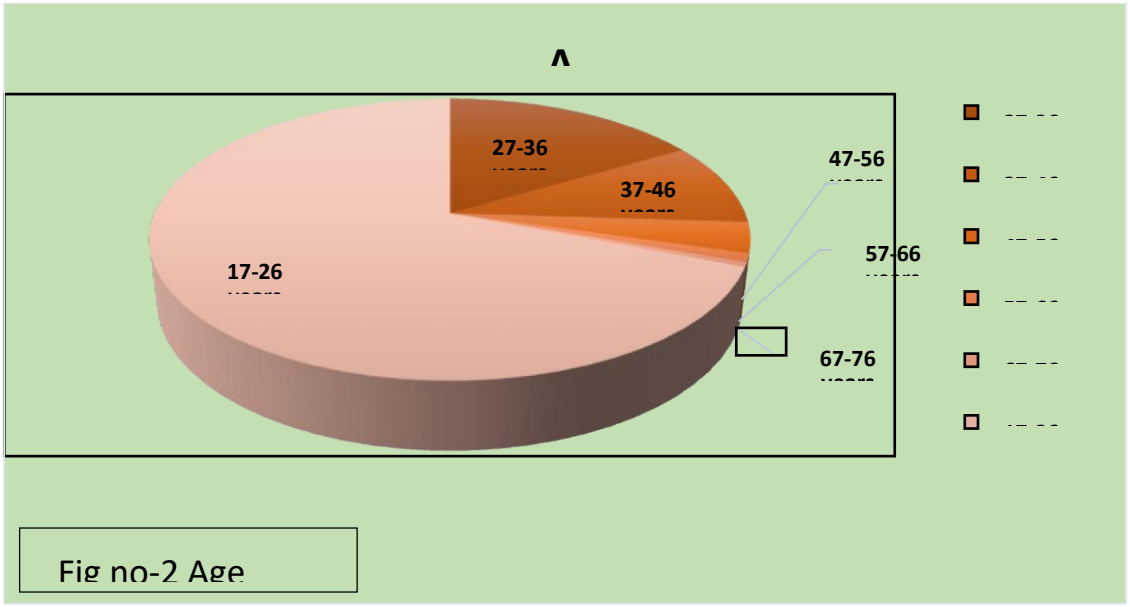


Table No.1 and fig no.2 displays almost 69% of the health care workers visited the vaccination OPD at selected hospital belong to age group 17-26 years,16% to 27-36 years, 9% to 37-46 years,4% to 47-56 years,1% to 57-66 and 67-76 years.

Table No.2- Distribution of Health care workers according to their demographic dataand gender

Gender	Frequency	Percentage %
Female	64	30.2
Male	136	64.2
Total	200	94.3

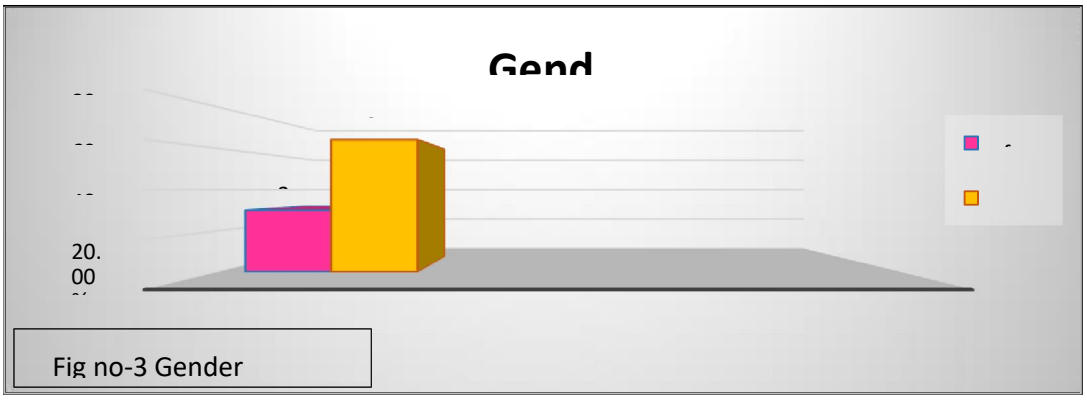


Table no.2 and Fig no.3 reveals 30.2% of health care workers visited to vaccination OPD at selected hospital were female and 64.2% were male.

SECTION-II

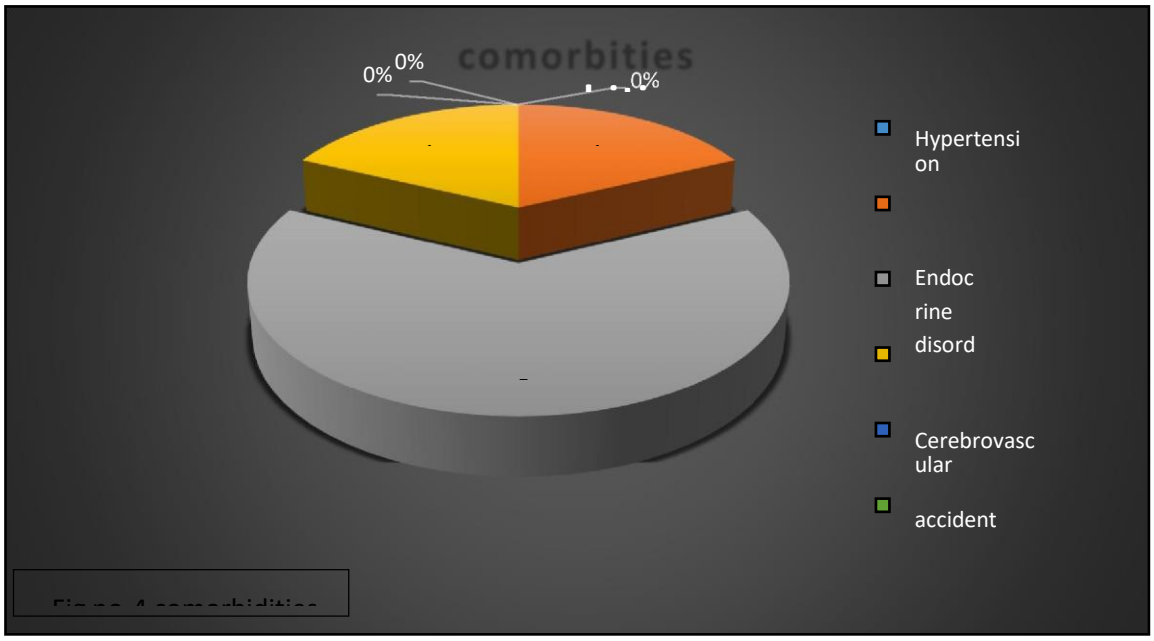
Table No.3- Distribution of Health care workers according to their Clinical History of co-morbidities.

Clinical history(co morbidities)	Frequency	Percentage %
Diabetes Mellitus	1	5
Hypertension	0	0
Endocrine disorders	3	1.4
Renal disorders	1	5
Lung disorders	3	1.4
Cerebro vascular accident	0	0
Coronary Artery disease	0	0

Table no.3 and Fig no.4 reveals among the co-morbidities mentioned,5% of the health care workers visiting vaccination OPD were having diabetes mellitus,1.4% were having endocrine disorders and lung disorders,5% were having renal disorders and others were nil.

Table No. 4 - Distribution of Health care workers according to their clinical history of being on medication.

Question	Frequency	Percentage %
Are you currently taking any medication?	0	0



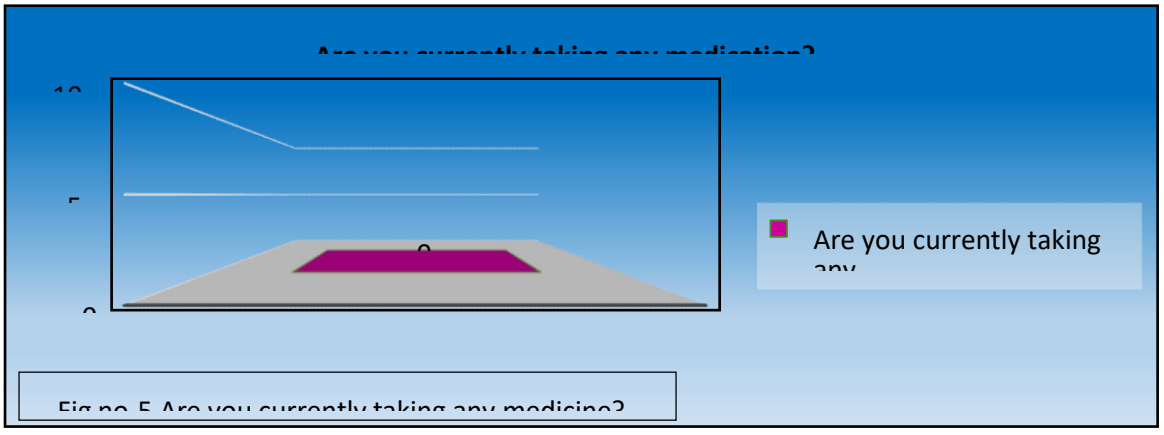


Table no.4 and Fig no.5 show none of the health care workers visiting vaccination OPD at selected hospital were on any type of medications.

Table No.5 Distribution of Health care workers according to their Clinical History of allergy.

Question	Frequency	Percentage %
Do u have allergy?	12	5.7

Table no.5 and Fig no.6 unveil; about 5.7% of the health care workers visiting vaccination OPD at selected hospital were having history of allergy.

Table No.6- Distribution of Health care workers according to their Clinical History of covid- 19.

Question	Frequency	Percentage %
Do you have history of Covid-19?	15	7.1

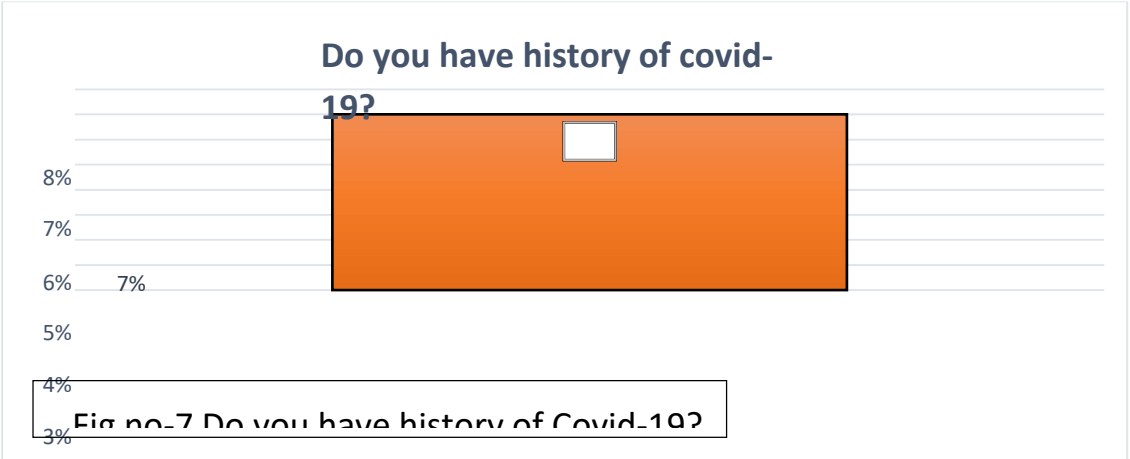


Table no.6 and Fig no.7 displays, about 7.1% of health care workers visiting vaccination OPD at selected hospital were having history of Covid-19.

Table No.7- Distribution of Health care workers according to their Clinical History.

SN	Questions	Frequency	Percentage%
1.	Before vaccination did u take any medication?(Pain killers)	0	0
2.	Presently are you suffering of any illnesses?	0	0

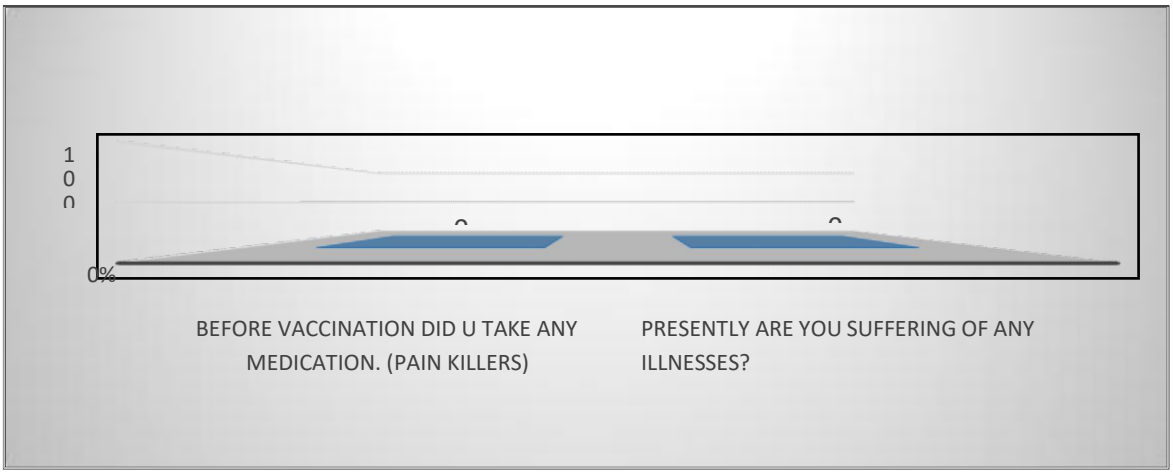


Table no.7 and Fig no.8 exhibit the data that among the health care workers visiting vaccination OPD at selected hospital neither of them had taken any of medication before coming nor were suffering from any Illnesses.

SECTION-III

Table No.8- Numbers of health care workers presenting the side effects of Covishield vaccine.

SN	Questions		Frequency	Percentage %
1	Do you have any side effects ofvaccine?	Yes	168	84
		No	32	16
	Total sample		200	100

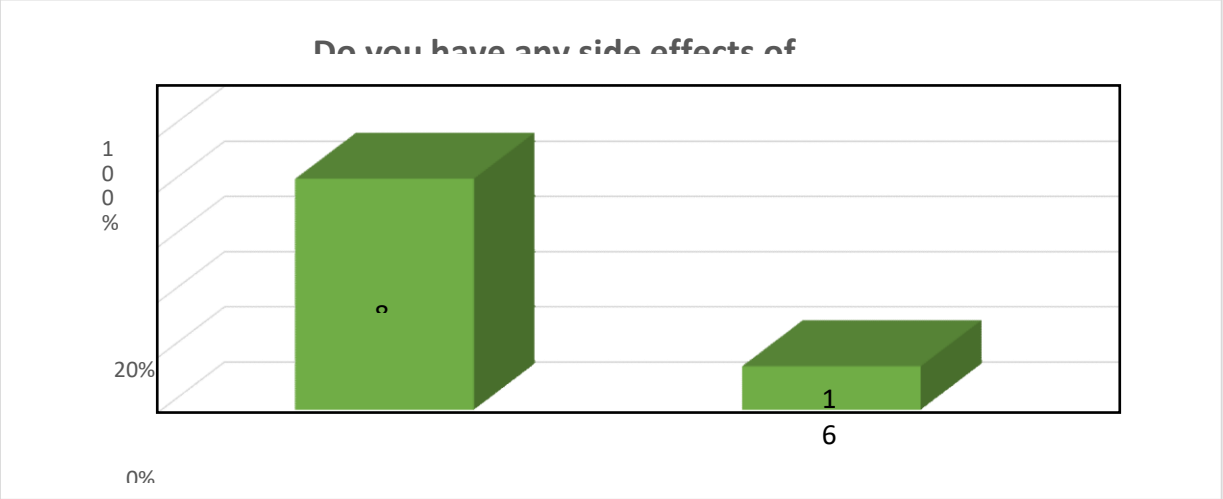


Table no.8 and Fig no.9 reveals, among the health care workers visiting vaccination OPD at selected hospital,84% of them developed side effects after getting vaccinated whereas 16% did not developed side effects.

Table No. 9 – Signs and symptoms developed in the health care workers after getting vaccinated.

	Question	Frequency	Percentage %
1.	Feeling unwell	23	10.8
2.	Injection site pain	129	60.8
3.	Injection site redness	11	5.2
4.	Injection site itching	1	0.5
5.	Injection site tenderness	18	8.5
6.	Warmth at the Injection site	2	0.9
7.	Stiffness at the vaccinated site	5	2.4
8.	Weakness at the vaccinated arm	4	1.9
9.	Joint pain (if it has occurred after vaccination only)	2	.9
10.	Rashes developed	1	0.5
11.	Headache	26	12.3
12.	Dizziness	11	5.2
13.	Vertigo	1	0.5
14.	Malaise	9	4.2
15.	Weakness	18	8.5
16.	Enlarged lymph nodes	0	0
17.	Diaphoresis	0	0
18.	Sore throat	0	0

19.	Running nose	0	0
20.	Cough	1	0.5
21.	Chills	7	3.3
22.	Nausea	7	3.3
23.	Vomiting	3	1.4
24.	Abdominal pain	1	0.5
25.	Lack of appetite	1	0.5
26.	Fever	23	10.8
27.	Myalgia	6	2.8
28.	Body ache	10	4.7

Table no.9 shows, among the health care workers visiting vaccination OPD at selected hospital side effects such as; Injection site pain was seen in most of the health care workers that is about 60.8% , 10.8% were feeling unwell. Injection site redness, Itching, tenderness, warmth, stiffness were observed in 5.2%, 0.5%, 8.5%, 0.9%,2.4% of the health care workers. Weakness at the vaccinated arm in 1.9%, Joint pain in 0.9%, rashes were developed in 0.5%, headache in 12.3%, dizziness in 5.2% vertigo in 0.5% malaise in 4.2% weakness in 8.5% cough in 3.3% chills 3.3% nausea 3.3% vomiting in 1.4% abdominal pain in 0.5% lack of appetite in 0.5% fever in 10.8%, myalgia in 2.8%, body ache in 4.7% were developed.

Table no-10 Chi square association of age and gender with side effects?

Sr.no	ıic variable of health careworker	df	i-squarevalue	Table value ofChi square
1	Age	1	1.302	3.84
2	Gender	1	1.302	3.84

Table no- 10 displays association of side effects of covisheild vaccine among health care workers with age and gender. Based on chi square test the calculated value is 1.302 for both age and gender with side effects. The calculated value is not more than their respective chi square table value at 0.05 levels. From above we can state that there is no statistically significant difference between the group of demographic variable age and gender. Hence null hypothesis is accepted, and alternate hypothesis is rejected for age and gender. Hence side effect is not association with age and gender.

DISCUSSION

A Cross Sectional study on Health care workers receiving Covishield vaccine at selected hospital is conducted and majority of health care workers are in the age group of 17-26 years. Among 200 samples,168 receivers developed side effects.5% of them were having comorbidities of diabetes mellitus and renal disorder. Among 15 of them were having history of Covid 19. Most health care workers had injection site pain that is 60.80%. Data was collected through structured questionnaire through phone calls. Researchers from Patan academy of Health

Sciences were approached through phone calls to collect data on AEFI. Out of 5591 vaccines recipient, 3994 developed side effects. Covid history among recipient were 807. The study stated that the most common side effects were injection site pain (55%),fever (37.1%), myalgia (30.1%), lethargy(27.6%).[9]

RESULT:

A **t**otal of 200 health care workers participated in our study. Among them 84% of them developed side effects after getting vaccinated whereas 16% did not developed side effects. Almost 69% of the health care workers visited the vaccination OPD at selected hospital belong to age group 17-26 years,16% to 27-36 years, 9% to 37-46 years,4% to 47-56 years,1% to 57-66 and 67-76 years. Majority of them were male (64.2%) and others were female (30.2%). Among the comorbidities mentioned,5% of them were having diabetes mellitus,1.4% endocrine disorders and lung disorders,5% renal disorders and others were nil.About 5.7% and 7.1% of the receivers were having history of allergy and Covid 19.The findings of the study revealed side effects observed in majority were Injection site pain that is about 60.8% .10.8% were feeling unwell. Injection site redness, Itching, tenderness, warmth, stiffness were observed in 5.2%, 0.5%, 8.5%, 0.9%,2.4% of the health care workers. Weakness at the vaccinated arm in 1.9%, Joint pain in 0.9%, rashes were developedin 0.5%, headache in 12.3%, dizziness in 5.2% vertigo in 0.5% malaise in 4.2% weakness in cough in 3.3% chills 3.3% nausea 3.3% vomiting in 1.4% abdominal pain in 0.5% lackof appetite in 0.5% fever in 10.8%, myalgia in 2.8%, body ache in 4.7% were developed. The study found no association of side effects with age and gender.

CONCLUSION

The active study on side effects experienced after the first dose of Covishield vaccine conducted at selected hospital of navi Mumbai with a cross sectional study of 200 health care workers showed that the vaccine is safe with most of the recipients having only mild side effects. Out of 200 vaccine recipients, 168 receivers developed side effects. Injection site pain was most common side effects experienced by health care workers that is about 60.8%. No association is seen of side effects with gender and age group.

RECOMMENDATIONS:

Based on findings of the study the investigator proposed the following recommendations,

- The same study can be done with large sample size so that the results canbe generalized.
- The same study can be performed by focusing on adverse effect onparticular organ.
- The same study can be done for 3 days since side effects were observedafter the 3 days also.

SCOPE OF THE STUDY

- To identify Vaccine product-related reaction, Vaccine quality defect-related reaction, Immunization error-related reaction, coincidental event.

- Immunization safety monitoring it is used as a database of health insurance claims to identify and evaluate possible safety issues for licensed vaccines.
- This continued monitoring can pick up on adverse events that may not have been seen in clinical trials
- -This monitoring is critical to help ensure that the benefits continue to outweigh the risksfor people who receive vaccines.
- Vaccines promote health: unlike many other health interventions, they help healthy people stay healthy, removing a major obstacle to human development.
- Vaccines have an expansive reach: they protect individuals, communities, and entire populations.
- Vaccines have rapid impact: the impact of most vaccines on communities and populations is almost immediate.
- Vaccines save lives and costs.

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