Monitoring Adverse Events Following Immunization (AEFIs) for COVID– 19

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ABSTRACT
The COVID-19 vaccine aids in the prevention of COVID-19 infection. Vaccine sideeffectsinsomepeoplearenaturalevidencethattheir bodiesarebuildingprotectivemechanisms. During the pandemic, people's motivation to get vaccinated against COVID-19hasplummeted,withmorethanhalfofthepopulation hesitatingorunwillingtogetvaccinated. As a result, a questionnaire-based study was designed to track adverse eventsfollowing vaccination (AEFIs) for COVID-19 vaccinesin the generalpopulation, examinethe evidence on COVID-19 vaccine safety, and promote public understanding and uptake ofCOVID-19 vaccines. The study drew a total of 1018 participants. The results found that 51.1percent of those polled were male, 48.6 percent were female, and 47.5 percent were in the agegroup of 18-24 years. Almost all of the respondents (97.5%) agreed that the COVID-19vaccination is required in this pandemic circumstance. In our survey, 66% of side effectsoccurred after 1-2 days of vaccination, and 29% occurred within 3-7 days of immunization.According to our research, 85 members (8%) have been infected with COVID 19, whereas 92percent have not been infected with COVID 19. Overall, there were no serious side effectsobserved among the study participants, according to the findings. In addition, recovery from afewadverseeffectstookonlyafewdays,whichmightbeusedtominimizepublicvaccinationapprehension.

KEYWORDS: Adverseeffects,COVID-19,mRNAvaccine,SARS-CoV-2,COVID Vaccines,Immunization.

I.INTRODUCTION

In contemporary history, the year 2020 will be recognized as the most difficultyear in the fight against SARS CoV-2, a virus that causes severe respiratory sickness. Thisepidemic put a strain on health professionals around the world, resulting in unparalleledhealth-caresystem paralysis and aglobal economiccrisis[1].

The task of providing suitable prevention and treatment modalities to battle the pandemicwasplacedathealthcarepractitioners,academics,andpoliticiansallaroundtheworld.ScientistshavebeenworkingoneitherrepurposingcurrentmedicationsorgeneratingCOVID-19vaccines sincethe beginningof thepandemic[2].

Severe Acute Respiratory Syndrome (SARS) causes Corona virus Disease 2019 (COVID-19). As the disease causes a significant public health emergency, Coronavirus-2 (SARS CoV-2) is changing the pattern of emergency services around the world. The illness originallysurfaced in Wuhan, China, in December 2019 and quickly spread around the world. Thevaccine plan against COVID-19 is seen as the last solution to this global crisis. The COVID-19 vaccination prepares the immune system to fight the virus by triggering the production ofantibodies. mRNA vaccines, such as Pfizer-Biotech COVID-19 vaccines, vector vaccines,suchas Covishieldvaccinations, andinactivated vaccines,such as Covaxinvaccine [3,4,5,6].

COVID-19 vaccination helps to prevent COVID-19 infection. Vaccine side effects insome people are natural evidence that their bodies are building protective mechanisms. Theseside effects may make it difficult for them to perform daily duties, but they should pass in afewdays. Somepersonsexperienceno sideeffects,and allergicreactions areunusual[7].

InEurope,the firstmassimmunizationeffortbeganinearlyDecember 2020.Morethan 1.9 billion doses of the COVID-19 vaccination were administered globally till June 2021.Throughout the deployment of vaccination programs, the general public expressed hesitancyand reluctance to take the COVID-19 vaccines, as well as concerns about them. Many

factorshavecontributedtopublicdistrustanddread,including therapidmanufactureofvaccinations,alackofknowledge,anduncertaintyabouttheeffectsthatemerge aftervaccination,aswell as reports ofadverseeffects disseminatingthrough themedia[8,9].

Many cases of adverse effects have been recorded as vaccination rates have increased,including those that are common and less severe, as well as those that are unusual butimportant.Becauseofvariancesin age,race,andunderlyingconditions, thereportedratesof adverseeffectshavebeeninconsistent.Previousresearchhasconcentratedonthefrequencyof local and systemic adverse effects. However, the widely used system for reporting theserates relies on a binary response (yes or no) for each adverse effect, making it impossible todeterminethe severityofthe problem and its impact on work and dailylife[10,11].

People'sdesiretogetvaccinatedagainstCOVID-19hasfallendramaticallyduringthepandemic, with over half of the population were hesitant or unwilling to get vaccinated.Hence, the study was planned to monitor the adverse events following immunization (AEFIs)for COVID-19 vaccines among the general population and to analyze the evidence on safetyofCOVID-19vaccineandtoincreasepublicunderstandinganduptakeofCOVID-19vaccinesusingaquestionnairebased study.

II. METHODS

AcomparativeobservationalstudywasconductedfollowingPRISMAguidelinesamongthepeopleaged18yearsandabove.Theresponseswerecollectedthroughaquestionnaire, which included questions related to demographics of the participants as well asto examine the experience after COVID 19 vaccinations. The participants were detailed aboutthe nature of the survey and an informed consent was obtained from all the respondents. Thesurvey was carried out using goggle form, which was circulated through various social mediaande-services.

A total of 1018participants took part in the survey. At the start of the survey, there was a detailed consent section that explained the study'sintent, the types of questions we would ask, the anonymity of the study, and the study'svoluntarynature.

TABLENO:01 SurveyQuestionnaire

COVID-19VaccineAdverseEffectsMonitoringQuestionnaire
SectionA:Socio-demographicprofile
Name: Age: Gender: Residencearea: Education:
SectionB:Questionnaire regardingtheadverse effectsofCOVID–19vaccine
Pleasereadthegiven questions/statementscarefullyand respondtobestofyour knowledge:
HaveyoutakentheCOVID–19vaccine? HowmanydosesofCOVID–19vaccineshave youtaken?HaveyourfamilymembersreceivedCOVID –19 vaccine? Have you received any other vaccine(s) (apart from COVID – 19 vaccine)?Whichvaccine wouldyou prefer? Wheredidyou getvaccinated? HaveyoubeeninfectedbytheCOVID –19virus? Haveyoutestedtoseeif youhaveCOVID –19(PCRtest)?Do you haveanychronic diseases? Do you haveanyof thefollowingdisease?

Haveyoubeenallergictofooditems/drugs?
Aftervaccination,didyousuffer anyadverseeffects?Severityof sideeffects/adverseeffects
Durationofsideeffects/adverseeffects?
Did youexperienceanyofthefollowingconditionsaftervaccination?Do you thinkthat COVID-19vaccinations isnecessary?

III. RESULT

A total of 1018 people took part in the research. Findings revealed that 51.1% of surveyedparticipantswere maleand48.6% were female,and47.5% were intheage group of 18-24years.

The majority of the participants in our study, 1018 (100%) were graduates (Table 2). Forobtaining information, the participants were requested to complete a standardized questionnairethat was pre-validated by three independent reviewers whose replies were not included in thestudy.
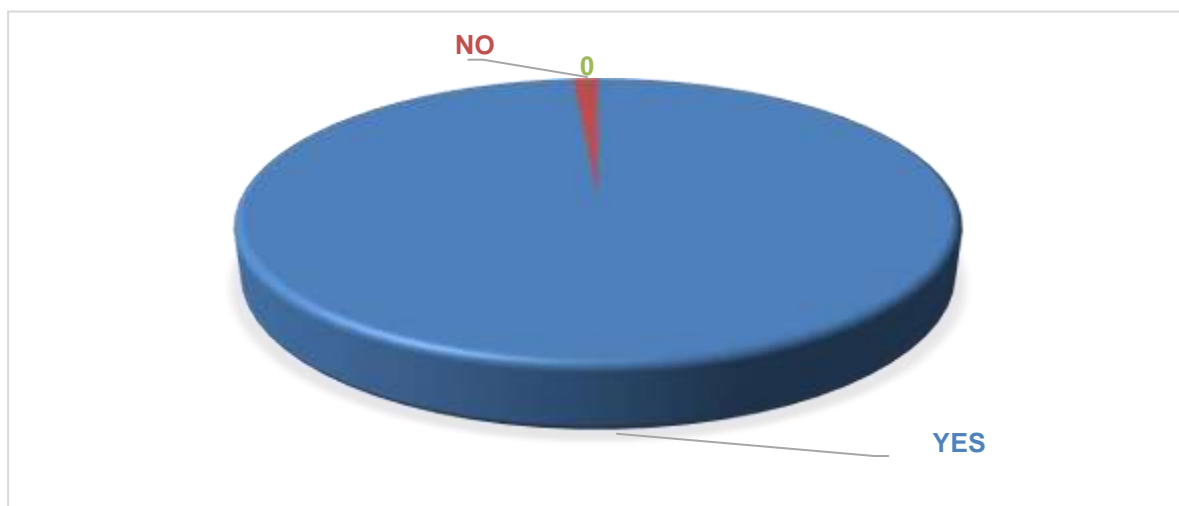
TABLENO:2DemographiccharacteristicsofParticipants

Socio-demographic variable	Frequency(n= 1018)	Percentage (%)
Age (years)18-24		
25-34	484	47.5%
35-44	227	22.3%
45-64	177	17.4%
>64	93	9.1%
	37	3.7%
GenderMaleFemale		
Prefernot to say		
	520	51.1%
ResidenceareaUrban	495	48.6%
Rural	03	0.3%
Education IlliteratePrimary		
	325	31.9%
	693	68.1%
	38	3.7%
	86	8.5%

HighSchoolGraduation	320	31.4%
Post -graduationOther	350	34.4%
	194	19.1%
	30	2.9%

TABLENO:3Responsetoquestionnaire

SURVEY CHARACTERISTICS	Frequency (n=1018)	Percentage (%)
HaveyoutakentheCOVID –19vaccine?Yes No	1008 10	99 01
How many doses of COVID – 19 vaccine have youtaken? 1 2	226 752	26.1 73.9
HaveyourfamilymembersreceivedCOVID –19vaccine? YesNo	889 129	89.9 10.1
Haveyoureceivedanyothervaccine(s)(apartfromCOVID– 19 vaccine)? YesNo	20 998	02 98
Whichvaccinewouldyouprefer?Covaxin CovishieldSputnikPfizer	273 593 56 96	26.8 58.3 5.5 9.4
Wheredidyougetvaccinated?Governmenthospital Private hospitalVaccination campOthers	504 191 317 06	49.5 18.8 31.1 0.6
Haveyoueverbeeninfected bytheCOVID –19virus? YesNo	86 932	8.4 91.6
Have youtestedtoseeifyouhaveCOVID–19(PCRtest)? YesNo	868 150	85.3 14.7

|		
Doyouhaveanychronicdiseases?Yes	89	8.7
No	929	91.3
Doyouhaveanyofthefollowingdiseases?Diabetesmellitus	32	35.8
Rheumatoid arthritisHypertensionAsthma	15	16.7
Anaemia	21	24.1
	10	10.9
Have	11	12.5
youbeenallergictofooditems/drugs?Yes		
No		
	140	13.8
Aftervaccination,didyousufferanyadverseeffects?	878	86.2
YesNo		
	1002	98.4
Severityofsideeffects/adverseeffectsMildeffects	16	1.6
ModerateeffectsSevereeffects		
	342	33.6
Duration of side effects/adverse effects?1–2	399	39.2
days	277	27.2
3–7days		
Morethan aweek		
	671	65.9
Didyouexperienceanyofthefollowingconditionsaftervaccination?	292	28.7
	55	5.4
Pain at injection siteFatigue		
HeadacheMusclepainFeverOthersDiarrhoea		
	410	40.3
DoyouthinkthatCOVID-	75	7.4
19vaccinationsisnecessary?	71	7
YesNo	172	16.9
	217	21.2
	51	5
	22	2.2
	973	95.6
	45	4.4

Figure:1Percentageofvaccinatedrespondents

Figure 1 shows almost all the respondents 99% (1008 members) out of 1018 respondentsarevaccinated that COVID-19 vaccine is necessaryat this pandemicsituation.
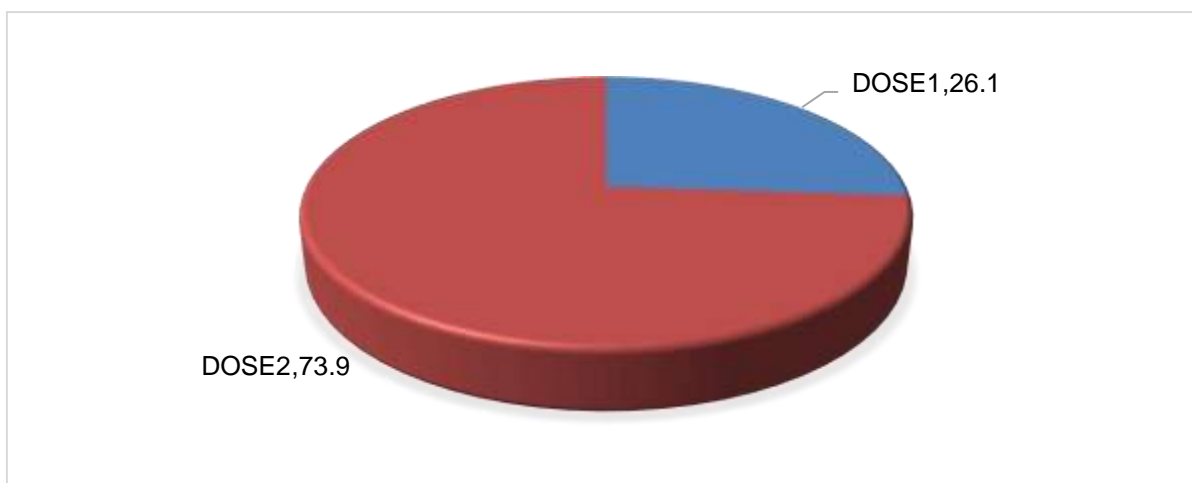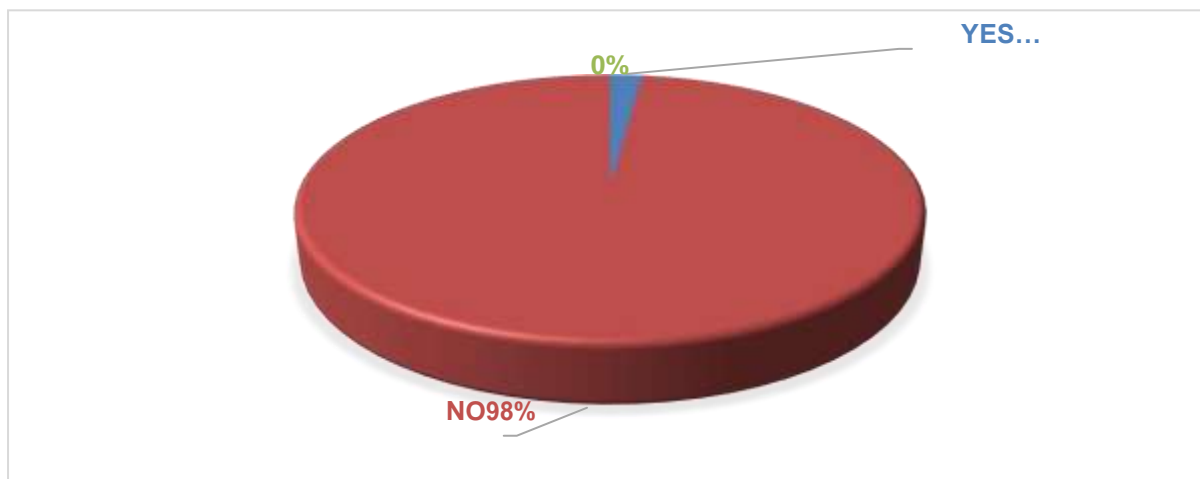

Figure:2DoseofVaccination

Majority of the respondents 73.9% were vaccinated with 2nd dose and26.1%with1[st] dose as indicated in figure 2.
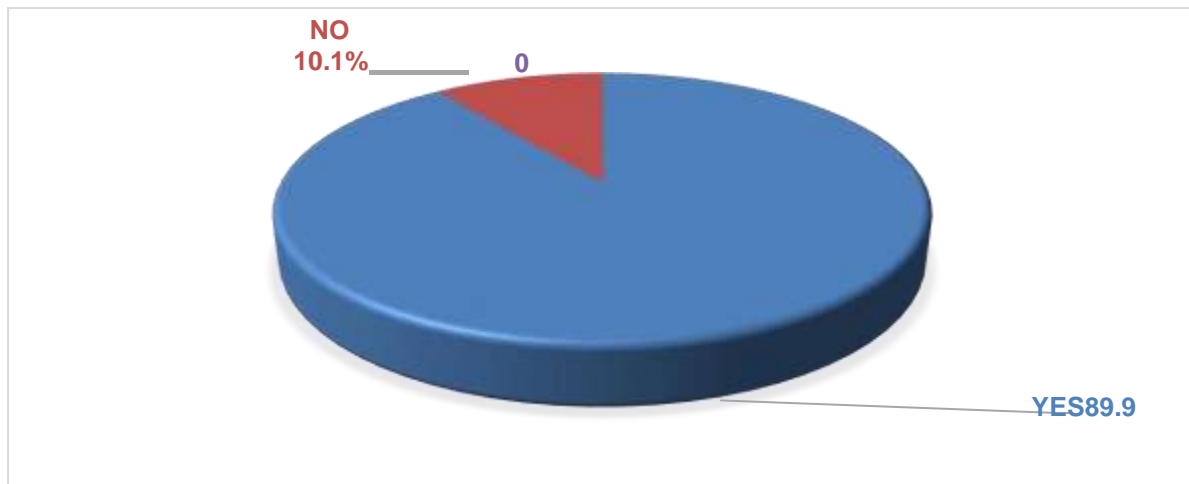
Figure:3Vaccinationdetailsoffamilymembers.

Almost (89.9%) of the respondents family members are vaccinatedwithCOVID-19 vaccine (figure-3).

Figure:4Patientimmunizationhistory

Among 1018 respondents only 2% of peoples are received vaccineotherthan COVID–19vaccine as shown in figure-4.
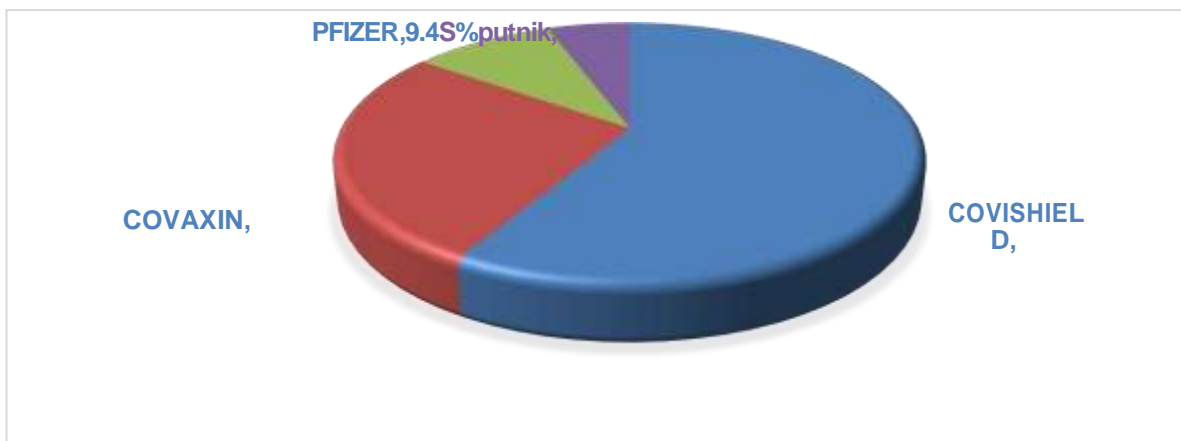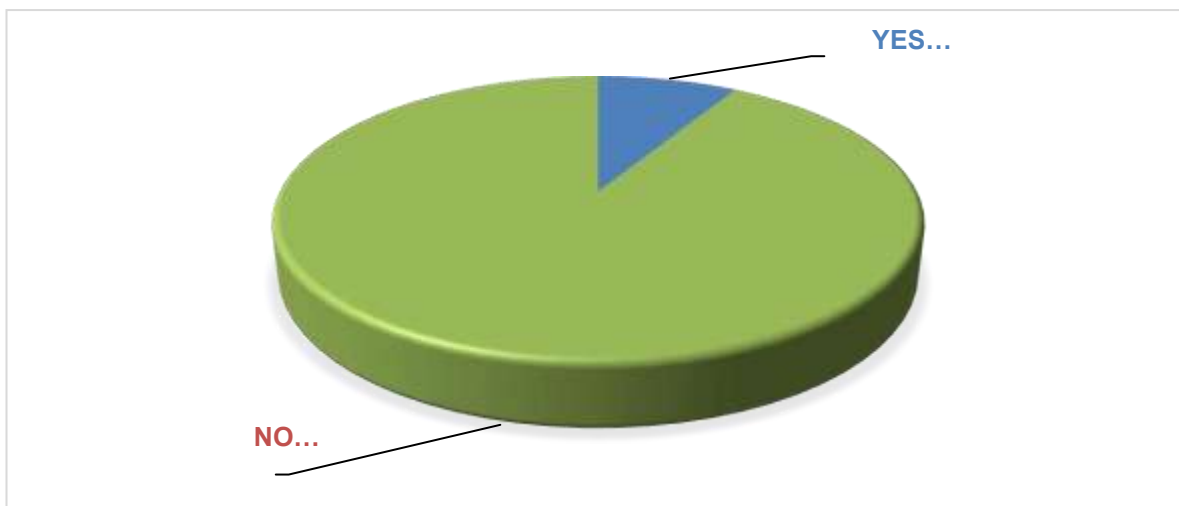
Figure:5VaccinePreference

593participants (58.8 %) out of 1018participantsarevaccinated with COVISHIELD.
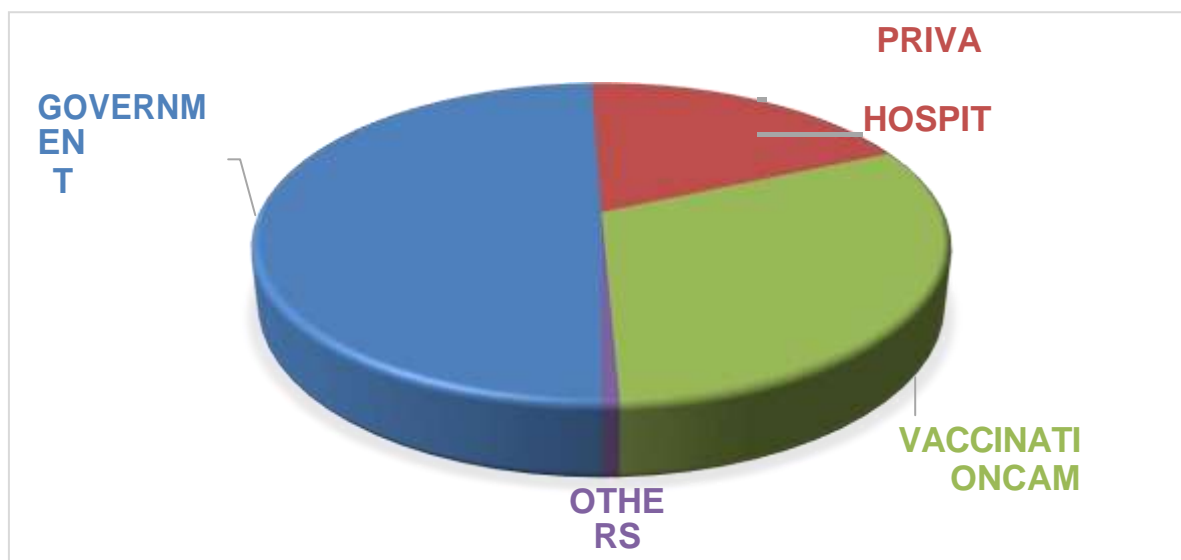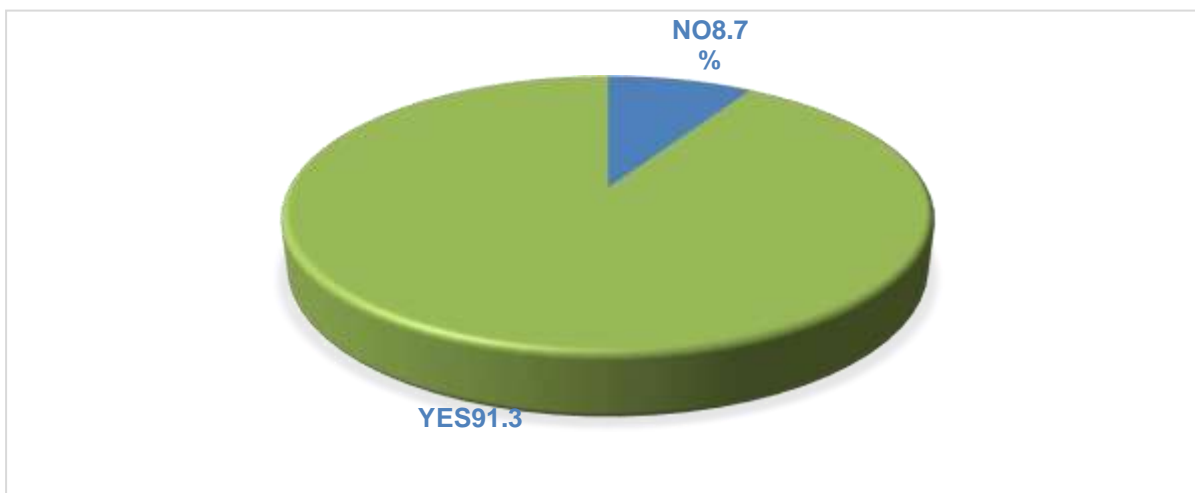

Figure:6Vaccinationcentre

Government hospitalswere the placewheremostof theparticipants 49.5%(473members) got vaccinatedas reported in the figure.

Figure:7COVID-19Infectiondetails

Only8.37%(85)respondentshavebeeninfectedwithCOVID-19 virus after vaccination.

Figure:8Respondentswithcomorbidities

Figure 8,9 shows that only 89 participantsare havingchronicdiseases out of which 32 members are having Diabetesmellitus.

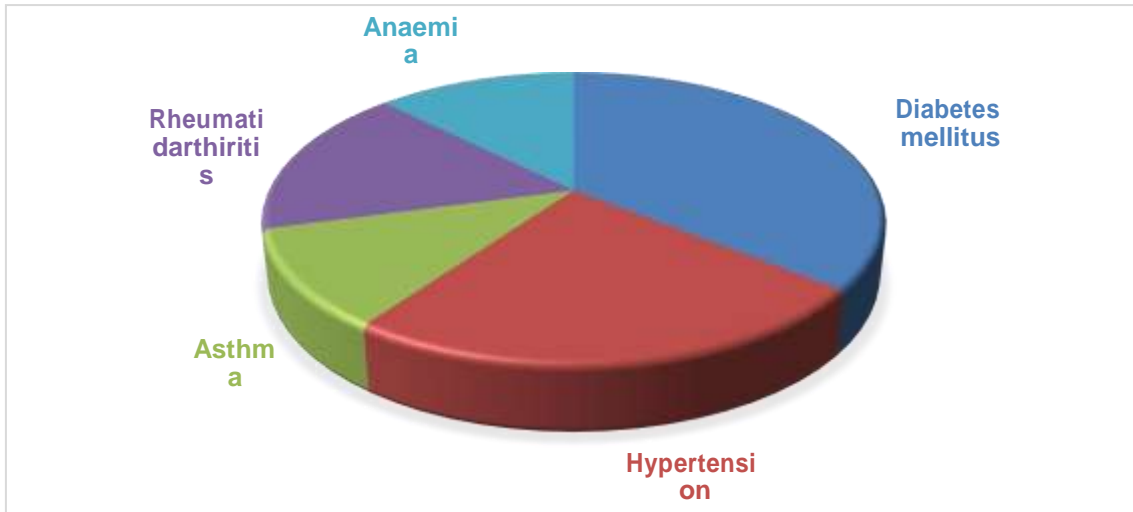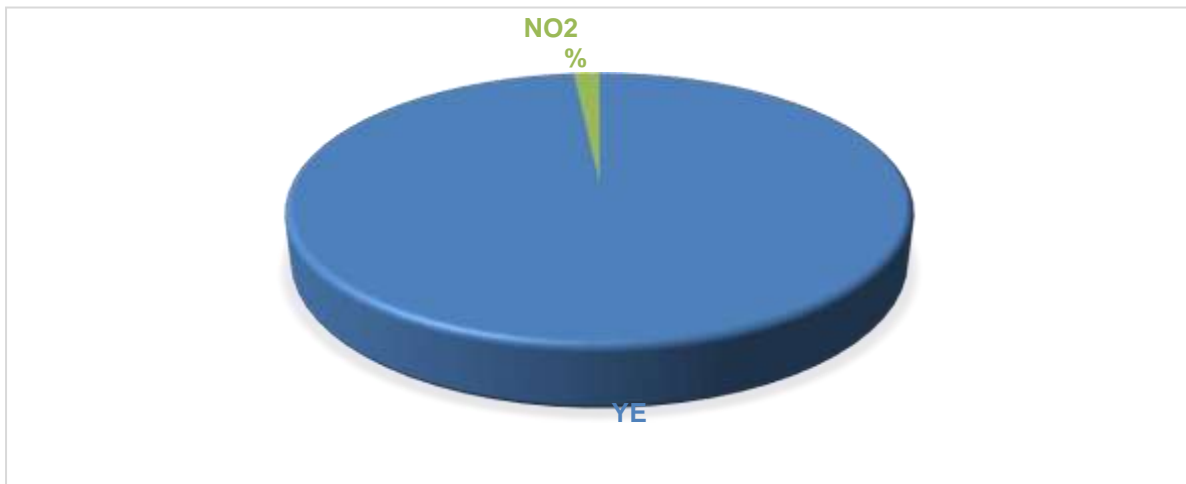**Figure:9Chronicdiseasedetails**

Figure:10Percentageof adverseeffectsfromrespondents.

Majority of the respondents reported adverse effects after COVID-19vaccination and 38% participants reported mild to moderate symptoms (figure-10,11).
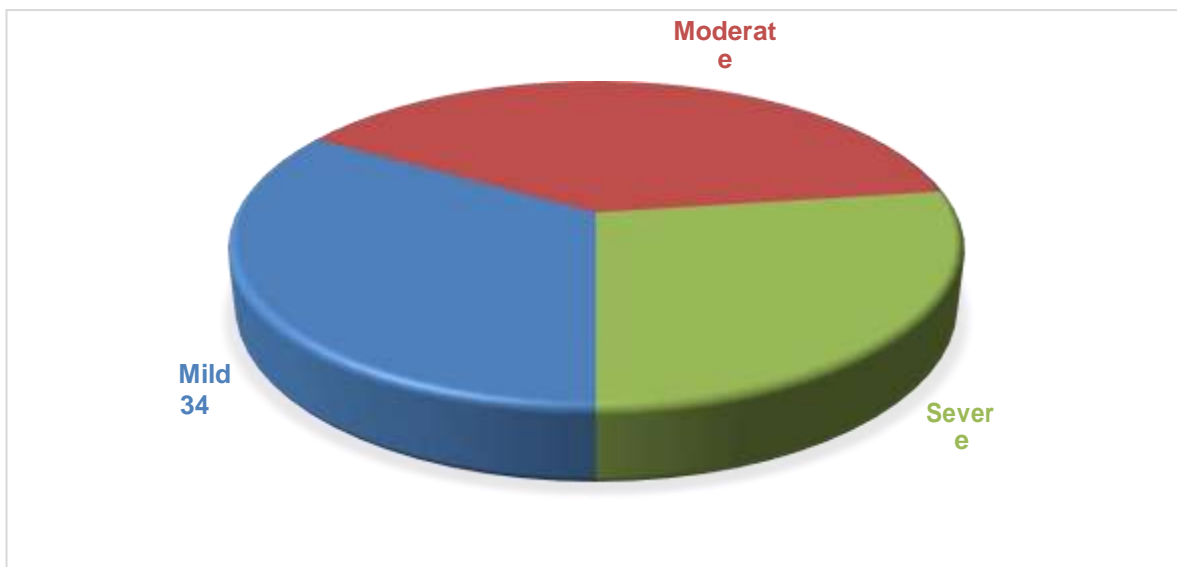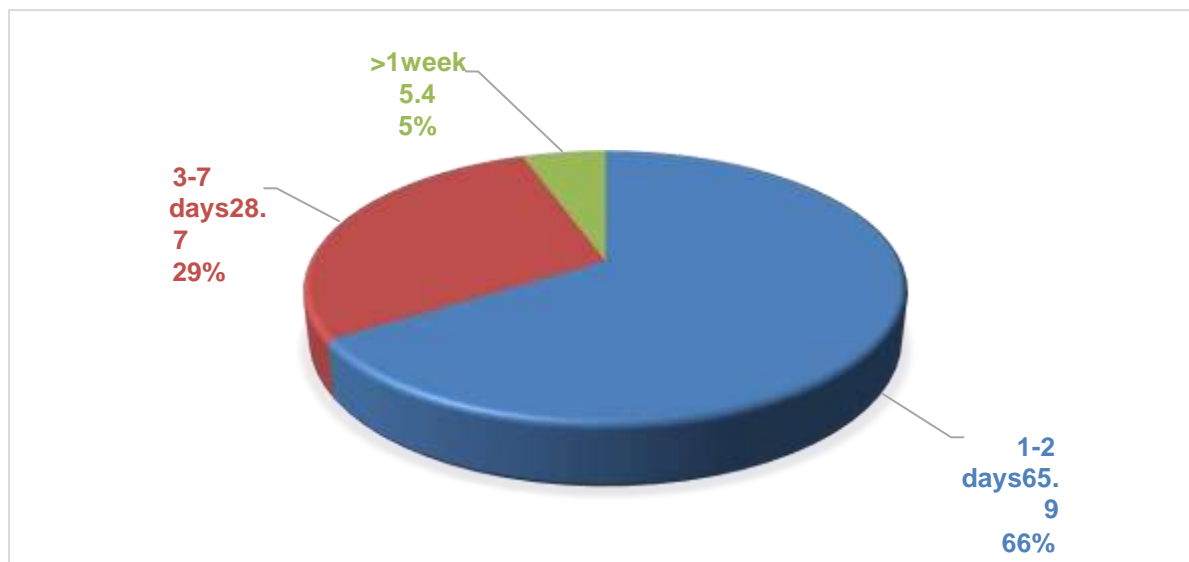
Figure:11 Severity of adverse effects.

Figure:12 Duration of adverse effects

Figure 12 indicates the duration of side effects after COVID– 19 vaccination, with majority of the respondents (66% - 671 participants) stated that the duration of side effects ranged for a period of 1-2 days and most of the adverse effects are included mainly, Pain at the site of injection 40% (407 members) followed by Fever 21 % (213 members). Muscle pain was experienced by 17 %(173 members) out of 1018 participants (figure-13).
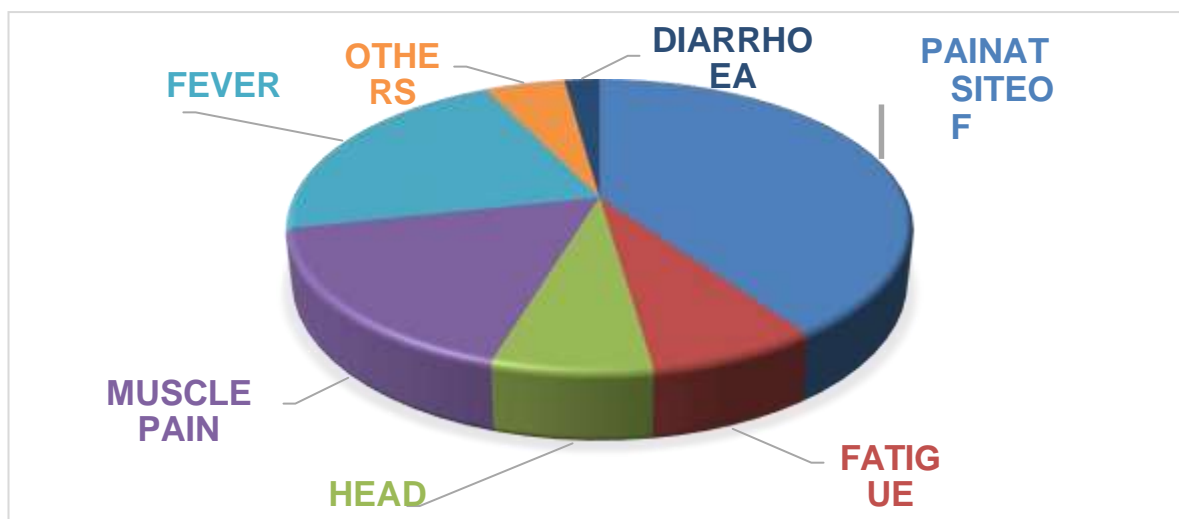
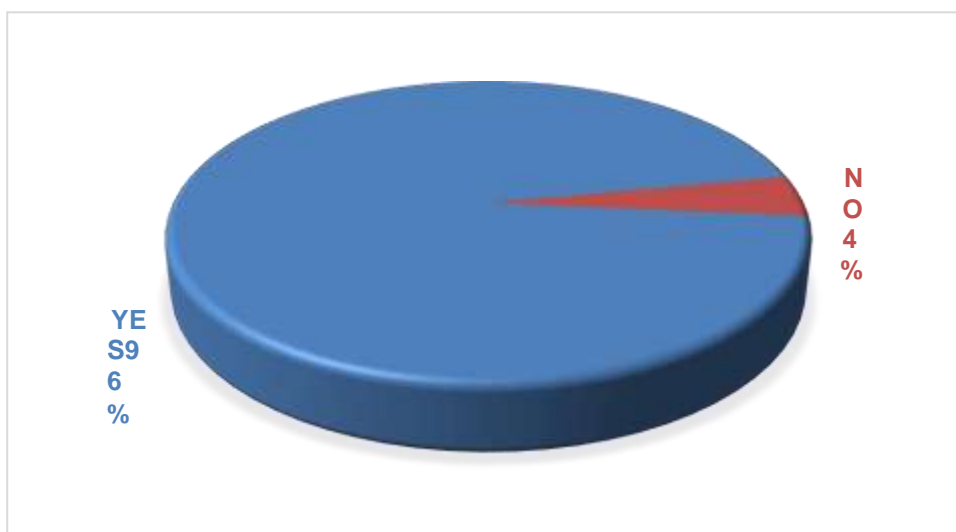**Figure:13AdversereactionsafterCOVID-19vaccination.**

Figure:14Percentageofvaccinationacceptance.

As shown in thefigure16, almost all there spondents95.8%(975members)agreedthatCOVID-19vaccine is necessaryat this pandemicsituation.

IV. DISCUSSION

A validated questionnaire was developed to understand the adverse events (AE) followingvaccination. In this questionnaire, the COVID-19 vaccine AE was assessed by asking variousquestions related to eligibility of different population groups and time duration in which theAEs started. The results of the questionnairewill give government officials and healthcare practitioners a better understanding of theCOVID-19vaccine'sadverseeffects.

An online survey link was distributed to the vaccinated people during the first week ofDecember 2021 to collect information on the first and second doses, symptoms, severity, andoutcome following immunization.

The study included 1018 vaccinated individuals, of which 1008 participants had receivedtwo doses. Findings revealed that 51.1% of surveyed participants were male & 48.6% werefemale, and 47.5% were in the age group of 18–24 years. Only 13.8% had a history ofallergy. Overall, 98.4% had AEs after vaccination, especially those younger than 34 years

ofage,female, historyof co-morbidity.

The most common AE were pain at the injection site (40.3%), fever (21.2%) and musclepain (16.9%). Most AEs started very early (within 1-2 days), and rarely delayed in recovery(>1weeks). Only1.7%requiredhospital admission.

Duetothevaccine confidenceuncertainty surrounding new vaccinations and infectious illnesses, public vaccine trust wouldbelowered[25].Despite the fact that estimates of herd immunity and vaccination are always changing,some estimates imply that at least 60% of a population must be vaccinated to obtain herdimmunity. It is critical to project public acceptability of the COVID-19 vaccine and discoverdeterminantsofvaccine acceptanceinordertoensureequaldistributionof thevaccinations[26].

The results of this survey revealed that a substantial percentage of people requested to getvaccinated, and the acceptance rate was almost at the level needed to develop herd immunity(60 percent). However, the majority of them would postpone immunization owing toconcerns about the new vaccine's safety and efficacy. There was a reasonable linkbetween COVID-19 vaccination acceptance and socio-demographic variables such age,gender, greater educational attainment, and work position. These findings are in line withthoseofotherrecent studies donein other nations[27].

The determinants of vaccine acceptance or immediate vaccination arecomplicated and context-specific, and they vary with time, place, and vaccine type [27,28]. Forexample, 13 percent of a large vaccine-accepting population (67 percent) preferred topostpone immunization to assess effectiveness and safety [30].The research has beenconducted in a number of factors that influence people's immediate vaccination intentions inBangladesh. Immediate immunization was shown to be linked to gender, religion, area, andmarital status. Males and those who reside in rural regions were more likely to get vaccinatedright away. Previous vaccination experience beyond the age of 18 was substantially relatedwith vaccine acceptability, but not with rapid vaccination, which contradicts earlier researchfromother countries[28,29].

Vaccine safety has been reported as the main barrier for deciding for immediatevaccination among people especially for vaccines that are newly developed [28,29]. A studyconducted to look at the acceptability of the newly developed COVID-19 vaccine amongBangladesh people reports similar findings. Thepresent state of public opinions and readiness to get COVID-19 vaccine was examined whichhelpthepolicymakerstousethe datato determinewhichpopulations (over 70, rural,andwomen) or communities need extra attention during COVID-19 immunization efforts.Because achieving herd immunity requires a high vaccination rate, the general public must beencouragedto becomevaccinated[31].

In a research conducted by Riad and othersamong Turkish healthcare professionals, morethan 10% of the participants reported injection site discomfort (41.5%), weariness (23.6%),and headache (18. 7%); which was identical to our findings. Younger individuals (ages 49and less) were more likely to be impacted in our research than older persons (ages 49 andover). Because an injection into a relaxed muscle causes less pain than an injection into atensed muscle, experts recommend lowering the patient's arm to be injected to lessendiscomfort.Furthermore,vaccinations shouldbe maintained ata lowtemperaturein situ.

Injections given without adequate warming may result in discomfort at the injection site [32].Serious adverse effects, such as anaphylaxis or allergy, were uncommon as identified in acohort of 19 586 patients who reported getting COVID-19 immunization. Participants with ayounger age, female sex, past COVID-19, Asian race, pregnancy at baseline, and marijuanausage were more likely to experience adverse effects after receiving the entire immunizationdosage [33]. Lower likelihood of reporting unfavourable symptoms were connected with olderage, Black or African American race, greater subjective social position, asthma, and anemia[34]. The low prevalence of significant side effects identified in our study is in line with theevidences from randomized clinical trials and government-sponsored vaccination safetysurveillance [35]. A meta-analysis found that people with asthma may appear to have lowerriskofCOVID-19 than thegeneral population[36].

In our survey, side effects have been produced within the duration of 1-2 days (66%) aftervaccination and 29% has been produced within 3-7 days of vaccination. Our study reportsshow that 85 members (8%) have been infected in COVID 19 disease while 92% has notbeen infected in COVID 19. Overall reports show that there were no severe

adverse effectsreported among the study population. Also, the recovery from the reported mild side effects took only fewdayswhich maybeestablished to reducethe vaccination hesitancyamongthepublic.

V. CONCLUSION

The data on vaccine safety and adverse effects are strongly required to strengthen thepublic confidence in the vaccine, and toprovide a better understanding ofreducing thepotentialriskfactorsofvaccineadverseeffects.Ours tudyreportshowsthatthemostcommonsideeffects oftheCOVID-19vaccine amonggeneral populationwerepainatinjection site, fatigue, headache, muscle pain, chills, and joint pain. It was observed that theadverse effects were mild and no severity was observed among the study population. Furtherresearch in varied population and larger sample size may help in improving the acceptanceratefor vaccination.

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