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KNOWLEDGE, ATTITUDE, AND PRACTICE STUDY OF ADVERSE EVENTS FOLLOWING IMMUNISATION WITH REGARD TO COVID VACCINES AMONG MBBS STUDENTS IN A TERTIARY CARE HOSPITAL

A. Archana [1], S. Deepa [2], A. Anandhalakshmi [*2] and A. Meeradevi [2]

Department of Pharmacology [1], Government Medical College Krishnagiri, Krishnagiri - 635115, Tamil Nadu, India.
Institute of Pharmacology [2], Madras Medical College & RGGGH, Chennai - 600003, Tamil Nadu, India.

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Correspondence to Author:
Dr. A. Anandhalakshmi, MD

Assistant Professor,
Institute of Pharmacology,
Madras Medical College & RGGGH,
Chennai - 600003, Tamil Nadu, India.

E-mail: dranuartha2013@gmail.com

ABSTRACT: Aim: To evaluate the knowledge, attitude and practice (KAP) related to Adverse Events Following Immunisation (AEFI) of COVID-19 vaccines among MBBS students of Madras Medical College. **Materials and Methods:** A cross-sectional online survey was conducted using a Google Forms questionnaire circulated *via* e-mail and WhatsApp. A total of 256 MBBS students participated in the study. Responses related to knowledge, attitude and practice of AEFI reporting were collected and analysed descriptively. **Results:** Among the respondents, 98% knew the correct expansion of AEFI, 94.1% identified the symptoms of mild AEFI, and 92.7% were aware of cluster AEFI. Regarding attitude, 64.8% agreed that local post-vaccination symptoms resolve spontaneously, and an equal proportion strongly agreed that AEFI reporting contributes to vaccine safety. For practice, 95.7% strongly agreed that they would encourage their peers to report AEFI, and mobile applications were the most commonly used reporting method. **Conclusion:** MBBS students demonstrated adequate knowledge and a positive attitude towards AEFI associated with COVID-19 vaccines. However, the actual practice of AEFI reporting was relatively lower, indicating the need for enhanced awareness and continuous training to strengthen reporting practices.

INTRODUCTION: COVID-19, caused by SARS-CoV-2, a novel coronavirus, is a highly contagious disease that was declared a pandemic by the World Health Organization (WHO) on 11 March 2020 [1, 2]. The rapid development of effective vaccines became essential to control this global threat. Several COVID-19 vaccines were granted Emergency Use Authorisation (EUA) and made available to the public by December 2020 [3].

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Adverse Events Following Immunisation (AEFIs) are defined as untoward medical occurrences that follow immunization and do not necessarily have a causal relationship with vaccine administration [4]. Vaccine pharmacovigilance aims to reduce misconceptions regarding vaccines by continuously monitoring immunization safety and improving the quality of vaccination services [5].

An efficient AEFI surveillance system is crucial for implementing safe and cost-effective public health immunization programmes [6, 7]. COVID-19 vaccines were made freely available nationwide, with priority for high-risk groups, including healthcare professionals and MBBS students, from January 2021 to promote herd immunity.

Reporting of AEFIs, particularly by undergraduate medical students, provides valuable safety data for future reference and helps guide the development of vaccine safety policies [8]. This study was conducted among MBBS students to assess their knowledge, attitude and practice regarding AEFIs related to COVID-19 vaccines and their reporting to the Pharmacovigilance Programme of India (PvPI) using a structured questionnaire.

MATERIALS AND METHODS:

Study Centre: Institute of Pharmacology, Madras Medical College and RGGGH.

Study Period: November 2021-December 2021.

Study Population: Second, Third & Final year MBBS students of Madras Medical College, Chennai.

Study Tool: Questionnaire (Google form).

Sample size: 255

The sample size was calculated using the formula,

$$N = (Z_{1-\alpha/2})^2 \, SD^2 / d^2$$

d = Absolute error (or) precision= 0.5, SD = Standard deviation of the variable= 4.075, Z (95% CI) = 1.96(Z1-α/2 – Standard normal variate for 95% confidence interval = 1.96), Substitute:

$$N = (1.96)^2 \times (4.075)^2 / (0.5)^2$$

N= 255

Inclusion Criteria:

1. MBBS students of the Second, Third and Final year who are willing to take part in the study.
2. MBBS students of the Second, Third and Final year who had received at least one dose of any one of the COVID vaccines available in India.

Exclusion Criteria:

1. MBBS Students of Second, Third and Final year who are not willing to take part in the study.
2. MBBS students of Second, Third and Final year who had not received even one dose of any one of the COVID vaccines available in India.

Study Procedure:

Study Design and Participants: A cross-sectional survey was conducted among second-, third-, and final-year MBBS students of Madras Medical College, Tamil Nadu, from November 2021 to December 2021. The study was approved by the Institutional Ethics Committee (IEC Approval No.: 21112021). First-year MBBS students were excluded, as many had not yet attained 18 years of age. Students who had received at least one dose of any COVID-19 vaccine available in India and who provided informed consent were included.

Questionnaire Development and Data Collection: A validated questionnaire was developed based on an extensive literature review and peer group review. Search strategies were executed in PubMed using keywords such as *AEFI* and questionnaire to identify relevant cross-sectional studies [9, 10]. Due to social distancing requirements during the pandemic, an online survey method was chosen. The questionnaire, along with an informed consent form, was created using Google Forms. The survey link was distributed to eligible MBBS students through e-mail and WhatsApp. Participants were informed about the study's purpose on the first page of the online form. Participation was anonymous, voluntary, and based on explicit informed consent. To prevent duplicate entries, the form was restricted to one submission per respondent. Students were requested to complete the survey within five days.

Questionnaire Structure: The questionnaire contained 24 items divided into four sections:

1. Demographic details: Age, gender, year of study, and the type of COVID-19 vaccine received.
2. Knowledge: Eight true/false questions assessing knowledge of AEFI related to COVID-19 vaccines.
3. Attitude: Eight statements rated on a 5-point Likert scale (strongly disagree to strongly agree)[11]
4. Practice: Four Questions assessing AEFI reporting practices to the Pharmacovigilance Programme of India (PvPI).

For attitude items, participant scores were summed, and mean scores were calculated. A mean score ≥4 indicated a favourable attitude, whereas a score <4 indicated an unfavourable attitude [12].

Data Analysis: Once the required sample size was reached, responses were exported to an Excel sheet and subjected to statistical analysis by frequency distributions as percentages and Likert scale.

RESULTS: In our study, we involved undergraduate medical students as our study population, and the AEFI with regard to COVID vaccines were analysed based on their responses to the questionnaire-based KAP survey through Google link.

For our analysis, we received responses from 256 medical students, excluding first year MBBS. Among the 256 students, the majority of the respondents were from the second year of MBBS (Pharmacology being one of their exam subjects in this current academic year) **Table 1.**

TABLE 1: DISTRIBUTION OF RESPONDENTS BASED ON YEAR OF PURSUING MBBS

Year of MBBS	Frequency (Number of respondents)	Percentage (%)
Second year	119	46.3
Third year	78	30.6
Final year	59	23.1
Total	256	100

On analysing the gender distribution of respondents, this study showed a male preponderance in actively taking up the questionnaire **Fig. 1.**

Among the respondents in our study, the majority received the Covishield type vaccine **Fig. 2, Table 2.**

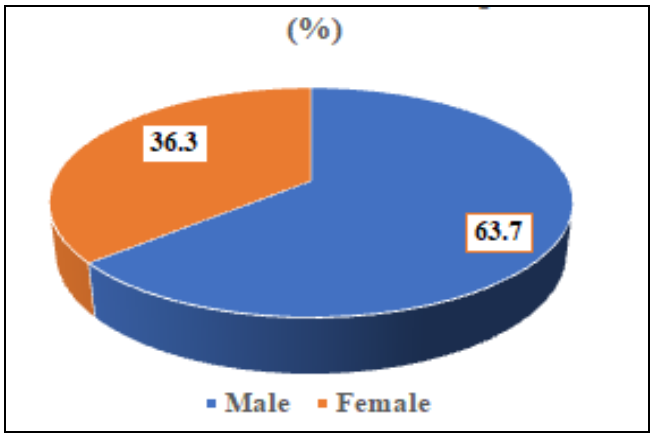

FIG. 1: GENDER-WISE DISTRIBUTION OF RESPONDENTS

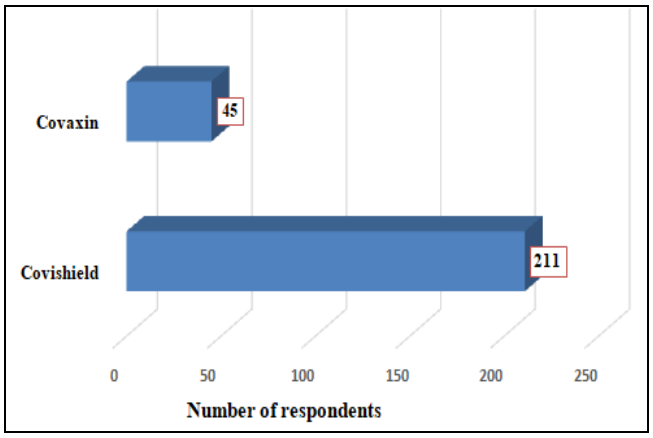

FIG. 2: TYPE OF COVID-19 VACCINES RECEIVED BY RESPONDENTS

TABLE 2: COVID-19 VACCINE TYPE DISTRIBUTION

Vaccine	Frequency (Number of respondents)	Percentage (%)
Covishield	211	82.4
Covaxin	45	17.6
Total	256	100

Analysing the knowledge aspect, the results of our study (denoted as percentage of respondents for each True/ False response) showed that almost all students had adequate knowledge regarding AEFI following COVID vaccines and their reporting to PvPI **Fig. 3.** The details of the questions and their coding are mentioned below **Table 3.**

TABLE 3: QUESTIONS (WITH CODES) ON KNOWLEDGE OF AEFI

Code	Knowledge Question
A	AEFI stands for Adverse Events Following Immunisation.
B	Fever, malaise and headache following COVID vaccines are only minor AEFI.
C	Immunization anxiety–related events do not come under AEFI.

D	Allergic reaction / anaphylaxis due to COVID vaccine is always a serious AEFI.
E	AEFI occurring in two or more persons in relation to time and place is called cluster AEFI.
F	ADR reporting, AEFI reporting, Haemovigilance, and Materiovigilance are components of PvPI.
G	Reporting forms for ADR and AEFI are different.
H	AEFI reporting can be done through a mobile application.
I	Only doctors can report an AEFI.

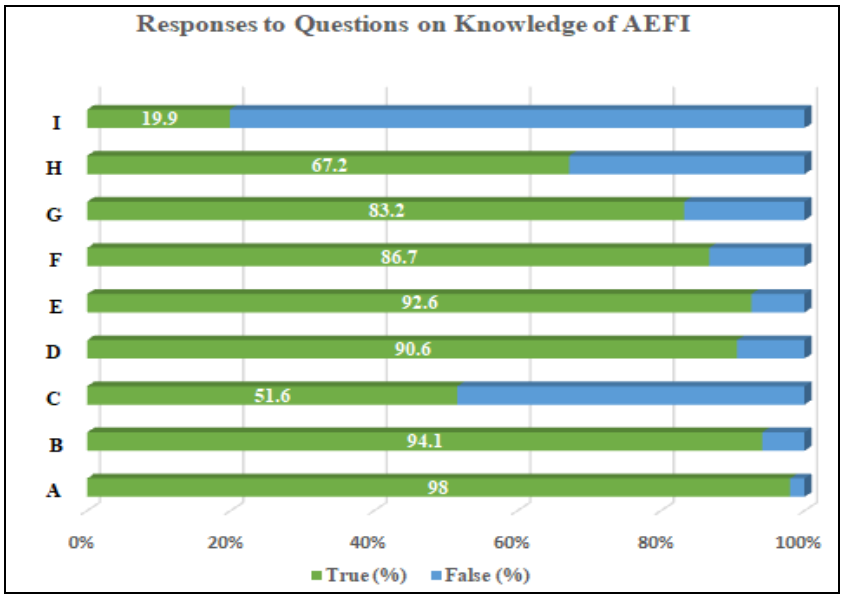

FIG. 3: DISTRIBUTION OF RESPONSES OF QUESTIONS ON KNOWLEDGE

On calculating the Likert scale score for these responses, two questions had a mean score more than 4, which indicates a positive attitude towards need for AEFI reporting. However, six questions had a mean score ranging between 2.89-3.95 which shows an acceptable students' attitude regarding AEFI symptomatology, occurrence, and reporting of all AEFI, irrespective of its seriousness and consequences, of AEFI reporting **Table 4.**

TABLE 4: DISTRIBUTION OF RESPONSES TO ATTITUDE BASED QUESTIONS

Code	Attitude Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean Score
J	Local symptoms like pain, swelling, redness may resolve spontaneously	20.7%	64.8%	4.3%	9.8%	0.4%	3.95
K	Systemic symptoms like fever, malaise, headache may not be related to vaccine	7.4%	31.3%	5.8%	39.5%	16%	3.25
L	Majority of AEFI are coincidental.	6.3%	35.9%	9%	38.3%	10.5%	2.89
M	It is necessary to report AEFI to the health system	59%	37%	1.6%	1.6%	0.8%	4.51
N	Only serious AEFI should be reported	5.1%	21.1%	4.3%	49.6%	19.9%	3.58
O	Reporting AEFI may cause vaccine hesitancy among peers	7.4%	42.2%	10.5%	30.1%	9.8%	2.92
P	Reporting AEFI is a time-consuming process	2.3%	24.2%	14.1%	43.8%	15.6%	3.46
Q	Reporting AEFI provides data for vaccine safety	64.8%	32.8%	1.6%	0.8%	0	4.61

TABLE 5: QUESTIONS (WITH CODES) REGARDING AEFI REPORTING PRACTICES

Code	Questions on Practices
R	Have you experienced any AEFI following COVID vaccine?
S	If yes, have you reported the AEFI that you experienced?
T	Through which one of the following have you reported AEFI?
U	Are you willing to insist fellow students to report any AEFI?

Among the 256 respondents, 93 (36.3%) of our MBBS students who participated in this study experienced AEFI **Fig. 4**. Only 15 among those who experienced AEFI had reported it **Fig. 5.**

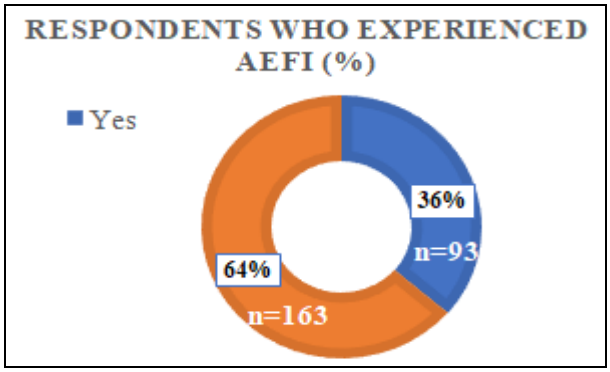

FIG. 4: PERCENTAGE OF RESPONDENTS WHO HAVE EXPERIENCED AEFI

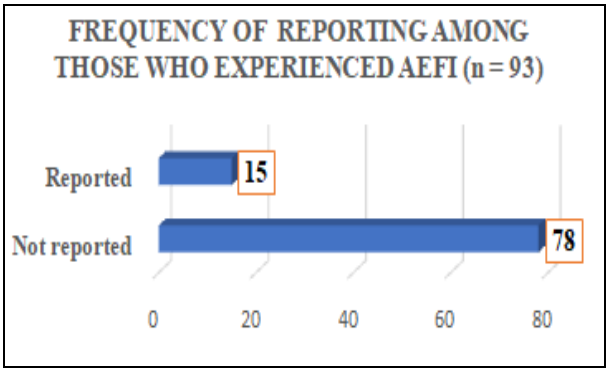

FIG. 5: FREQUENY OF REPORTING AMONG THOSE WHO EXPERIENCED AEFI

The most commonly used modality to report AEFI was the mobile app, which was considered convenient compared to other modes of reporting **Fig. 6.**

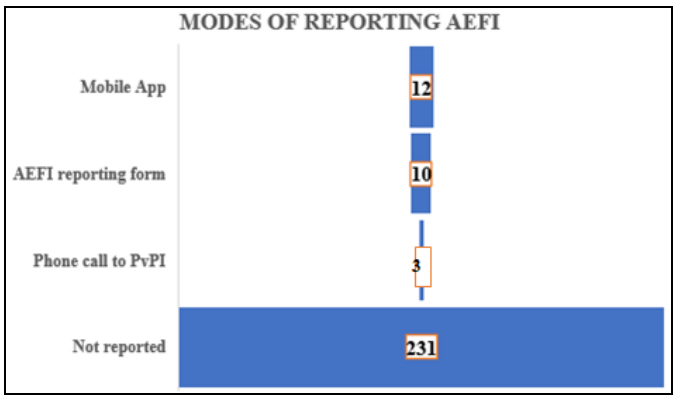

FIG. 6: DISTRIBUTION OF MODES USED FOR REPORTING AEFI

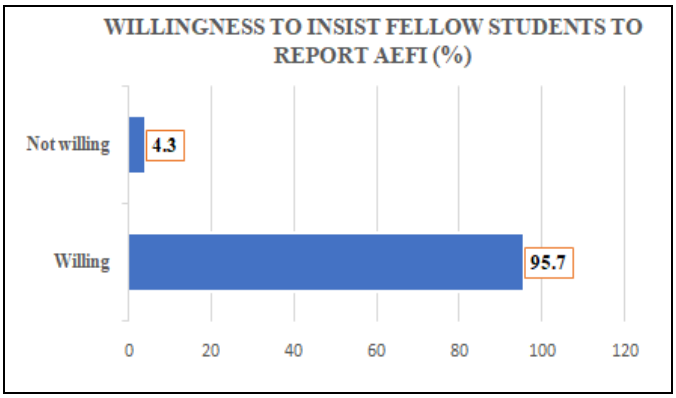

FIG. 7: PERCENTAGE OF RESPONDENTS BASED ON WILLINGNESS TO INSIST FELLOW STUDENTS TO REPORT AEFI

DISCUSSION: COVID-19, being a life-threatening disease with no definitive curative treatment, necessitated the rapid development and deployment of vaccines as the primary preventive strategy. In India, Covishield and Covaxin were the two vaccines introduced under Emergency Use Authorization (EUA) [9]. As with any newly developed vaccine, continuous monitoring of Adverse Events Following Immunisation (AEFI) becomes essential to establish a robust safety profile [10, 11].

In this context, vaccine safety data serves as an important tool for both ongoing public health decision-making and future immunization programs [13].

In the present study, 256 MBBS students (excluding first-year students) participated in a questionnaire-based KAP survey conducted through an online platform. Among the respondents, the highest proportion was second-year MBBS students (46.3%), followed by third-

year (30.6%) and final-year students (20.1%). This distribution may be attributed to active academic engagement, particularly among second-year students who study Pharmacology during the current academic cycle.

63.7% of the respondents were male, showing relatively higher male participation in the survey. Regarding vaccination, a significant majority (82.4%) had received Covishield, whereas 17.6% had received Covaxin.

Knowledge on AEFI: Overall, the respondents demonstrated a high level of knowledge related to AEFI and COVID-19 vaccines. Nearly all participants (98%) correctly expanded the term AEFI. A substantial majority recognized minor AEFI such as fever, malaise, and headache (94.1%), and most correctly identified allergic reactions and anaphylaxis as serious AEFI (90.6%). Awareness of the concept of cluster AEFI (92.6%) and knowledge regarding the components of PvPI such as reporting of ADRs, Haemovigilance, and Materiovigilance was also high (86.7%). Additionally, 83.2% knew that ADR and AEFI reporting forms differ, and 67.2% were aware of digital platforms available for AEFI reporting. Importantly, 80.1% knew that reporting is not restricted to doctors alone. These findings indicate that the majority of students had strong foundational knowledge of AEFI and reporting mechanisms. In a study on KAP regarding AEFI among health care workers by Mehmeti *et al,* a very few respondents (2%) demonstrated good Knowledge, but the majority (86.3%) had inadequate knowledge [14].

Attitude towards AEFI Reporting: In a KAP study conducted by Al-Marshoudi S *et al,* [15] 60% of participants who were unwilling to receive the vaccine cited uncertainty about the vaccine's safety as the primary reason. Similarly, a study by Bassi S *et al,* [16] reported a larger gap in the perceptions regarding vaccine safety wherein 28.8% of respondents believe that the COVID-19 vaccine might cause adverse effects.

In our study, Participants generally exhibited a better attitude toward AEFI reporting. Most students (64.8%) agreed that local AEFI commonly resolve spontaneously, and 39.5% disagreed with the misconception that systemic symptoms might not be vaccine-related. More than half (59%) strongly agreed on the necessity of reporting AEFI to the health system, and 49.6% disagreed that only serious AEFI should be reported. While 42.2% felt that AEFI reporting might induce vaccine hesitancy among peers, nearly half of the respondents (43.8%) disagreed that AEFI reporting is time-consuming. A strong majority (64.8%) acknowledged that reporting AEFI contributes to vaccine safety data. Based on the calculated Likert scale scores, two attitude-related questions had scores above 4, indicating a distinctly positive attitude toward AEFI reporting. However, six items had scores ranging from 2.5 to 3.9, suggesting that students' perceptions regarding the symptomatology of AEFI can still be strengthened through targeted educational interventions.

Practice of AEFI Reporting: Although 93 participants experienced an AEFI after receiving the COVID-19 vaccine, only 15 of these individuals reported it. In a study done in South India by Suresh A *et al,* [17] infrequent AEFI reporting by immunisation health care providers was observed similar to the findings of our study.

Among the various reporting modalities, mobile applications were used most frequently (12 students), followed by AEFI reporting forms (10 students). The pattern aligns with the findings of Parrella A *et al* [18], in which phone was noted as the preferred mode of reporting.

Importantly, 95.7% expressed willingness to insist on AEFI reporting among their peers, indicating a strong positive inclination toward strengthening AEFI reporting practices.

Overall, the practical aspects of reporting remain suboptimal, which underscores the need for targeted interventions to improve actual reporting behaviour.

CONCLUSION: From this study, the following conclusions can be drawn:

Knowledge: Second, third and final-year MBBS students demonstrated a high level of knowledge regarding AEFI following COVID-19 vaccination and the associated reporting procedures.

Attitude: The participants exhibited a promising attitude toward AEFI reporting to the Pharmacovigilance Programme of India (PvPI), recognizing its importance in strengthening vaccine safety surveillance.

Practice: Despite familiarity with AEFI reporting modalities and willingness to promote reporting, the actual practice of reporting remains inadequate.

These outcomes reflect adequate awareness and acceptance of the importance of vaccine safety surveillance among future healthcare professionals.

However, the knowledge-practice gap highlights the necessity for hands-on workshops, practical training sessions and sensitization programs integrated into the undergraduate curriculum to enhance AEFI reporting practices and strengthen vaccine vigilance at the institutional level.

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CONFLICT OF INTEREST: None declared

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