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A CROSS-SECTIONAL STUDY ON COVID-19 VACCINE SIDE-EFFECTS SELF-REPORTS COLLECTED VIA AN ONLINE SURVEY IN MALAYSIA

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ABSTRACT

Objective: It is important to collect data on adverse events following vaccination in order to evaluate the safety of any new vaccine, such as the Coronavirus-19 (COVID-19) vaccines. This study aimed to collect data on adverse effects following COVID-19 immunisation (AEFCI) among the Malaysian population via an online data collection portal and to ascertain if a similar report was made to the National Pharmaceutical Regulatory Agency (NPRA). This study also explored the patients' perspectives on how responsive the doctors were when they reported an AEFI as well as any patterns of non-reporting.

Method: This cross-sectional study used the convenient sampling method to collect data. The questionnaire was placed on the online Zoho Form platform from July 2021 to February 2022. The questionnaire was in Malay and the link 'bit.ly/Laporankesansampingan' was distributed widely using social media platforms such as of Facebook, WhatsApp, and Telegram. The questionnaire design was partly based on the Vaccine Adverse Event Reporting System (VAERS), with modifications tailored to acceptance by the Malaysian populations towards the type and design of the questionnaire.

Results: There were 2667 AEFCI reports received through the web link up to 26 Feb 2022. Around 30.6% and 6% of the respondents reported their adverse events to MySejahtera and to NPRA, respectively. In addition, only 24.2% of the medical doctors acknowledged the possibility of AEFCI, while 31.2% disagreed and 44.6% did not comment. The mean age of the respondents was 39 years. The majority were female (59%) and were Malays (91%). Most of the AEFCI appear to occur with the first dose (53%), and in particular with the Pfizer vaccine (53.5%). The majority (87.1%) of AEFCI occurred at two weeks or less after vaccine administration, of which 87.6% were moderate to severe events.

Conclusion: There should be concerted effort on the part of relevant authorities to improve the reporting of AEFCI since only 30.6% of the respondents of this study reported on My Sejahtera. This study found that only 24.2% acknowledged the possibility of AEFCI as such health authorities should make reporting of AEFCI by doctors mandatory to reduce under-reporting and under-recognition of rare but serious AEFCI.

Keywords: adverse events following COVID-19 immunisation

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1.0 INTRODUCTION

COVID-19 vaccination programme in Malaysia initiated on 24th February 2021.[1] Three main brands of Coronavirus-19 (COVID-19) vaccines that were rolled out for mass vaccination in Malaysia were Pfizer-Comirnaty, Sinovac-Coronavac and Oxford-Astrazeneca, which were still undergoing clinical trials at the time of roll-out in Malaysia. This means that the long-term safety and efficacy of these vaccines were not yet tested to ascertain their long-term safety and efficacy. [2,3,4]. The adverse effects following COVID-19 (AEFI) is a way of collecting the incidence or information on side-effects following vaccination, which does not necessarily have a causal relationship with the use of the vaccine. [5,6]. The adverse event may be, an adverse sign, abnormal laboratory finding, abnormal symptom or diseases and it is categorized into minor, rare and serious AEFI as defined below: [5,7]

- Minor AEFI - Reaction on the injection site, fever, headache, myalgia and body weakness
- Serious AEFI – death, life-threatening situation, requires hospital admission, disability or requires treatment to avoid permanent disability and lead to congenital anomaly in foetus
- Rare AEFI – anaphylaxis, severe allergy, and lymphadenopathy

In Malaysia, the adverse events following vaccination with COVID-19 vaccines can be reported to the government via two platforms, i.e., the MySejahtera and the National Pharmaceutical Regulatory Agency (NPRA) reporting systems. The MySejahtera is a digital application developed by the Government of Malaysia to assist in monitoring COVID-19 outbreaks.[8] The Malaysian Muslim Consumers Association (PPIM) is a platform for citizens to convey reports on consumer issues, which is used mainly by Muslims, while Malaysian Association of Social Impact assessment (IMPAK) is a society that focuses on the consumer rights with regards to information on health services received by the people. PPIM started receiving reports from laypersons on various adverse effects following COVID-19 vaccinations, which started in June 2021 via the link https://bit.ly/Laporankesansampingan. This platform was established for citizens who did not want to or know how to report the adverse event on the government platform for reasons only known to them. The main objective of this study was to describe the occurrence of Immunisation (AEFCI) AEFCI among the Malaysian population who made reports via the online data collection portal and to identify patterns to sociodemographic data and vaccine brands. The study would provide insights into AEFCI to event occurrence and severity and to how medical personnel responded to reported AEFCI

2.0 MATERIALS AND METHODS

This was a cross-sectional study using responses from the convenient sampling method through the online Zoho Form platform from July 2021 to February 2022. The questionnaire was in Malay and the link 'bit.ly/Laporankesansampingan' was distributed using social media platforms such as Facebook, WhatsApp, and Telegram. The questionnaire design was partly based on the Vaccine Adverse Event Reporting System (VAERS) [5] with modifications tailored to Malaysian acceptance towards the type and design of questionnaire (mainly for simplicity of responding).

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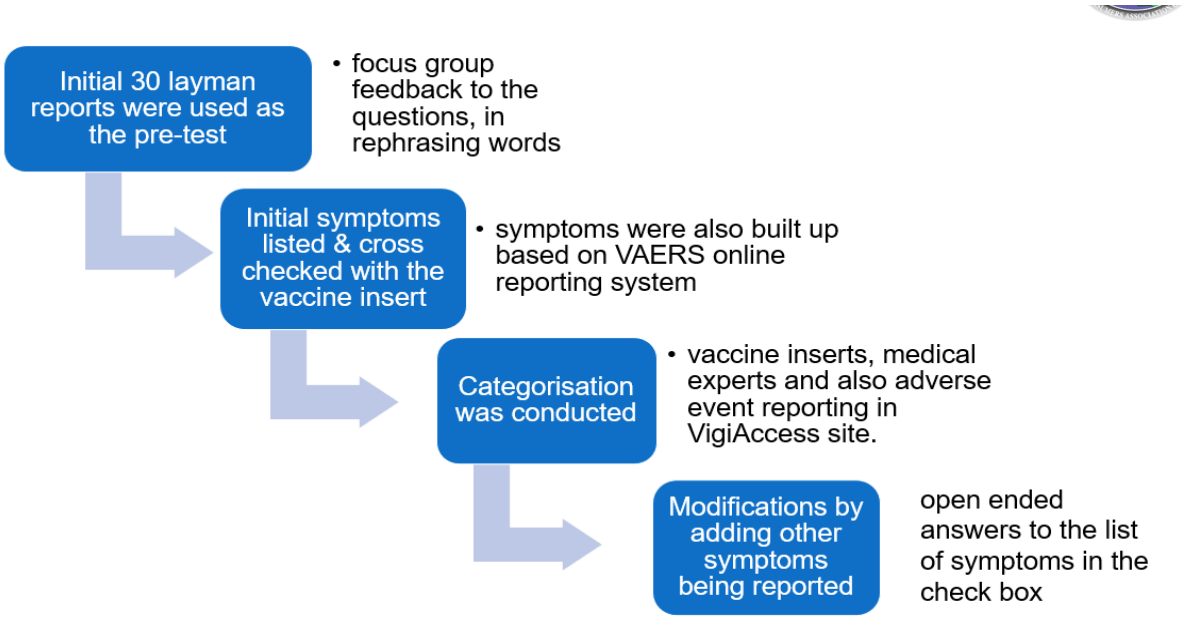
The initial layman reports (30 in total) were used as the pre-test and focus group feedback to the questions, in rephrasing words that were difficult to understand by the layperson. The focus group gave these initial symptoms listed. They were cross-checked with the vaccine inserts of Pfizer, AstraZeneca and Sinovac, which were the COVID-19 vaccine brands available in Malaysia at that time. Some of the symptoms were also built based on the VAERS online reporting system. Categorisation of adverse events was conducted by referring to the vaccine inserts, consulting medical experts and also adverse event reporting on the VigiAccess site.[6] This list was finalised by consulting with medical experts, consisting of medical doctors and pharmacists, for confirmation of the authenticity of the content. Modifications of the list of the adverse events was carried out by adding symptoms reported in the open-ended questions in the questionnaire symptoms in the check box, after analysing the feedback from respondents. The flow of the development of the research tool is summarised in Figure 1.

Figure 1: Flow chart of development of the research questionnaire



The questionnaire was divided into five sections, which were Part 1: Participants' sociodemographic characteristics; Part 2: Details of vaccine received; Part 3: Report on adverse event; Part 4: Reporting to official channel; and Part 5: Consent, contact information, additional comments, and images. Anyone can submit a report through the weblink shared. This included patients, parents/caregivers, and healthcare providers. In addition, there were no restrictions that were based age, gender, or ethnicity.

The data was initially saved in the CSV format from the online reporting database. Then, the data was cleaned and imported into Microsoft Excel to check for redundancy and fraudulent entries. The data analysis was done in the R.4.1.0. Application. Only descriptive statistics were used in the analysis.

3.0 RESULTS AND DISCUSSION

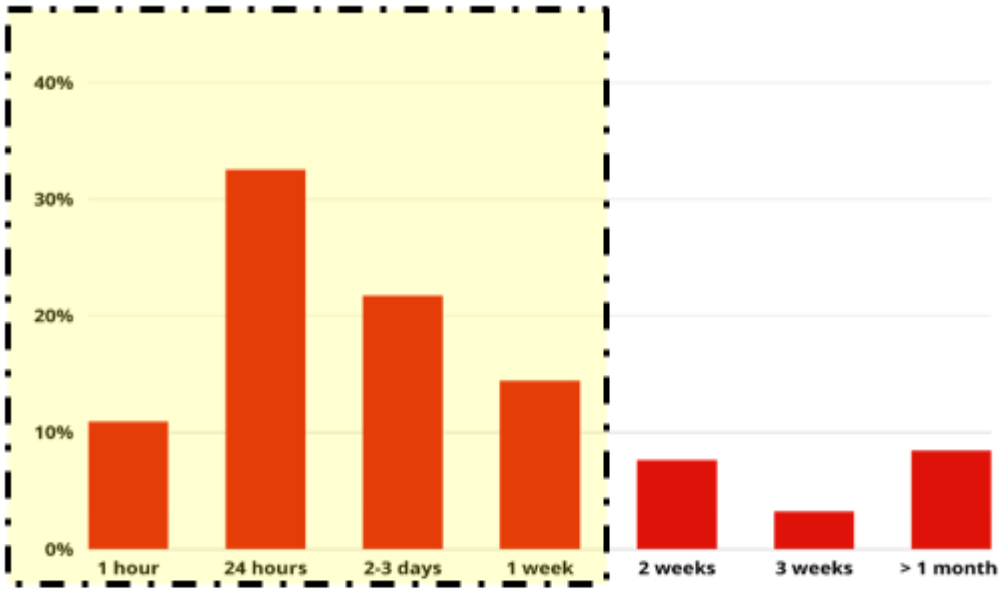
A total of 2696 reports were received during the study period (July to February 2022). After removing double entries and incomplete reports, 2667 valid responses were included in the analysis. Of the 2667 responses 47.4% (1265/2667) were previously healthy and 52.5% (1402/2667) had a history of co-morbidity. However, there were 4.4% (117/2667) of unverified AEFCI deaths. Around 15.2% (405/2667) of the respondents were awarded in hospitals after experiencing severe AEFCI. In total only 30.6% and 6% reported AEFCI via the MySejahtera and NPRA, respectively? About 78% of the respondents were aged between 19 to 48 years old with mean age being 29- years-old. Female and male respondents made up 59% and 41%, respectively of the study population. The ethnic distribution was Malay 91%, Chinese 6% and Indians 1%. There were probably more Malay respondents as this platform was mainly accessed by the Malay Muslim community.

3.1 Breakdown of AEFCI data by vaccine brands and dose

The first dose formed 53% of the AEFCI reports, while for the second and booster doses, the AEFCI incidence was 42% and 5%, respectively. The reduction AEFCI incidence observed for the second and booster doses could be due to those experiencing adverse events in the first dose not taking subsequent doses. The AEFCI reports according to vaccine received were Sinovac (938/2667= 35.1%), Pfizer (1427/2667=53.5%), (AstraZeneca (279/2667=10.5%), Cansino (2/2667= 0.07%) and Unknown (21/2677=0.8%). The incidence of serious AEFCI was 43.6% (1164/2667) and while mild AEFCI was 56.4% (1503/2667).

Figure 2 shows the onset of AEFCI symptoms. Around 45% of serious AEFCI occurred within the first 24 hours after the administration of the COVID-19 vaccine. Around 82% of serious AEFCI occurred within the first week of vaccine administration.

Figure 2: Duration to onset of AEFCI symptoms



3.2 Breakdown of AEFCI data by event occurrence and severity

The main complaints were 58.3% musculoskeletal disorders with painful/stiff/weak limbs, which were reported by 44.2% (1179/2667) of the respondents. This was followed by walking/standing stability issues [12.6% (337/2667)]; nervous system disorders (54.8%) that included severe headache [46.2% (1232/2667)], Bell's palsy [2.1% (55/2667)], Stroke [2% (53/2667)], neuropathic pain [1.8% (47/2667)] and syncope [1.6% (44/2667)] (Table 1). Respiratory complaints consisted of shortness of breath [37.6% (1002/2667)], prolonged cough (2%) and coryza/rhinitis [1.6% (43/2667)] (Table 1).

Table 1: Symptoms reported according to system.

Symptom's category	**Percentages**
Psychiatric disorders	8.7% (232/2667)
Musculoskeletal disorder	***58.3% (1556/2667)***
Ear disorder	2.1% (55/2667)
Infection	9.8% (262/2667)
Immune system disorder	31.8% (849/2667)
Reproductive	7.2% (192/2667)
Respiratory	***43.4% (1158/2667)***
Eye disorder	9.5% (252/2667)
Gastrointestinal disorders	25.3% (675/2667)
Cardiac disorder	39.3% (1049/2677)
General disorders	41.7% (1112/2667)
Nervous system disorders	**54.8% (1468/2677)**
Vascular disorders	8.0% (214/2667)
Neoplasm (benign, malignant)	1.3% (36/3667)
Hepatobiliary disorder	0.4% (9/2667)
Renal disorder	0.4% (9/2667)
Skin disorder	1.1% (29/2667)

3.3 Response of medical personnel to complaints of AEFCI

Amongst the respondents who sought medical treatment for their AEFCI reported that only 24.2% of the medical doctors acknowledged the possibility of AEFCI, while 31.2% disagreed and 44.6% were non-committal.

A search of studies assessing knowledge of adverse events and AEFI reporting was searched for the period of 01/01/1990 and 01/01/2019. Studies from under-developed countries such as Lagos10 showed that knowledge of looking out for and reporting of AEFI was high amongst

primary health care workers. However, a study from a middle income country such as Albania and developed country like Australia showed that reporting of AEFI was low amongst health care workers 11, 12

4.0 CONCLUSION

Although 30.6% of the respondents in our sample also reported on MySejahtera, only 6% reported to the NPRA. Hence, there should be some concerted effort on the part of the relevant authorities to improve these statistics. In addition, it is disturbing to note that only 24.2% of medical doctors acknowledged the possibility of AEFCI, while 31.2% disagreed and 44.6% were non-committal. These statistics are also a matter of concern, which needs to be addressed in a timely manner.

4.1 Limitations

A major limitation of in this study was that this study appears to be limited to the Malay population due to the nature of how the link to this study was disseminated. As this was not a nationwide study it is not possible to conclude on the reasons for non-reporting to NPRA amongst the Malaysian population.

4.2 Recommendations

1. Educating doctors that reporting AEFCI is a necessary initial step, without which causation cannot be investigated. In addition, doctors should be aware that without proper reporting of AEFCI, victims may be ineligible for compensation.
2. Making doctors to be aware that they need to understand the value of "signals" generated by rapid reporting of AEFCI can help prevent injury to subsequent patients by creating a list of "contraindications".
3. The health authorities should make reporting of AEFCI/AEFI by doctors mandatory so that under-reporting and thereby under-recognition of rare but severe and serious adverse events can be prevented.

4.3 Disclaimer

PPIM online AEFCI reporting link receives unverified reports of adverse events (illnesses, health problems and/or symptoms) following covid-19 immunisation with Malaysia-licensed vaccines.

Reports are accepted from anyone and can be submitted electronically at https://bit.ly/Laporankesansampingan

4.4 Conflicts of Interest,

We, the author(s) declare that we have no conflict of interests.

4.5 Acknowledgments,

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