



COVID-19 Vaccine Safety in Adults: A Narrative Review of Adverse Reactions in ASEAN Countries

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Abstract

The spread of the SARS-CoV-2 virus, known as the COVID-19 virus, which causes the coronavirus disease 2019 known as "COVID-19", has led to a rapid response from governments around the world. In response to the significant threat it presents to global health, comprehensive strategies have been implemented to mitigate worldwide transmission and reduce mortality rate. Association of South East Asian Nations (ASEAN) countries have also taken steps to encourage people to get vaccinated. The use of vaccines from many global pharmaceutical companies has led to the collection of reports on adverse drug reactions to monitor and evaluate the use of pharmaceutical products after administrated. This study aimed to evaluate the adverse drug reactions of COVID-19 vaccines administered in ASEAN countries through a narrative review of relevant scientific literature. A narrative review was conducted using *PubMed* and *ScienceDirect* databases to identify original, open-access studies published between 2020 and 2025. Eligible articles involved adults aged 18–59 years and reported adverse events following COVID-19 vaccination in ASEAN countries. Nine studies met the inclusion criteria and were qualitatively analysed. Six vaccines were evaluated: Ad26.COV2.S (*Johnson & Johnson*), AZD1222 (*AstraZeneca*), BNT162b2 (*Pfizer-BioNTech*), CoronaVac (*Sinovac*), "Sputnik V" and mRNA-1273 (*Moderna*). The most adverse drug reactions reported included injection site pain, fever, headache, fatigue and muscle pain, respectively, based on the severity of side effects. Current evidence confirms that COVID-19 vaccines used in Southeast Asian demonstrated favourable safety and tolerability profiles among adults, consistent with global pharmacovigilance data. These findings support continued vaccination programs and highlight the importance of strengthening regional pharmacovigilance systems and harmonised AEFI reporting to sustain public confidence in immunisation efforts across ASEAN.

Key word: Adverse drug reactions; COVID-19 vaccines; Pharmacovigilance; Southeast Asian.

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Introduction

The pandemic of COVID-19 has emerged as the most significant global health crisis between 2019 to 2022. Its impact has extended beyond health systems, affecting economic and social structures worldwide.^{1,2} By the end of 2023, the

Association of South East Asian Nations (ASEAN) region, with over 630 million people (about 8 % of the global population), reported approximately 61 million confirmed COVID-19 cases (7.9 % of the worldwide total) and 806,166 deaths, repre-

senting 11.6 % of global fatalities, with a case fatality rate of 1.3 %. The development of effective COVID-19 vaccines has been critical in mitigating transmission and reducing mortality.³

The rapid study, development, testing and production of multiple effective SARS-CoV vaccines in 2020 marked a remarkable achievement in global health. In the case of COVID-19, vaccine rollout commenced shortly after the identification of the novel pathogen, contrary to the typical vaccine development timeline, which often spans years or even decades.^{3,4} This acceleration was driven by urgent public health demands, the use of novel vaccine platforms such as mRNA and viral vectors and the optimisation of emergency regulatory procedures, including conditional Marketing Authorisation (CMA) and Emergency Use Authorisation (EUA).^{5,6}

The vaccine development was pioneered by *Pfizer/BioNTech* with the mRNA-based BNT162 vaccine, followed by *Moderna* Inc with the mRNA-1273 vaccine. The *Pfizer/BioNTech* vaccine was the first COVID-19 vaccine to be approved by the U.S Food and Drug Administration (FDA), followed by *Moderna's* vaccine. Subsequently, other countries, including the United Kingdom, Bahrain, Canada and Mexico, also granted emergency authorisations for the use COVID-19 vaccine.^{7,8}

Due to resource limitations, ASEAN countries lacked the capacity for domestic vaccine production and thus relied heavily on imports from the global market. Vaccine procurement across the region happened through various channels. This included bilateral donations, such as China donating Corona Vac to Indonesia and Vietnam beginning in December 2020; regional partnership, which was primarily for Indonesia; multilateral platforms, such as the covid-19 Vaccines advance market commitment (COVAX AMC), which distributed to Indonesia, Cambodia, Laos, Myanmar, Philippines and Vietnam; and direct purchases, such as Singapore and Malaysia Sourcing Comirnaty from *Pfizer/BioNTech*.^{9,10} Despite these efforts, data on vaccine usage and adverse drug reactions in Southeast Asian remain limited and fragmented.¹¹

Common adverse reactions to COVID-19 vaccines include injection site pain or tenderness, fatigue, headache, rash, fever, chills, muscle aches (myalgia) and joint aches (arthralgia).^{7,8} However, more serious adverse reactions have also been report-

ed post-vaccination, including thrombocytopenia, myocarditis or pericarditis, inflammatory myositis, anaphylactic reactions, vascular disorders, cardiac and nervous system disorders.¹²⁻¹⁴

Pharmacovigilance systems for COVID-19 vaccines in Southeast Asian face substantial challenges, including inadequate reporting infrastructure, limited human resource capacity and heterogeneous readiness levels among countries in managing adverse events following immunisation (AEFI). While several ASEAN member states, such as Indonesia, Malaysia, Singapore and Thailand, have developed pharmacovigilance systems that meet the World Health Organisation's minimum standards, other countries in the region continue to struggle with comprehensive reporting and analysis.^{2,11,15} These gaps may undermine public trust in COVID-19 vaccines and vaccination programs overall.

Therefore, this narrative review aimed to assess the adverse reactions profiles and effectiveness of COVID-19 vaccines in ASEAN countries specifically Indonesia, Philippines, Thailand, Cambodia, Malaysia and Singapore to inform vaccine safety surveillance and evidence-based policy in the region. The findings are expected to provide insights into strengthening vaccine safety surveillance systems and supporting evidence-based policy formulation in the ASEAN region.

Methods

This study employed a narrative review approach, with references primarily obtained from international scientific journal literature. A comprehensive literature search was conducted using the *PubMed* database, applying a search strategy by combined free-text terms with Medical Subject Headings (MeSH). The final search string was: ["COVID-19 Vaccines"[MeSH Terms] OR "COVID-19 Vaccine"[All Fields] OR "SARS-CoV-2 Vaccine"[All Fields]) AND ("Adverse Effects"[MeSH Terms] OR "Adverse Events"[All Fields] OR "Adverse Reactions"[All Fields] OR "Side Effects"[All Fields] OR "Safety"[All Fields]) AND ("Asia, Southeastern"[MeSH Terms] OR "ASEAN"[All Fields] OR "Brunei"[All Fields] OR "Cambodia"[All Fields] OR "Indonesia"[All Fields] OR "Laos"[All Fields] OR "Malaysia"[All Fields] OR "Myanmar"[All Fields] OR "Philippines"[All Fields] OR "Singapore"[All Fields] OR "Thailand"[All Fields] OR "Vietnam-

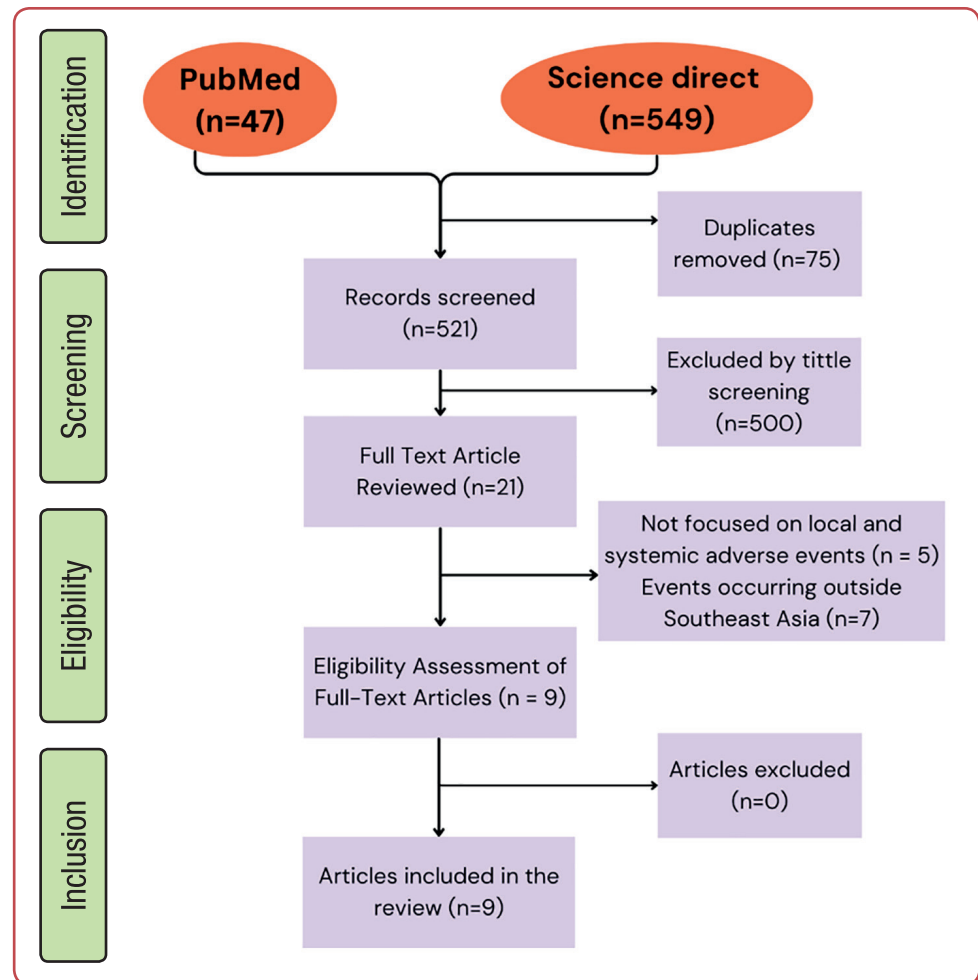


Figure 1: Narrative literature review process flowchart

”[All Fields]). The objective of the search was to identify relevant publications that reported adverse events following COVID-19 vaccination in ASEAN countries.

Eligible articles for this review were required to be original research, open access, full-text articles, published between 2020 and 2025, written in English and involving participants aged 18-59 years old within Southeast Asia. Studies designed as non-trial or conducted in drive-through vaccination settings were excluded to ensure consistency in study context and population. The preliminary search of the *PubMed* database yielded a total of 47 unique publications and 549 articles from *Science Direct*. After the screening of titles and abstracts, 521 articles were selected for further evaluation. Following the application of the inclusion and exclusion criteria during the process of full-text review, there were 9 articles that met all the eligibility requirements and were included in the final synthesis. These studies were analysed for reported adverse reactions, qualita-

tively synthesised and presented in tabular form with supporting narrative discussion. The selection process is summarised in Figure 1. Notably, 66.6 % of the studies (six out of nine) focused on high-risk populations, particularly healthcare workers.

Results

All included studies were observational and conducted in Southeast Asian countries, including Indonesia, Malaysia and Vietnam. The study populations consisted of adults aged 18–59 years and the reported outcomes were limited to post-vaccination local (eg injection site pain) and systemic (eg fever, headache, fatigue) adverse reactions. None of the selected articles involved clinical trial settings or drive-through vaccination models, in accordance with the exclusion criteria.

Table 1: Reported adverse reactions associated with COVID-19 vaccines administered

Author, year	Vaccine name	Company	Vaccine type	Country	Reported adverse reactions
Tan-Lim, 2023 ¹⁶	CoronaVac	<i>Sinovac</i>	Inactivated viruses	Philippines	Pain at the injection site, heaviness in the arm, drowsiness, headache, body pain, fatigue, fever, diarrhoea, chills.
	AZD1222	<i>Astra Zeneca</i>	Chimpanzee adenovirus vector	Philippines	Fever, injection site pain, body pain, headache, fatigue, chills, heaviness in the arm.
	Ad26. COV2.S	<i>Janssen</i>	Recombinant vaccine	Philippines	Pain at the injection site, body pain, fatigue, fever.
	BNT162b2	<i>Pfizer</i>	mRNA vaccine	Philippines	Injection site pain, body pain, fever, headache, heaviness in the arm, fatigue, chills, diarrhoea, nausea.
	mRNA-1273	<i>Moderna</i>	mRNA vaccine	Philippines	Fever, body pain, pain at the injection site, fatigue, headache, heaviness in the arm, chills, nausea, drowsiness.
Supangat, 2021 ¹⁷	CoronaVac	<i>Sinovac</i>	Inactivated viruses	Indonesia	Pain at the injection site, discomfort, drowsiness, headache, fever, localised skin redness.
Simatupang, 2024 ¹⁸	CoronaVac	<i>Sinovac</i>	Inactivated viruses	Indonesia	Pain at the injection site, drowsiness, bloating, nausea, fever, swelling at the injection site.
Simatupang, 2024 ¹⁸	CoronaVac	<i>Sinovac</i>	Inactivated viruses	Indonesia	Pain at the injection site, drowsiness, bloating, nausea, fever, swelling at the injection site.
	AZD1222	<i>Astra Zeneca</i>	Chimpanzee adenovirus vector	Indonesia	Pain at the injection site, headache, fever, nausea, bloating, swelling at the injection site.
Ramatillah, 2024 ¹⁹	CoronaVac	<i>Sinovac</i>	Inactivated viruses	Indonesia	Pain at the injection site, fever, fatigue, headache, drowsiness, diarrhoea cough and nausea.
Rahmat, 2022 ²⁴	BNT162b2	<i>Pfizer</i>	mRNA Vaccine	Malaysia	Pain at the injection site, arm pain, fever, myalgia, swelling at the injection site, chills.
Gan, 2022 ²¹	BNT162b2	<i>Pfizer</i>	mRNA Vaccine	Malaysia	Injection site pain, fatigue, fever, chills, swelling at the injection site, headache, dizziness, myalgia, nausea, vomiting.
Benjamanukul, 2022 ²⁰	CoronaVac	<i>Sinovac</i>	Inactivated viruses	Thailand	Injection site pain, myalgia, headache, fever, nausea, diarrhoea, drowsiness, fatigue.
Tawinprai, 2022 ²²	AZD1222	<i>Astra Zeneca</i>	Chimpanzee adenovirus vector	Thailand	Myalgia, fever, headache, fatigue, injection site pain.
Lim, 2021 ²³	BNT162b2	<i>Pfizer</i>	mRNA vaccine	Singapore	Rash/redness, swelling at the injection site, injection site pain, fever, fatigue, malaise, body pain.

Several COVID-19 vaccine platforms and brands were evaluated across the included studies, including chimpanzee adenoviral vectors, human adenoviral vectors, inactivated virus vaccines, combination vaccines and mRNA-based vaccines. The inactivated virus vaccine developed by Sinovac was assessed in five studies,¹⁶⁻²⁰ while both the adenoviral vector vaccine AZD1222 (*AstraZeneca*)

and the mRNA vaccine BNT162b2 (*Pfizer-BioNTech*) were each examined in six studies.^{16, 18, 21-24}

This study examined and compiled the adverse reactions profiles of various COVID-19 vaccines administered in ASEAN countries, specifically Indonesia, Philippines, Cambodia, Thailand, Malaysia and Singapore. The reviewed vaccines include

Ad26.COV2.S (*Johnson & Johnson*), AZD1222 (*AstraZeneca*), BNT162b2 (*Pfizer-BioNTech*), Corona Vac (*Sinovac*), “Sputnik V” and mRNA-1273 (*Moderna*). Each vaccine showed a distinct pattern of adverse reactions by type and frequency (Table 1).

Adverse reactions of CoronaVac®

Observational studies across Southeast Asian consistently demonstrate that CoronaVac® had a favourable safety profile. In the Philippines, common adverse reactions included injection site pain, body pain, arm heaviness, drowsiness, headache, fatigue, fever, diarrhoea and chills,¹⁶ findings consistent with clinical trial data and product information. In Indonesia, mild reactions such as injection site pain, headache, fever, fatigue and drowsiness were predominant, occasionally accompanied by bloating, cough, or nausea.¹⁷⁻¹⁹ Similar results were observed in Thailand, where injection site pain, myalgia, headache, fever, nausea, diarrhoea and fatigue were frequently reported.²⁰

Across these studies, adverse reactions were mild, self-limiting and typical of inactivated vaccines.²⁵⁻²⁷ A meta-analysis confirmed that CoronaVac® produced fewer adverse events than mRNA and adenoviral vector vaccines.²⁸ Minor local or systemic symptoms, more common in Indonesian cohorts, likely reflected individual or contextual variations rather than unexpected events. Overall, evidence from clinical trials, surveillance and observational data supports CoronaVac® as safe, well tolerated and suitable for mass immunisation programs prioritising stability and safety.

Adverse reactions of AZD1222 (*AstraZeneca*)

Adverse reactions following AZD1222 vaccination in Southeast Asian are consistent with global findings. In the Philippines, common symptoms included fever, injection site pain, myalgia, headache, fatigue, chills and arm heaviness,¹⁶ in Indonesia, injection site pain, headache, fever, nausea and swelling were noted¹⁸ and in Thailand, myalgia, fever and fatigue predominated.²² These align with clinical and post-licensure data, where systemic effects such as chills and gastrointestinal symptoms were occasionally observed.²⁹⁻³¹ Compared to inactivated vaccines, AZD1222 more often induced systemic reactions such as fatigue, myalgia, headache, fever and injection

site pain that resolving spontaneously within 1–3 days.^{28, 32-34} Overall, reactions were mild to moderate, with regional variations reflecting biological or methodological factors rather than safety concerns.^{29, 30, 34}

Adverse reactions of the “Sputnik V” vaccine

In the Philippines, “Sputnik V” recipients frequently reported injection site pain, headache, fever, myalgia, fatigue, drowsiness and chills, consistent with clinical trial data.¹⁶ Similar mild-to-moderate symptoms were observed across other studies, typically occurring within 24 hours and resolving within 2–3 days without treatment.³⁵⁻³⁹ No serious vaccine-related events were identified, confirming its favourable tolerability. Minor variations, such as drowsiness or mild gastrointestinal complaints, likely reflect demographic or methodological factors. Consistency across studies from Russia, Iran, the Philippines and India underscores “Sputnik V’s” robust safety profile and suitability for widespread use, particularly in low- and middle-income countries.^{16, 36, 37}

Adverse reactions of the Ad26.COV2.S vaccine

Ad26.COV2.S, a single-dose adenoviral vector vaccine, offers logistical advantages due to its stability at 2–8 °C.⁴⁰ Post-marketing data from the Philippines report injection site pain, headache, myalgia, fatigue and fever as the most frequent reactions—mild, transient and consistent with clinical trial findings.^{16, 40-42} Although rare cases of Guillain–Barré syndrome (GBS) and thrombocytopenia syndrome (TTS) have been recorded, their incidence remains extremely low and regulatory authorities affirm that the vaccine’s benefits outweigh its risks.^{42, 43} Overall, Ad26.COV2.S shows predictable, manageable reactogenicity and remains suitable for broad immunisation programs.

Adverse reactions of the BNT162b2 vaccine

Southeast Asian studies report BNT162b2 as generally well tolerated, with adverse reactions consistent with global data. In the Philippines, injection site pain, headache, fatigue and fever were common,¹⁶ in Malaysia, fatigue, dizziness, nausea and localised swelling were frequent^{21, 24} and

in Singapore, rash, injection site pain, fever and fatigue were observed.²³ These patterns mirror large clinical trials, where most reactions were mild to moderate and resolved within days.^{7, 29, 44} Rare events such as myocarditis or neurological effects have been reported but remain uncommon relative to total doses administered.⁴⁵⁻⁴⁷ Overall, BNT162b2 maintains an excellent safety profile across populations, with benefits far outweighing transient adverse effects.

Adverse reactions of the mRNA-1273 vaccine

In the Philippines, mRNA-1273 recipients reported fever, injection site discomfort, fatigue, headache and chills, with no cases of anaphylaxis, myocarditis, or pericarditis.¹⁶ Common reactions included injection site pain, fatigue, myalgia, arthralgia and fever, often after the second dose.^{8, 48} Regulatory data confirm that both local and systemic reactions were mild to moderate and self-limiting.⁵ No serious vaccine-related events were identified.⁴⁹ Collectively, evidence supports that mRNA-1273 induces predictable immune responses without major safety issues.

Discussion

This review synthesised nine observational studies from Southeast Asian involving adults aged 18–59 years who received different COVID-19 vaccine platforms.¹⁶⁻²⁴ Across all studies, most adverse reactions were mild, transient and aligned with global pharmacovigilance data.^{25, 50} Local effects such as injection site pain predominated, while systemic symptoms like fever, fatigue and myalgia were less frequent and typically resolved within one to three days.^{17, 19, 22} Inactivated vaccines (CoronaVac) produced the lowest systemic reaction rates,^{17-19, 22} whereas adenoviral vector (AZD1222, “Sputnik V”, Ad26.COV2.S) and mRNA vaccines (BNT162b2, mRNA-1273) had slightly higher but acceptable reactogenicity.^{16, 20, 21, 23, 24}

Variations in adverse event frequency likely reflect differences in demographics, vaccine availability and national pharmacovigilance capacity.²⁸⁻³⁰ Singapore and Malaysia reported more complete AEFI data, highlighting disparities in surveillance maturity within ASEAN.^{28, 29} These differences emphasise the need for harmonised reporting and regional cooperation to enhance data comparability.³⁰

No serious or unexpected adverse events were reported,¹⁶⁻²⁴ reinforcing vaccine safety and tolerability. Limitations include the small number of studies, self-reported outcomes and predominance of healthcare worker participants,^{17, 19, 22} which may limit generalisability. Future multi-country studies using standardised methods are essential to improve post-marketing safety monitoring.²⁸⁻³⁰

Overall, current evidence confirms that COVID-19 vaccines used in Southeast Asian demonstrate high safety and tolerability, consistent with global data.^{25, 26, 50} Strengthening regional pharmacovigilance and collaborative surveillance remains crucial to maintain public confidence and guide evidence-based vaccination policies across ASEAN.

Conclusion

Evidence synthesised from nine studies across Southeast Asian demonstrates that COVID-19 vaccines including inactivated, adenoviral vector and mRNA platforms exhibit favourable and predictable safety profiles among adults aged 18–59 years. Most adverse reactions were mild, transient and consistent with global pharmacovigilance data, with no serious or unexpected vaccine-related events reported. These findings confirm the overall safety and tolerability of COVID-19 vaccines used in the region and emphasise the importance of strengthening regional pharmacovigilance systems, harmonising AEFI reporting and fostering cross-country collaboration to ensure continuous safety monitoring and sustain public confidence in vaccination programs across ASEAN.

Ethics

This study was a secondary analysis based on the currently existing data and did not directly involve with human participants or experimental animals. Therefore, the ethics approval was not required in this paper.

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Conflicts of interest

The authors declare that there is no conflict of interest.

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Data access

The data that support the findings of this study are available from the corresponding author upon reasonable individual request.

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References

1. Mathieu E, Ritchie H, Ortiz Ospina E, Roser M, Hasell J, Appel C, et al. A global database of COVID 19 vaccinations. *Nat Hum Behav.* 2021 Jul;5(7):947–53. doi: 10.1038/s41562-021-01122-8.
2. World Health Organization. WHO Coronavirus (COVID 19) Dashboard [Internet]. 2025 [Cited:22-Jun-2025]. Available from: <https://covid19.who.int/>.
3. Kalinke U, Barouch DH, Rizzi R, Lagkadinou E, Türeci Ö, Pather S, et al. Clinical development and approval of COVID 19 vaccines. *Expert Rev Vaccines.* 2022;21:609–19. doi: 10.1080/14760584.2022.2042257.
4. Barouch DH. COVID 19 vaccines — immunity, variants, boosters. *N Engl J Med.* 2022 Sep 15;387(11):1011–20. doi: 10.1056/NEJMra2206573.
5. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee December 10, 2020 Meeting Briefing Document [Internet]. 2020. [Cited:22-Jun-2025]. Available from: <https://www.fda.gov/>.
6. European Medicines Agency. Safety of COVID 19 vaccines [Internet]. 2021 [Cited:22-Jun-2025]. Available from: <https://www.ema.europa.eu/>.
7. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and efficacy of the BNT162b2 mRNA Covid 19 vaccine. *N Engl J Med.* 2020 Dec 31;383(27):2603–15. doi: 10.1056/NEJMoa2034577.
8. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and safety of the mRNA 1273 SARS CoV 2 vaccine. *N Engl J Med.* 2021 Feb 4;384(5):403–16. doi: 10.1056/NEJMoa2035389.
9. Fu JYL, Pukhari MH, Cruz KA Dela, Soebandrio A, Van Tan L, Jantarabenjakul W, et al. Charting the path forward in Southeast Asia: learning from the COVID 19 vaccination challenges in six ASEAN countries. *J Glob Health.* 2024;14:03016. doi: 10.7189/jogh.14.03016.
10. UNICEF. COVAX: ensuring global equitable access to COVID 19 vaccines [Internet]. 2021 [Cited:22-Jun-2025]. Available from: <https://www.unicef.org/supply/covax-ensuring-global-equitable-access-covid-19-vaccines>.
11. Garashi HY, Steinke DT, Schafheutle EI. A systematic review of pharmacovigilance systems in developing countries using the WHO pharmacovigilance indicators. *Ther Innov Regul Sci.* 2022;56:717–43. doi: 10.1007/s43441-022-00415-y.
12. Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyrle PA, Eichinger S. Thrombotic thrombocytopenia after ChAdOx1 nCov 19 vaccination. *N Engl J Med.* 2021 Jun 3;384(22):2092–101. doi: 10.1056/NEJMoa2104840.
13. Li X, Ostropolets A, Makadia R, Shoaibi A, Rao G, Sena AG, et al. Characterising the background incidence rates of adverse events of special interest for COVID 19 vaccines in eight countries: multinational network cohort study. *BMJ.* 2021 Jun 14;373:n1435. doi: 10.1136/bmj.n1435.
14. Karam R, Iskandar K, Watfa M, Zeitoun A. Serious adverse events following immunization with COVID 19 vaccines in Lebanon: a retrospective analysis of the

- national pharmacovigilance database. *BMC Public Health.* 2024 Oct 21;24(1):2905. doi: 10.1186/s12889-024-20297-z.
15. Suwankesawong W, Dhipayom T, Tan Koi WC, Kongkaew C. Pharmacovigilance activities in ASEAN countries. *Pharmacoepidemiol Drug Saf.* 2016 Sep;25(9):1061-9. doi: 10.1002/pds.4023.
 16. Tan Lim CSC, Gonzales MLAM, Dans LF, Cordero CP, Alejandria MM, dela Paz ECC, et al. Reinfection rates, change in antibody titers and adverse events after COVID 19 vaccination among patients previously infected with COVID 19 in Metro Manila, Philippines: a secondary analysis of a completed cohort study. *BMC Infect Dis.* 2023 Dec 1;23(1):634. doi: 10.1186/s12879-023-08743-6.
 17. Supangat, Sakinah EN, Nugraha MY, Qodar TS, Mulyono BW, Tohari AI. COVID 19 vaccines programs: adverse events following immunization (AEFI) among medical clerkship students in Jember, Indonesia. *BMC Pharmacol Toxicol.* 2021 Dec 1;22(1):64. doi: 10.1186/s40360-021-00528-4.
 18. Simatupang A, Sitompul YRMB, Simanungkalit B, Kurniyanto K, Achmad LN, Sitompul F, et al. Adverse event following immunisation of adsorbed-inactivated Coronavac (Sinovac) and ChAdOx1 nCoV-19 (Astra Zeneca) of COVID-19 vaccines. *Med J Malaysia.* 2024 Sep;79(5):507-11. PMID: 39352150.
 19. Ramatillah DL, Gan SH, Novarticia J, Araminda GN, Michael M, Elnaem M, et al. Side effects of CoronaVac® COVID 19 vaccination: investigation in North Jakarta district public health center communities in Indonesia. *Heliyon.* 2024 May 15;10(9):e30087. doi: 10.1016/j.heliyon.2024.e30087.
 20. Benjamanukul S, Traian S, Yorsaeng R, Vichaiwattana P, Sudhinaraset N, Wanlapakorn N, et al. Safety and immunogenicity of inactivated COVID 19 vaccine in health care workers. *J Med Virol.* 2022 Apr;94(4):1442-9. PMID:34783049.
 21. Gan LL, Zahidah AR, Hazirah T, Nabilah HK, Aisyah Z, Amin INM, et al. Adverse events following BNT162b2 mRNA COVID 19 vaccination among healthcare workers: a single centre experience in Malaysia. *Med J Malaysia.* 2022 May;77(3):300-5. PMID:35638485.
 22. Tawinprai K, Siripongboonsitti T, Porntharukcharon T, Dechates B, Monprach H, Sornsamdang G, et al. Persistence of immunogenicity, contributing factors of an immune response, and reactogenicities after a single dose of the ChAdOx1 (AZD1222) COVID 19 vaccine in the Thai population. *Hum Vaccin Immunother.* 2022 Dec 31;18(1):2035573. doi: 10.1080/21645515.2022.2035573.
 23. Lim SM, Chan HC, Santosa A, Quek SC, Liu EHC, Somani J. Safety and side effect profile of Pfizer BioNTech COVID 19 vaccination among healthcare workers: a tertiary hospital experience in Singapore. *Ann Acad Med Singap.* 2021 Sep;50(9):703-11. doi: 10.47102/annals-acadmedsg.2021160.
 24. Rahmat H, Leelavathi M, Wan Ismail WF. Adverse events following immunisation of COVID 19 vaccine among health care workers in the first phase of vaccination. *Med J Malaysia.* 2022 Nov;77(6):637-42. PMID:36448378.
 25. Tamin S, Bashiruddin J, Zachreini I, Priyono H, Mayangsari ID, Ranakusuma R, et al. Factors affecting SARS CoV 2 vaccine's adverse events. *eJKI (eJ Kedokt Indones).* 2022 Aug;10(2):xx. doi: 10.23886/ejki.10.165.129.
 26. Tanriover MD, Doğanay HL, Akova M, Güner HR, Azap A, Akhan S, et al. Efficacy and safety of an inactivated whole virion SARS CoV 2 vaccine (CoronaVac): interim results of a double blind, randomised, placebo controlled, phase 3 trial in Turkey. *Lancet.* 2021 Jul 17;398(10296):213-22. doi: 10.1016/S0140-6736(21)02787-2.
 27. Taş BG, Demir İ, Basanmay M, Öztürk GZ, Akyol BÇ, Tektaş MH, et al. Frequency and factors associated with adverse reactions after administration of inactivated COVID 19 vaccine among health workers. *Rev Soc Bras Med Trop.* 2023 Sep 22;56:e01522023. doi: 10.1590/0037-8682-0152-2023.
 28. Jiesisibieke ZL, Liu WY, Yang YP, Chien CW, Tung TH. Effectiveness and safety of COVID 19 vaccinations: an umbrella meta analysis. *Int J Public Health.* 2023;68:1605526. doi: 10.3389/ijph.2023.1605526. PMID:37485047.
 29. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P, et al. Vaccine side effects and SARS CoV 2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. *Lancet Infect Dis.* 2021 Jul;21(7):939-949. doi: 10.1016/S1473-3099(21)00224-3.
 30. Ramasamy MN, Minassian AM, Ewer KJ, Flaxman AL, Folegatti PM, Owens DR, et al. Safety and immunogenicity of ChAdOx1 nCoV 19 vaccine administered in a prime boost regimen in young and old adults (COV002): a single blind, randomised, controlled, phase 2/3 trial. *Lancet.* 2020 Dec 19;396(10267):1979-93. doi: 10.1016/S0140-6736(20)32466-1.
 31. Alghamdi AN, Alotaibi MI, Alqahtani AS, Al Aboud D, Abdel Moneim AS. BNT162b2 and ChAdOx1 SARS CoV 2 post vaccination side effects among Saudi vaccinees. *Front Med (Lausanne).* 2021 Oct 8;8:760047. doi: 10.3389/fmed.2021.760047.
 32. Al Bahrani S, Albarrak A, Alghamdi OA, Alghamdi MA, Hakami FH, Al Abaadi AK, et al. Safety and reactogenicity of the ChAdOx1 (AZD1222) COVID 19 vaccine in Saudi Arabia. *Int J Infect Dis.* 2021 Sep;110:359-62. doi: 10.1016/j.ijid.2021.07.052.
 33. Park C, Sakong J, Jo S, Kim M, Baek K. Adverse effects on work and daily life interference among healthcare workers after the first and second ChAdOx1 and BNT162b2 COVID 19 vaccine doses. *Vaccines (Basel).* 2021 Aug 19;9(8):926. doi: 10.3390/vaccines9080926.
 34. Falsey AR, Sobieszczyk ME, Hirsch I, Sproule S, Robb ML, Corey L, et al. Phase 3 safety and efficacy of AZD1222 (ChAdOx1 nCoV 19) Covid 19 vaccine. *N Engl J Med.* 2021 Dec 16;385(25):2348-60. doi: 10.1056/NEJMoa2105290.
 35. Amer SA, Al Zahrani A, Imam EA, Ishteiwy EM, Djelleb IF, Abdullh LR, et al. Exploring the reported adverse effects of COVID 19 vaccines among vaccinated Arab populations: a multi national survey study. *Sci Rep.* 2024 Feb 27;14(1):4785. doi: 10.1038/s41598-024-54886-0.
 36. Babamahmoodi F, Saeedi M, Alizadeh Navaei R, Hedayatizadeh Omran A, Mousavi SA, Ovaive G, et al. Side effects and immunogenicity following administration of the Sputnik V COVID 19 vaccine in health care workers in Iran. *Sci Rep.* 2021 Nov 2;11(1):21464. doi: 10.1038/s41598-021-00963-7.
 37. Logunov DY, Dolzhenkova IV, Shcheblyakov DV, Tukhvatulin AI, Zubkova OV, Dzharullaeva AS, et al. Safety and efficacy of an rAd26 and rAd5 vector based heterologous prime boost COVID 19 vaccine: interim analysis of a randomised controlled phase 3 trial in Russia. *Lancet.* 2021 Feb 20;397(10275):671-81. doi: 10.1016/S0140-6736(21)00234-8.
 38. Montalti M, Soldà G, Di Valerio Z, Salussolia A, Lenzi J, Forcellini M, et al. ROCCA observational study: early results on safety of Sputnik V vaccine (Gam COVID Vac)

- in the Republic of San Marino using active surveillance. *EClinicalMedicine*. 2021 Aug;38:101027. doi: 10.1016/j.eclinm.2021.101027.
39. Zare H, Rezapour H, Mahmoodzadeh S, Fereidouni M. Prevalence of COVID 19 vaccine (Sputnik V, AZD 1222, and Covaxin) side effects among healthcare workers in Birjand city, Iran. *Int Immunopharmacol*. 2021 Dec;101:108351. doi: 10.1016/j.intimp.2021.108351.
 40. Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, et al. Safety and efficacy of single dose Ad26.COV2.S vaccine against Covid 19. *N Engl J Med*. 2021 Jun 10;384(23):2187–201. doi: 10.1056/NEJMoa2101544.
 41. Tsuchiya Y, Tamura H, Fujii K, Numaguchi H, Toyozumi K, Liu T, et al. Safety, reactogenicity, and immunogenicity of Ad26.COV2.S: results of a phase 1, randomized, double blind, placebo controlled COVID 19 vaccine trial in Japan. *Vaccine*. 2023 Feb;41(9):1602–10. doi: 10.1016/j.vaccine.2023.01.006.
 42. Woo EJ, Gee J, Marquez P, Baggs J, Abara WE, McNeil MM, et al. Post authorization safety surveillance of Ad.26. COV2.S vaccine: reports to VAERS and v safe, February 2021–February 2022. *Vaccine*. 2023 Jul;41(30):4422–30. doi: 10.1016/j.vaccine.2023.06.023.
 43. Hanson KE, Goddard K, Lewis N, Fireman B, Myers TR, Bakshi N, et al. Incidence of Guillain Barré syndrome after COVID 19 vaccination in the Vaccine Safety Datalink. *JAMA Netw Open*. 2022 Apr 26;5(4):e228879. doi: 10.1001/jamanetworkopen.2022.8879.
 44. U.S. Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document [Internet]. 2020 Dec. [Cited:22-Jun-2025]. Available from: <https://www.fda.gov/>.
 45. Ab Rahman N, Lim MT, Lee FY, Lee SC, Ramli A, Saharudin SN, et al. Risk of serious adverse events after the BNT162b2, CoronaVac, and ChAdOx1 vaccines in Malaysia: a self controlled case series study. *Vaccine*. 2022 Jul;40(32):4394–402. doi: 10.1016/j.vaccine.2022.05.075.
 46. Barda N, Dagan N, Ben Shlomo Y, Kepten E, Waxman J, Ohana R, et al. Safety of the BNT162b2 mRNA Covid 19 vaccine in a nationwide setting. *N Engl J Med*. 2021 Sep 16;385(12):1078–90. doi: 10.1056/NEJMoa2110475.
 47. García Grimshaw M, Ceballos Liceaga SE, Hernández Vanegas LE, Núñez I, Hernández Valdivia N, Carrillo García DA, et al. Neurologic adverse events among 704,003 first dose recipients of the BNT162b2 mRNA COVID 19 vaccine in Mexico: a nationwide descriptive study. *Clin Immunol*. 2021 Aug;229:108786. doi: 10.1016/j.clim.2021.108786.
 48. Santi Laurini G, Montanaro N, Broccoli M, Bonaldo G, Motola D. Real life safety profile of mRNA vaccines for COVID 19: an analysis of the VAERS database. *Vaccine*. 2023 May;41(18):2879–86. doi: 10.1016/j.vaccine.2023.03.054.
 49. Ito S, Tsuchida N, Kusunoki S, Kaneko Y, Naito T, Hori S, et al. Safety comparison between Pfizer BNT162b2, Moderna mRNA 1273, and AstraZeneca AZD1222 in a nationwide prospective cohort survey at the beginning of SARS CoV 2 vaccination in Japan. *Vaccine*. 2025 Mar;49:126754. doi: 10.1016/j.vaccine.2025.126754.
 50. Sinovac Life Sciences Co., Ltd. COVID 19 Vaccine (Vero Cell), Inactivated — CoronaVac®: Product Information Leaflet [Internet]. 2022 Mar [Cited:30-May-2025]. Available from: internal product leaflet (COR Philippines 40 vials insert EN D03.pdf).