



COVID-19 Vaccine Adverse Events

CLINICAL QUESTION

What does real world evidence tell us about adverse effects from available COVID-19 vaccines?

BOTTOM LINE

Best evidence finds systemic adverse events related to COVID-19 vaccines are mostly short-lived and differ by type of vaccine, dose given, age, and gender. Anaphylaxis to mRNA vaccines occurs in 2.5 to 5 per million doses. Vaccine-induced thrombotic thrombocytopenia (VITT) is associated with viral vector vaccines (AstraZeneca or Johnson and Johnson). Best estimates of incidence: ~0.5 to 2 per 100,000 and more commonly in women.

EVIDENCE

- From published prospective or retrospective cohort/case control studies.
- General systemic adverse events:
 - Best evidence from solicited adverse events up to 8 days post-dose in 655,590 patients with Pfizer (2 doses) or AstraZeneca (1 dose) adults:¹
 - Most commonly short lived and last 1-2 days:
 - Fatigue, headache: Each 13-23%.
 - Adverse events more common among:

- Recipients of AstraZeneca (versus Pfizer), Pfizer second dose versus first.
 - Individuals 55 or younger.
 - Women.
 - Similar findings in clinical trials.²
 - Anaphylaxis risk: Based on ~10 million Pfizer doses, ~8 million Moderna.³
 - Incidence (per million doses): 5 (Pfizer), 2.5 (Moderna).
 - 1/3 reported previous anaphylaxis episodes, ~80% with known allergies.
 - No deaths reported.
- VITT:
 - VITT leading to rare thromboses, particularly cerebral venous sinus thrombosis (CVST), 4-28 days post AstraZeneca vaccine.
 - Risk varies^{4,5} from 0.4 per 100,000 in 80+ years to ~2 per 100,000 in 20-49.
 - Majority in women under 60 within 14 days of vaccination.⁵
 - Cohort of 281,264 AstraZeneca recipients in Denmark/Norway⁶ calculated thrombosis events in excess of natural background risk:
 - Additional venous thromboembolisms (includes deep venous thrombosis, pulmonary embolism and CVST) possibly attributed to vaccine: 11 per 100,000 doses and mostly in women.

CONTEXT

- Suspect VITT if AstraZeneca or Johnson & Johnson vaccine 4-28 days prior, signs/symptoms or positive imaging of serious thrombosis with thrombocytopenia.⁷
 - Diagnosis confirmed with positive heparin-induced thrombocytopenia assay.^{4,7}
 - Clinical pathways available to guide approach to suspected VITT⁸:
<https://is.gd/71P712>
- Patient decision tool for AstraZeneca vaccine available:⁹ <https://is.gd/Bn4EPJ>
- To report possible vaccine related adverse events in Canada:¹⁰ <https://is.gd/LwKQNDI>

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