

The Incidence of Myocarditis/Pericarditis and New Onset Cardiac Symptoms Following Smallpox and Influenza Vaccination

A Prospective Study

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We have been barraged by government agency statements and peer-reviewed publications from academic medical centers asserting that serious complications from COVID-19 vaccination are "rare." Often, investigators take a number of spontaneously reported events from a data system, and in error, divide that number by the total injections given in a period of time. This is incorrect since not all individuals who took the vaccine were assessed for the outcome and we cannot assume they are OK.

Engler et al from Military Vaccine Agency-Vaccine Healthcare Centers Network (currently Defense Health Agency, Immunization Healthcare Branch), make this point with an analysis of myocarditis after smallpox and trivalent influenza vaccination. Both study cohorts were evaluated during a pre-immunization visit and up to 2 post-vaccine visits (day 5-8 and/or day 9-28).

Baseline data including age, race/ethnicity, sex, cardiac risk factors, atopic/medical history, and fitness assessments as measured by physical training abilities, were collected on the day of the SPX or TIV immunization. Clinical data including cardiac symptoms with visual analogue scale rating (0-10) of severity, 12-lead electrocardiograms (ECG), and troponin-T were collected at baseline and at between days 5 and 30.

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RESEARCH ARTICLE

A Prospective Study of the Incidence of Myocarditis/Pericarditis and New Onset Cardiac Symptoms following Smallpox and Influenza Vaccination

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Table 1. Myocarditis case definition for surveillance of adverse events after smallpox vaccination in the United States, 2003¹³.

Evidence Level of Diagnostic Certainty	Signs & Symptoms	Testing	Imaging Studies ¹	Histopathology
Suspected Myocarditis Symptom onset within 4–30 days post smallpox vaccine (applies to all diagnostic levels of certainty)	Dyspnea, palpitations, and/or chest pain of probable cardiac origin, in the absence of any other likely cause of symptoms	Cardiac enzymes: Normal or not performed ⁸ ECG findings: New, beyond normal variant ⁹	Evidence of diffuse or focal depressed left ventricular function of indeterminate age	Not performed or normal
Probable Myocarditis	Dyspnea, palpitations, and/or chest pain of probable cardiac origin, in the absence of any other likely cause of symptoms	Cardiac enzymes: Elevated cTnT, cTnI or CK-MB ⁸ ECG findings: New, beyond normal variant ⁹	Evidence of focal or depressed left ventricular function that is documented new onset or increased severity ¹⁰ ; myocardial inflammation	Not performed or normal
Confirmed Myocarditis	Dyspnea, palpitations, and/or chest pain of probable cardiac origin, in the absence of any other likely cause of symptoms	Cardiac enzymes: Not performed, normal or elevated ⁸ ECG findings: Not performed, normal or abnormal ⁹	Not performed, normal or abnormal	Evidence of myocardial inflammatory infiltrate with necrosis and myocyte damage

*Cardiac enzymes: Cardiac-specific troponin I (cTnI) or T (cTnT) preferred but includes creatine kinase-myocardial band (CK-MB).

⁸ECG findings: Electrocardiogram findings (beyond normal variants) not previously documented to include ST-segment or T-wave abnormalities; paroxysmal or sustained atrial or ventricular arrhythmias; atrial ventricular nodal conduction delays or intraventricular conduction defects; continuous ambulatory electrocardiographic monitoring that detects frequent atrial or ventricular ectopy.

¹⁰Imaging studies: Include echocardiograms and radionuclide ventriculography using cardiac MRI with gadolinium or gallium-67; in absence of a previous study, findings of depressed left ventricular function are considered of new onset if, on follow-up studies, these findings improve or worsen.

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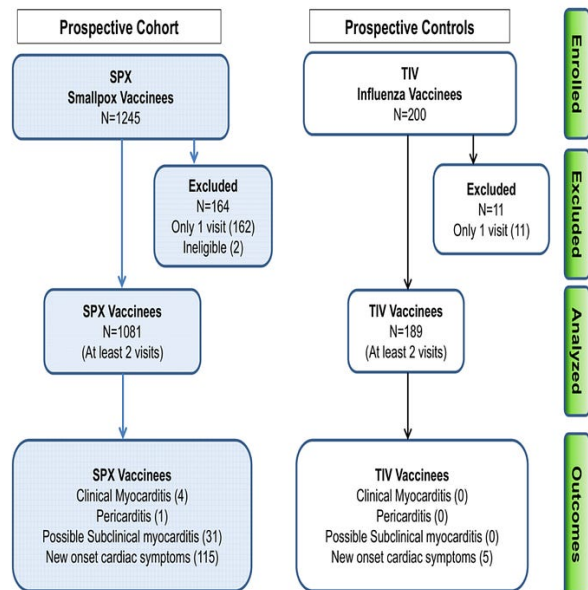


Fig 1. Subject enrollment, exclusions and outcomes for two prospective cohorts, post-smallpox and annual trivalent influenza vaccine. doi:10.1371/journal.pone.0118283.g001

Engler RJ, Nelson MR, Collins LC Jr, Spooner C, Hemann BA, Gibbs BT, Atwood JE, Howard RS, Chang AS, Cruser DL, Gates DG, Vernalis MN, Lengkeek MS, McClenathan BM, Jaffe AS, Cooper LT, Black S, Carlson C, Wilson C, Davis RL. A prospective study of the incidence of myocarditis/pericarditis and new onset cardiac symptoms following smallpox and influenza vaccination. PLoS One. 2015 Mar 20;10(3):e0118283. doi: 10.1371/journal.pone.0118283. PMID: 25793705; PMCID: PMC4368609.

While there were no myopericarditis events with the influenza vaccine, there were 5 cases with the smallpox shot. Compared to historical rates of spontaneous reporting, there was a fourfold increased incidence of cardiac symptoms when assessed prospectively.

In vaccine safety research, we should not trust any assertions of “rarity” unless it is a prospective cohort study in which all recipients are checked. We should focus on the absolute number of serious adverse events which are the crude data. These numbers cannot be argued with our understanding that they indeed happened, but are likely to be a gross underestimate of reality.

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