

Comprehensive study of vaccine safety concludes that vaccines are 'remarkably safe'

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A comprehensive review of vaccine data over a 20-year period finds that vaccines are remarkably safe.

A large proportion of safety issues were identified through existing postmarketing surveillance programs and were of limited clinical significance. Findings from a [cohort study](#) are published in *Annals of Internal Medicine*.

Vaccines are considered one of the greatest achievements of modern public health, saving countless lives and all but eliminating once prevalent diseases such as mumps, measles and poliomyelitis. The current COVID-19 pandemic is a reminder of life with contagious infectious diseases without an effective [vaccine](#). However, vaccination hesitancy has reduced [vaccination rates](#) in recent years and outbreaks linked to intentional unvaccination have been reported.

Researchers from Tel Aviv Sourasky Medical Center studied initial and subsequent labels of 57 vaccines that were FDA-approved between January 1996 and December 2015 to explore postmarketing safety modifications in U.S. Food and Drug Administration (FDA)-approved vaccine labels.

The researchers aggregated hundreds of thousands of reports from the FDA's Vaccine Adverse Event Reporting System (VAERS) following hundreds of millions of administered vaccines for their study. They found 58 postapproval, safety-related label modifications associated with 25 vaccines.

The most common safety issue triggering label modifications was restriction of vaccination for specific populations, such as immunocompromised patients or pre-term infants, followed by allergies. Most new [safety](#) data were identified through VAERS, underlining the quality of the FDA's postmarketing surveillance of vaccine side effects.

According to the researchers, these findings do not support vaccine hesitancy; but rather, show that vaccines are safe and that public

vaccination should remain as a major public health strategy.

More information:

<https://www.acpjournals.org/doi/10.7326/M20-2726>

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