Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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COVID-19 mRNA vaccine safety during the first 6 months of roll-out in the USA

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A primary mission of the US vaccination campaign, which began in December, 2020, following emergency use authorisation (EUA) of the BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) COVID-19 mRNA vaccines, was ensure vaccine benefit while monitoring vaccine safety.[1,2] This mission was facilitated by both the enormity of the roll-out and mRNA COVID-19 vaccine distribution and the administration by the US Government of all doses, giving an unprecedented opportunity to measure vaccine safety. As of Feb 28, 2022, over 530 million doses of mRNA COVID-19 vaccines had been administered in the USA.

In *The Lancet Infectious Diseases*, Hannah Rosenblum and colleagues[3] from the US Centers for Disease Control and Prevention report the first 6 months (Dec 14, 2020, to June 14, 2021) of safety monitoring of mRNA COVID-19 vaccines, in individuals aged at least 16 years, during which time over 50% of the eligible US population received at least one vaccine dose and more than 298 million doses were administered.

Post-EUA safety data were accrued through the Vaccine Adverse Event Reporting System (VAERS), a passive and spontaneous reporting system that was established in 1990, and active surveillance through the smartphone-based system v-safe.[4] V-safe was developed in 2020 to actively monitor mRNA COVID-19 vaccine safety, reactogenic symptoms, and health effects.[5] Reporting rates for adverse events were calculated using the number of doses of mRNA vaccines administered during the 6 months as a denominator.[6]

Of the 340 522 VAERS reports submitted following both mRNA vaccines, 313 499 (92·1%) were non-serious, 246 085 (72·3%) were from female recipients, and 154 171 (45·3%) were from those aged 18–49 years. The most common Medical Dictionary for Regulatory Activities (MedDRA) terms assigned to non-serious reports were headache, fatigue, and pyrexia, and to severe reports were dyspnoea, death, and pyrexia. Deaths comprised 4496 serious reports (1·3% of all reports to VAERS). 4471 reports were verified as unique deaths after review, of which more than 80% were reported in individuals aged 60 years and older. Of 808 (18·1%) reports for which death certificates or autopsy reports were available, 376 (46·5%) deaths were attributed to heart disease and 102 (12·6%) to COVID-19.

7 914 583 individuals enrolled in v-safe and completed at least one health survey 0–7 days after mRNA COVID-19 vaccination during the study period following dose one or two. Adverse events were mild, non-serious, more common after dose two than after dose one, and included injection-site pain, fatigue, and headache. More reactogenic symptoms were reported in female than in male recipients and in individuals younger than 65 years than in older recipients. Health effects, including the inability to do everyday activities, work, or seek medical care, were also greater after dose two than after dose one and affected female recipients more than male recipients.

Reassuringly, the 6-month VAERS data suggest that although approximately one in 1000 vaccinated individuals might have an adverse event, most events are non-serious. No unusual patterns emerged in causes of death or serious adverse events among VAERS reports. Deaths predictably were most common in those older than 65 years, which includes those who were most at risk of death before vaccination. The reactogenicity findings from v-safe following mRNA COVID-19 immunisation support those reported from clinical trials and a large population study in the UK.[1,2,7]

VAERS is affected by under-reporting, and although it can monitor for potential safety signals, the system cannot define a causal relationship between vaccination and adverse events. For adverse events of special interest, it is reassuring that there were no unexpected signals other than myopericarditis and anaphylaxis, already known to be associated with mRNA vaccines. The health effects following mRNA COVID-19 immunisation measured by v-safe are informative to allow planning of the timing of vaccination for those hesitant because of the threat of inability to work and lost income. Furthermore, the predictable, non-serious, and transient nature of the adverse events provides an objective basis for employees to be given provision for paid time off work to increase vaccine confidence and uptake by individuals. A limitation of the v-safe data is that they are biased away from older and socioeconomically disadvantaged populations who might not have access to electronic devices to complete web-based surveys. A future goal could be to find mechanisms to engage diverse populations in v-safe through both mobile web-based and non-web-based resources (eg, telephone surveys) for data collection. Although trends in differences in reactogenicity have emerged among the mRNA vaccines, neither VAERS nor v-safe is ideally placed to measure these safety differences.

Despite these limitations, with the VAERS, v-safe, and vaccine administration data, the safety monitoring of the mRNA COVID-19 vaccines stands out as the most comprehensive of any vaccine in US history. The use of these complementary monitoring systems has provided robust and reassuring data on the epidemiology of adverse events related to mRNA COVID-19 vaccines that reinforce the importance of both continued surveillance and safety of COVID-19 immunisation and support continued confidence in vaccination.

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SARS-CoV-2 transmission: time to rethink public health strategy

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As we enter the third year of the COVID-19 pandemic, many key questions about SARS-CoV-2 transmission dynamics remain unclear.[1,2] In *The Lancet Infectious Diseases*, Cheryl Cohen and colleagues explore the nuances involved in SARS-CoV-2 household transmission.[3] Current evidence supports transmission between household contacts as a substantial driver of SARS-CoV-2 spread.[4,5] Increased transmission in household settings is likely to be due to non-use of personal protective equipment and close prolonged contact during daily activities within the household.[2] Although evidence shows that people with asymptomatic COVID-19 can transmit SARS-CoV-2, the exact extent of this transmission was not known.[1]

The prospective household cohort study of SARS-CoV-2, influenza, and respiratory syncytial virus community burden, transmission dynamics, and viral interaction in South Africa (PHIRST-C) by Cohen and colleagues comprehensively investigated the incidence, reinfection, and transmission dynamics within urban