



Update: v-safe after vaccination health checker

Advisory Committee on Immunization Practices (ACIP) meeting

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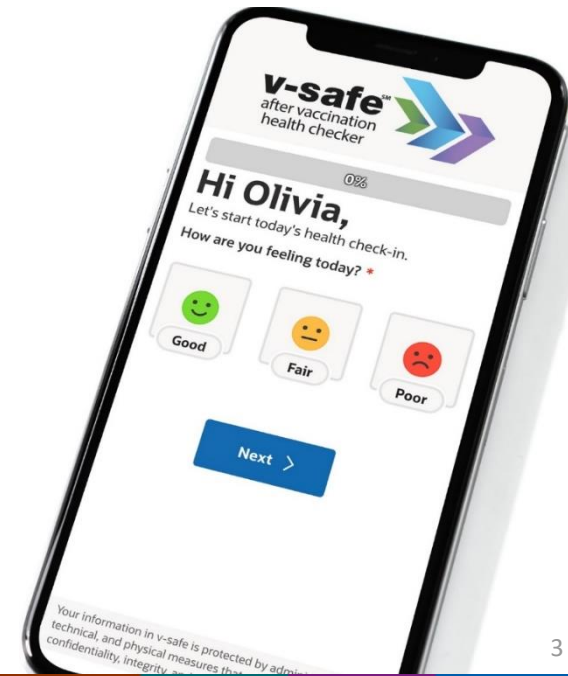
Centers for Disease Control and Prevention (CDC)

Topics

- Overview of v-safe
- Contributions of v-safe to the COVID-19 response
- Historical and current participation in v-safe
- Planning for the wind-down of the current system and development of next version of v-safe
- Continued safety monitoring of COVID-19 vaccines

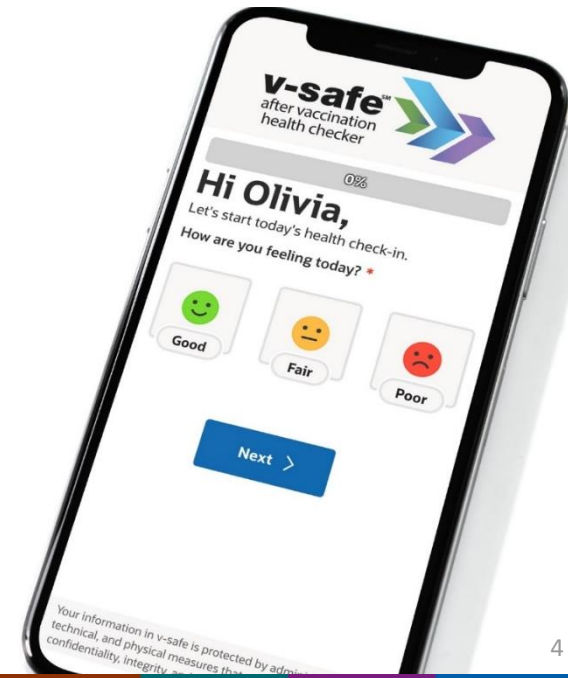
Overview of v-safe for COVID-19 vaccines

- Implemented December 2020
- Designed to collect near-real time data by direct outreach to COVID-19 vaccine recipients
 - Initially conceived to rapidly collect basic safety data (local and systemic reactogenicity, health impacts) at the onset of the COVID-19 vaccination program to provide early data while other systems, such as VAERS and the Vaccine Safety Datalink, were accruing data
 - Identified vaccinated pregnant persons for possible enrollment in the COVID-19 Vaccine Pregnancy Registry
 - Was useful in rapidly collecting early safety data when authorizations and recommendations expanded to other age and risk groups (e.g., additional doses for immunocompromised persons)
 - Was quickly adapted to capture simultaneous administration of other non-COVID vaccines (e.g., flu vaccine)
- Designed, built, and supported in collaboration with Oracle Health Services under a donation agreement with HHS



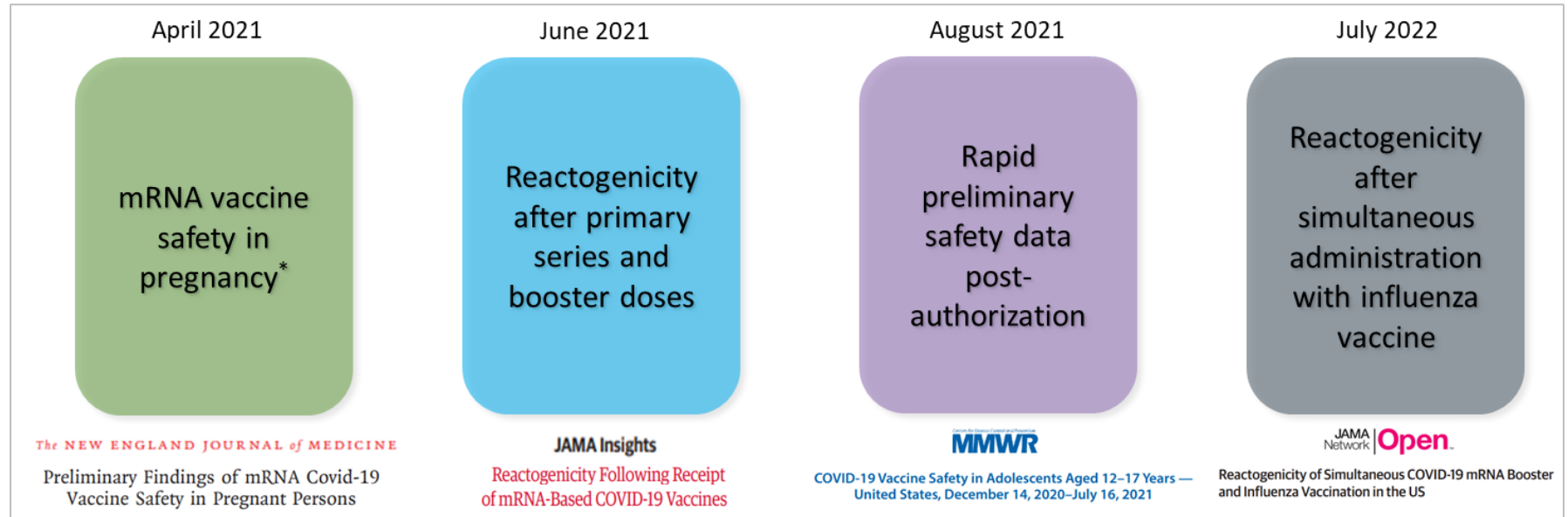
Overview of v-safe for COVID-19 vaccines (continued)

- Enrollment by self-registration on smartphone with any dependents added to guardian's account
- Survey completion prompted by text message reminders for "health check-ins"
- Call follow-up to all participants who report a medically attended event
- Robust participation in its first year
 - 9.3 million participants / 131 million health surveys completed
- Total participation to date
 - 10.1 million participants / 151 million health surveys completed



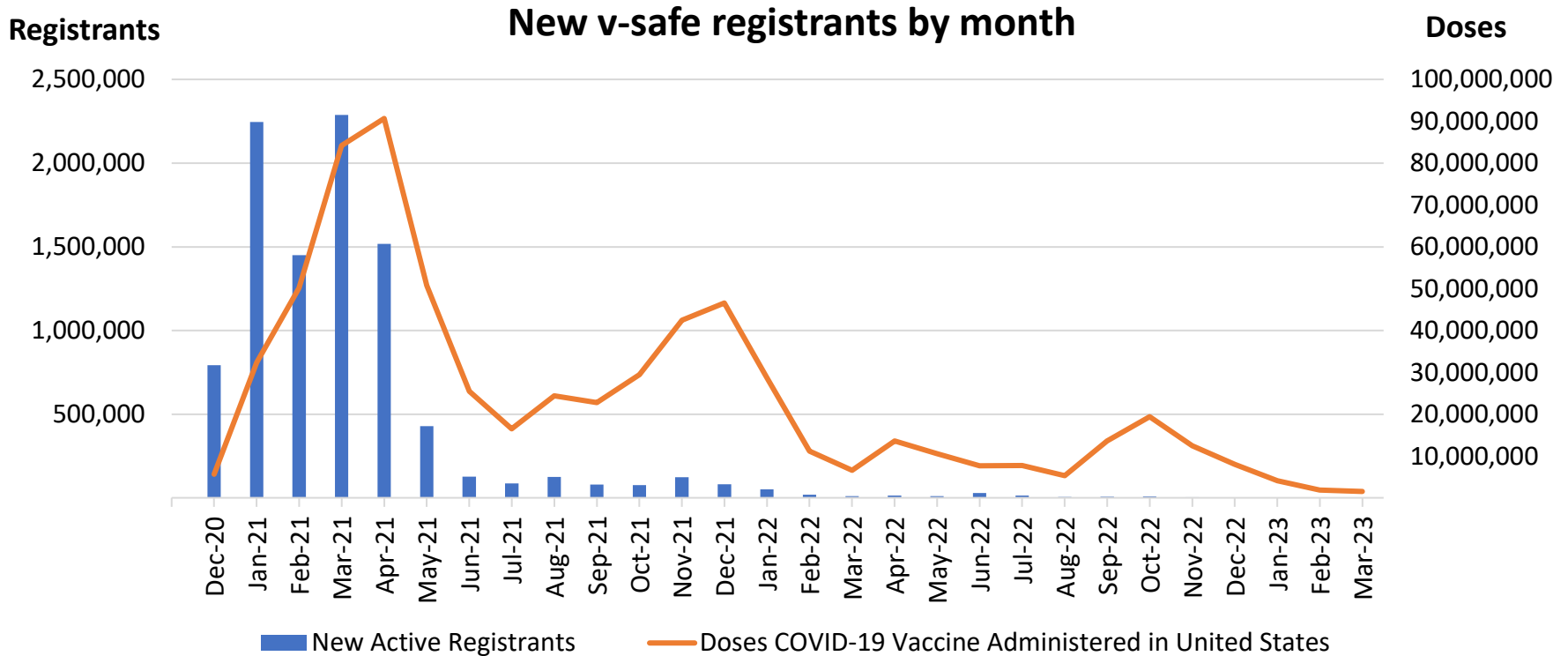
Key contributions of v-safe to COVID-19 vaccine safety

- V-safe has been particularly effective in characterizing the basic safety of COVID-19 vaccines during early vaccine introduction and following new authorizations and recommendations
- V-safe successfully accomplished its mission and worked as intended



*V-safe identifies pregnant people for enrollment in [Vaccine Pregnancy Registry | CDC](#)

Participation in v-safe for COVID-19 vaccines



Active registrants defined as those completing at least one survey by April 9, 2023

Doses COVID-19 vaccine administered sourced from COVID Data Tracker

Next steps for v-safe

- Timing for final registration and completing surveys will be announced soon
- Follow up will continue on reports of medically attended health events
- Next generation v-safe is under development
 - Plans to collect data on new vaccines
 - Will allow greater flexibility for surveys and use CDC IT infrastructure
 - Designed to permit longer-term support for collecting data rapidly from a large number of vaccine recipients

CDC vaccine safety monitoring for COVID-19 vaccines

- Safety monitoring and assessment of COVID-19 vaccines will continue in:
 - Vaccine Adverse Events Reporting System (VAERS)
[VAERS | Vaccine Safety | CDC, Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](#)
 - Vaccine Safety Datalink (VSD)
[Vaccine Safety Datalink \(VSD\) | VSD | Monitoring | Ensuring Safety | Vaccine Safety | CDC](#)
 - Clinical Immunization Safety Assessment (CISA) Project
[Clinical Immunization Safety Assessment \(CISA\) Project | CISA | Monitoring | Ensuring Safety | Vaccine Safety | CDC](#)

CDC vaccine safety monitoring

- Strong, complementary systems are in place—both new and established

VAERS



VSD



CISA Project



v-safe



Full list of U.S. COVID-19 vaccine safety monitoring systems

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

Vaccine Adverse Event Reporting System (VAERS), Vaccine Safety Datalink (VSD), Clinical Immunization Safety Assessment (CISA)

Acknowledgements

- CDC Immunization Safety Office
 - V-safe Team
- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
- CDC NCEZID and DHQP Communications Teams
- Oracle Health Services
- Participants in v-safe



For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Photo credit: James Gathany
(<https://www.cdc.gov/phil/Details.aspx?pid=8876>)

