FACT SHEET - Pandemic to Prevention: Charting the Course of COVID-19 Vaccines

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In summary: Why get vaccinated for COVID-19?

- **Vaccination provides safer, more reliable immunity than natural infection.**
- Vaccines **reduce the chance of hospitalization, severe disease, and death**, especially in seniors.
- **Vaccines administered during pregnancy reduce risks associated with severe COVID-19** and may prevent complications like stillbirth and preterm birth.
- **Vaccination offers added protection** to people who have had COVID-19, including protection against being hospitalized from a new infection.

Staying Up to Date: Guidance for Vaccination

- Vaccination during pregnancy can help protect newborns (under 6 months old) from COVID-19 hospitalization.
- Children from 6 months to 4 years require a series of vaccine doses, including an updated annual COVID-19 vaccine, to be fully up to date.
- **Everyone aged 5 years and older should receive an updated annual COVID-19 vaccine dose to protect against severe disease.**
- People 65 years and older who received 1 dose of an updated annual COVID-19 vaccine should receive 1 additional dose at least 6 months later.
- Vaccination is highly encouraged for anyone with **pre-existing health issues, such as diabetes or heart conditions**.
- People who are moderately or severely immunocompromised may get additional doses of updated COVID-19 vaccine.

Background: Development and Rollout of COVID-19 Vaccines

- May 15, 2020: Operation Warp Speed was initiated to expedite the development, authorization, and distribution of effective COVID-19 vaccines, while maintaining strict safety and efficacy standards.
- **COVID-19 vaccines were built on a foundation of existing coronavirus research**, based on to prior outbreaks of related coronaviruses such as MERS and SARS.
- mRNA technology, which is a cornerstone of some COVID-19 vaccines, is not new; it has been studied and used over several decades for various purposes, including cancer and other viral vaccines.
- The Pfizer-BioNTech mRNA vaccine was approved under Emergency Use Authorization (EUA) until August 23, 2021, at which point the FDA gave full approval to the Pfizer vaccine for individuals aged 16 years and above, marking a significant milestone in vaccination efforts.

Addressing COVID-19 Vaccine Concerns

- **The benefits of COVID-19 vaccination exceed the potential risks.** While all medical interventions, including vaccines, may have side effects, the risk of adverse events is rare.
- There is **no evidence of increased risk of miscarriage, preterm birth, stillbirth, or congenital anomalies**.
- **Cases of myocarditis and pericarditis after vaccination have been infrequent**, but when they occur, are predominantly observed in young males after the second mRNA vaccine dose (as determined through VAERS). The majority of affected individuals respond favorably to treatment and rest and recover quickly.
- Following a thorough review, a link between the J&J/Janssen COVID-19 vaccine and thrombosis with thrombocytopenia syndrome (TTS) was established (occurring in approximately 4 cases per 1 million doses administered), leading to a **preferential recommendation for mRNA COVID-19 vaccinations as advised by the ACIP**, and the cessation of the J&J/Janssen vaccine usage in the U.S.
- **Summary**: Severe adverse reactions following COVID-19 immunization are very rare, and preventive measures have been implemented to safeguard the public from potential adverse events.

Vaccine Adverse Event Reporting System (VAERS)

- VAERS is a system that accepts reports from diverse sources including patients, relatives, healthcare professionals, and vaccine manufacturers.
- The primary role of **VAERS is not to attribute causality, and submissions do not imply that a health event is vaccine-induced**.
- Should VAERS identify a consistent pattern of adverse events, more specialized vaccine safety systems conduct more thorough investigations to assess the findings.

Just the Facts: Addressing Vaccine Myths and Misinformation

- COVID-19 vaccines are **free of elements like preservatives, human tissues (e.g., cells from abortions), antibiotics, food proteins, medicines, latex, or metals**.
- Current evidence indicates that **neither COVID-19 vaccines nor any other vaccines affect fertility** in either women or men.
- **mRNA vaccines do not interact with or alter human DNA**. The delivered genetic material does not penetrate the cell nucleus, where DNA resides, thus it does not modify an individual's genetic material.
- Both of the major types of COVID-19 vaccines (mRNA and protein subunit vaccines) operate by supplying cells with instructions (genetic material) to start building immunity against SARS-CoV-2, the virus responsible for COVID-19.

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Sources

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