

Patient Safety Advisory



Age Requirements for COVID-19 Vaccine Administration

Situation

With the increase in administered COVID-19 vaccines, there has been a rise in the number of voluntary Joint Patient Safety Report (JPSR) submissions for COVID-19 vaccine errors. JPSR submissions continue to show accounts of vaccine administration to age groups outside the indicated range, as well as errors in administering second doses when this occurs.

Background

This advisory is a follow-on to a January 2021 advisory related to a similar error trend. To prevent the spread of COVID-19, the Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for three vaccines, Pfizer-BioNTech, Moderna, and Janssen. Under the EUAs, the vaccines are authorized for the following ages:

- **Pfizer-BioNTech: Age 16 years and above, two doses administered intramuscularly at least 21 days apart**
- **Moderna: Age 18 years and above, two doses administered intramuscularly at least 28 days apart**
- **Janssen (also known as Johnson & Johnson): Age 18 years and above, 1 dose**

Children and adolescents **outside the authorized age groups should not receive COVID-19 vaccinations** at this time, due to a lack of evidence that they are safe and effective in younger age groups. It is critical that every vaccination site conducts regular, effective training to ensure proper screening procedures are followed. Training should emphasize the importance of confirming patient age and dose timing for the vaccine being administered.

Recommendations

- At each appointment:
 - Verify the current age of patients in DHA Form 207, block 4 against the age requirements for the Pfizer-BioNTech, Moderna, and Janssen vaccines.
 - Review vial instructions with patients, ask patient to state their age prior to vaccination
 - Verbally reiterate the vaccine's authorized age range and the correct number of days between doses.
- Vaccination sites should include a daily "all hands safety huddle" and post clear visual reminders. Reminders could be posters for patients and families stating what the age limits are, correct spacing of vaccines by days, and what vaccine brand is being provided that day.
- Report vaccine administration errors, equipment or supply defects, injury, and reactions to the Vaccine Adverse Event Reporting System (VAERS) and the JPSR system. Include vaccine manufacturer and lot numbers in VAERS and JPSR submissions to help track events accurately.
- Review attachment COVID-19 Comparison Chart and make it readily available for applicable staff.

References

CDC: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Authorized in the US:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

<https://www.cdc.gov/vaccines/covid-19/info-by-product/Janssen/index.html>

ACIP: Interim Recommendation for Use of Moderna COVID-19 Vaccine:

https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w

Guidance if you give Vaccine to "Under Age Requirements" patients—see below link

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2F%2F%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html scroll down to table on: Vaccine Administration Errors