CDC Vaccine Task Force

All-State/All-Awardee Meeting: Janssen COVID-19 Vaccine Rollout Meetings

March 2 and March 3

Meeting Notes

The information contained in these notes should not be utilized as guidance.

Refer to officially cleared and published documentation from the manufacturers, ACIP, FDA and CDC for official guidance and information on the efficacy, use, ordering, distribution, storage, handling, and administration of the Janssen COVID-19 vaccine.

- **Moderator: Dr. Stephen Flores; Co-Deputy for Vaccine Implementation Unit, CDC Vaccine Task Force**

- **Opening Remarks**
  Dr. Nancy Messonnier; Senior Official, CDC Vaccine Task Force
  - Thank you for joining us and for all you are doing every day to fight the pandemic
  - Specifically discussing the vaccine program: We are doing something unprecedented, and we shouldn't be surprised that it is hard as we are trying to vaccinate the entire country as quickly as possible
    - Gaining momentum in a gratifying way, and each time there is a challenge in front of us we continue pressing forward with the knowledge that this vaccine is a way to get us back to seeing friends and family
  - Janssen is 3rd safe and effective vaccine against COVID-19
    - Important tool in our toolbox to equitably vaccinate as many people as possible as quickly as possible
    - We also need to make sure we are not leaving anyone behind in the vaccination program
  - Janssen program has some advantages
    - One-dose vaccine
    - Can be stored and transported at refrigerated temperatures for long periods of time
    - These characteristics and the way that it is packaged enhance its flexibility
  - More importantly, what we hope you will continue to emphasize that everyone should get vaccinated with the first vaccine available to them to ensure protection against COVID-19
    - Important message that we should make certain is front and center to the public

- **FDA Emergency Use Authorization**
  Dr. Amanda Cohn; Chief Medical Officer, CDC Vaccine Task Force
  - FDA Emergency Use Authorization

        - (Janssen COVID-19 Vaccine - EUA Fact Sheet for Healthcare Providers Administering Vaccine)
        - FDA authorized J&J/Janssen vaccine on February 27, 2021
        - 3rd vaccine for prevention of coronavirus disease 2019 caused by Severe Acute Respiratory Syndrome Coronavirus 2 or SARS-COV-2
        - EUA allows J&J vaccine to be distributed within the US for use in individuals 18 years and older
        - FDA determined that Janssen COVID-19 vaccine met the statutory requirements and criteria for issuance of an EUA, meaning totality of available data provides clear evidence that the vaccine may be effective in preventing COVID-19
        - Data also shows that vaccine's known and potential benefits outweigh its known and potential risks, supporting the company's request for the vaccine's use in people 18 years of age and older
        - FDA authorized this vaccine for all individuals 18 years of age and older with the only contraindication being a severe allergic reaction to one of the components in the vaccine
    - Brief Overview of VRBPAC meeting held Friday, Feb 26, 2021
        - Several issues discussed at length were two pieces of information related to the authorization briefing presented by the company
            - First was related to their data on persons age of 60 years and older with underlying medical conditions which had a lower point estimate in wide confidence intervals for prevention of moderate and severe disease in that particular group of individuals
                - After further discussion VRBPAC members felt this was due to limited person time in follow-up
                    - These persons were enrolled at the end of the study, and a limited number of cases in both the placebo and recipients
                    - That will continue to be monitored closely in the coming months
            - Second point of discussion around J&J currently conducting a two-dose clinical trial
                - This trial is ongoing at this time, and there was discussion regarding what to do in the setting of potentially higher efficacy results in the two-dose vaccine clinical trial compared to the one-dose that is being authorized at this time
                - After further discussion, in the context of a pandemic where we need as many options to provide protection as quickly as possible (and knowing we can adapt and modify use of vaccines and recommendations from vaccines based on additional data), it was determine that the benefits of a single dose do outweigh the risk
            - The VRBPAC committee emphasized the high efficacy against hospitalization and death and also indicated that due to the differences

in the strains that were circulating during the clinical trial, this vaccine should not be compared to the mRNA vaccines

- **ACIP Considerations**
  Dr. Kathleen Dooling; ACIP Workgroup Lead, CDC Vaccine Task Force
    - FDA issued their Emergency Use Authorization for Johnson & Johnson Janssen vaccine on Saturday, February 27
    - ACIP voted unanimously to recommend the vaccine in the us for persons 18 years of age and older on Sunday, February 28
    - Highlights of data considered to make those decisions
        - Clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed infection that occurred at least 14 days after the vaccine was received
        - Overall efficacy was 66.3%
        - Vaccine efficacy against hospitalization was 93%
        - Company reported that there was vaccine efficacy against asymptomatic seroconversion of 74%
        - When data stratified across age, sex, race, ethnicity, and underlying medical conditions, results were generally similar to the point estimate of 66%.
            - All had overlapping confidence intervals
        - ACIP focused on data that had been accrued for any COVID that occurred 14 days or more after receipt of the vaccine and any PCR-positive specimen that was tested peripherally or centrally
        - Adverse events observed in trial
            - Serious adverse events were reported in a similar proportion between vaccinated group and placebo group (0.4% in blinded arms)
            - Approximately 2.5% of vaccinated arm had a grade 3 reaction (any reaction that interferes with your daily life), whereas 0.7% of placebo recipients had a reaction that severe
            - Many people experienced much milder reactions
                - Local reactions
                    - Approximately 50% of vaccine recipients had some type of local reaction (pain being the most common)
                    - About 55% of vaccine recipients reported a systemic reaction (headache, fatigue, myalgia being the most common)
                        - Symptoms seemed to resolve within 1-2 days of receiving the shot, and the vast majority were mild to moderate in nature
        - Not possible to compare results of the Phase 3 trial for Janssen directly to the mRNA vaccines because they were never studied head to head
            - The Phase 3 trials took place in different calendar times, in different geographies, and as a result there were different circulating strains that they were tested against and different underlying background incidence which makes them noncomparable directly

        - Characteristics of the Janssen vaccine
            - Administered via intramuscular injection with a volume of .5mL
            - Vaccine shipment and storage conditions can occur at regular refrigeration temperatures of 2-8 degrees Celsius and stored for up to 3 months in that manner
            - Single-dose regime
            - No need for diluent or reconstitution at point of use
    - When ACIP discussed how the vaccine may be used, there was agreement that during a pandemic and under an EUA, offering the Janssen COVID-19 vaccine to persons 18 years and older according to established allocation and eligibility recommendations in a given jurisdiction was an effective implementation strategy
        - Allows for jurisdictional flexibility
        - Supports rapid vaccination and increased population immunity
        - Does not single out any group
        - Allows for individuals to be vaccinated with the earliest vaccine available to them
    - MMWR published on 3/2 reports the ACIP vote and the adoption of this recommendation by CDC
        - Within report will see links to links to clinical and implementation considerations as well as resources

- **Communications**
  Kristen Nordlund, Communications Team, CDC Vaccine Task Force
    - We understand that communicating about the Janssen vaccine presents some challenges
    - Public has been following the issue of COVID-19 very closely, and there has been a lot of press coverage around every aspect of the authorization and recommendation process
        - Additionally, considering early results from early results from Pfizer and Moderna clinical trials in which they reported 94% and 95% vaccine efficacy, it set the bar very high
        - Clinical trial data released about Janssen which showed a 66% vaccine efficacy could result in people pitting the vaccines against one another even though we realize we cannot compare the clinical trials directly
        - Created a perception amongst the public that people who received the Janssen vaccine were receiving a less effective vaccine
    - CDC's communication strategy has focused on talking about the Janssen vaccine in the context of the other two vaccines
        - Now we have 3 safe and effective vaccines available to us to protect people against COVID-19
        - Janssen vaccine, like Pfizer and Moderna, is in limited supply and still recommended for the same populations (those disproportionately affected by COVID such as those in long-term care facilities or those over 65, and those who are exposed to COVID because of their job such as healthcare personnel and essential workers)

        - We hope that the Janssen vaccine will help protect more people quicker and help us control the pandemic
    - Several emails sent out (Friday and Sunday) emphasizing general messages
        - Suite of vaccines available
        - Emphasizing that having different vaccine options to use can be helpful, especially when they have different storage and handling requirements
        - Highlighted that Janssen product has proven effective at preventing serious illness, hospitalization, and deaths from COVID-19 just as Pfizer and Moderna
    - People should get vaccinated with the first product available to them

- **Provider Training**
  JoEllen Wolicki, Nurse Educator on Disproportionately Affected Adult Populations Team, CDC Vaccine Task Force
    - In process of posting materials on CDC's Clinical Materials and Education page
        - Similar to materials for Pfizer or Moderna vaccines
        - Storage and handling summary and updated toolkit
        - Materials to facilitate proper use of vaccines in a clinical setting, such as storage unit labels
        - Administration summary
        - Adding a new transportation summary
        - Updated temperature logs
        - New transport temperature log
    - CDC.gov Training and Education page
        - Large number of healthcare professionals needed to vaccinate everyone, and we understand that each of the products is different
            - Training and education will be critical
        - Page updated to reflect recommendations or trainings required based on a professional qualification of different roles within clinics and level of experience with vaccine administration
            - Will post a training module for Janssen product similar to those created for Pfizer and Moderna products

- **Shipping and Distribution**
  Chris Duggar, Distribution and Federal Programs Team Co-Lead, CDC Vaccine Task Force
    - Janssen vaccine is refrigerated
    - Will come in a cooler
        - No dry ice
        - Coolers do not need to be returned
        - Similar to packouts used in Vaccines for Children program
    - 5 doses per vial
    - 50 doses per carton (10 5-dose vials)
    - 100-dose order minimum (2 cartons)
    - Carton dimensions are ~3.6"x1.5"x2.1"
    - Expiration date is not printed on vials or cartons

        - QR code or you can look up expiration date on webpage
    - Similar to all COVID vaccines being distributed, Janssen vaccines come with a 100-dose ancillary kit
        - Same size sent out with Moderna vaccine
        - Includes syringes, needles, additional materials, shot cards, overage
    - Will receive email confirmation and an email from McKesson when orders come through
        - They go to the email address in VTrckS —provider- or facility-level POC
    - Refrigerated shippers include a job aid

- **Storage and Handling**
    - Once providers receive Janssen vaccine it should be stored at refrigerated temperatures until expiration
        - **Unpunctured vials** may be stored at room temperature (47° – 77°F) up to 12 hours
        - After product is shipped it is no longer frozen and cannot be refrozen after thawing to refrigerated temperatures
            - NEVER REFREEZE THAWED COVID VACCINES
    - **Once punctured**, vials of Janssen vaccine can be stored in the refrigerator between 2° and 6°C (36° and 46°F) for up to 6 hours and can be stored at room temperature up to 25°C/77°F for up to 2 hours.
        - Discard the vial if vaccine is not used within these times.
    - Expiration date is not printed on vials or cartons
        - General expiration date of 90 days from manufacture, but please check your particular lot(s) to confirm
            - Can scan QR code or can look up expiration date on webpage using lot number
        - Once you've received product, scanned it and noted expiration date, we ask that you check again before disposal because the 3-month expiration timeframe may be extended as more stability data is obtained
            - This will help to ensure you are not discarding viable vaccine
        - CDC COVID-19 Vaccine product materials include a tracking tool for documenting expiration date extensions
    - CDC recommends when you're transporting that you transport at refrigerated temperatures, not at room temperatures
    - We see similar storage time with punctured Janssen vials at refrigerated temperatures as with Pfizer
        - Punctured vials of Janssen vaccine can be stored in the refrigerator between 2° and 6°C (36° and 46°F) for up to 6 hours and can be stored at room temperature up to 25°C/77°F for up to 2 hours
        - Pfizer vaccine, after mixture with diluent can be stored from 35° – 77°F for up to 6 hours

- **CDC Jurisdictional Watch Desk**

- To assist with questions around the Janssen vaccine rollout CDC has re-launched its Jurisdictional Watch Desk
- Toll-free and local call numbers, organized by region, have been sent to all awardees
- These numbers will allow the 64 funded jurisdictions and 5 federal entities to reach the Vaccine Coordination Cell for technical assistance.
- Calls received between 8:00 am and 8:00 pm EST will be triaged to our Regional Teams.
- Calls received between 8:01 pm and 7:59 am EST will be logged and responded to the next day.
    - If urgent, they will be triaged to CDC's Emergency Operations Center.

Call Center Numbers	
Regions 1-4	Toll-Free: 1(833) 731 - 5110 Local: (404) 718 - 8110
Regions 5-7	Toll-Free: 1(833) 348 - 7409 Local: (404) 718 - 8111
Regions 8-10	Toll-Free: 1(833) 896 - 8952 Local: (404) 718 - 8112

- **Pfizer-BioNTech COVID-19 Vaccine: Updated Storage and Handling Guidelines**
    - Pfizer-BioNTech COVID-19 vaccine recently add another storage option.
    - On February 25, 2021, FDA announced it will allow undiluted frozen vials of Pfizer vaccine to be transported and stored at conventional freezer temperatures for a period of up to 2 weeks.
    - Storage and handling materials, including the summary and beyond-use date labels have been updated to reflect the new storage temperatures, of note:
        - Vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.
        - The **total time** vials are stored at these temperatures should be tracked and should not exceed 2 weeks.
        - These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter.
            - If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
        - Use the CDC's updated beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine to monitor how long the vaccine has been in the freezer.
        - Vaccine stored in the freezer
            - Can be returned ONCE to ultra-cold storage
                - If returned to ultra-cold storage, the 2-week time frame is suspended
                - NOTE: This 2-week time frame is cumulative. For example: vaccine returned to ultra-cold storage after storage for 1 week

at frozen temperatures, can be stored in for 1 more week at frozen temperatures.
        - Can be transferred to refrigerator storage for an additional 120 hours (5 days)
            - NEVER REFREEZE THAWED COVID VACCINES
    - Pfizer vaccine will still be delivered in a thermal shipping container with thermal data logger; dry ice replenishments can still be sent to those you would like them
    - CDC COVD-19 Vaccination clinical materials, including storage and handling guidance for all COVID-19 vaccines, can be found at COVID-19 Vaccination | CDC

- **Q&A**

1. **Is there data available to demonstrate how effective the Janssen vaccine is against the 3 new variants?**
    - We do know from trials, which took place in the US and South Africa as well as many counties in Latin America (including Brazil)
        i. In S. Africa, more than 90% of cases observed were due to B351 variant
        ii. In Brazil, significant amount of samples were the types circulating there
    - Janssen pre-specified two primary outcomes
        - One where they studied events that happened 14+ days after the vaccine
        - One with events 28+= days
    - Vaccine efficacy estimates for the U.S. and South Africa at the endpoint of >=28 days (contained in the company's first press release of results) are 72% and 57%, respectively
        i. In sub-analysis, this differed
        ii. ACIP highlighted the >=14 day endpoints, which were 74% and 52% for US and S.A, respectively
    - UK strain was not predominant in any of the places where Janssen vaccine was studied; more of a mixture of strains circulating in Brazil
    - The vaccine demonstrated efficacy against severe disease that remained high across the world regions regardless of the predominant variant circulating there
    - If we look at primary outcome being 14 or more days after vaccination, the vaccine efficacy estimates are
        i. US: 74%
        ii. South: Africa 52%
        iii. Brazil: 66%
        iv. Other Latin American countries: 63%

2. **Is there any population for which you would recommend one product over another?**
    - The ACIP recommended that the Janssen vaccine be used and recommended for all persons 18 and older in the US based on the allocation and prioritization frameworks laid out in each jurisdiction

        i. There may be populations particularly interested in this vaccine (e.g., individuals who don't want to come back for a second dose, want protection quickly, have difficulties returning for a second dose)
    - This guidance is included in implementation considerations linked in the MMWR release.

3. **At what point after receiving the Janssen vaccine is someone considered fully vaccinated?**
    - An individual will be considered fully vaccinated 14 days after receiving a Janssen vaccine dose.

4. **How will the Janssen product be incorporated into CDC guidance for people who are exposed, and what are the quarantine recommendations after exposure for individuals who have received the Janssen vaccine?**
    - The guidance for quarantine after exposure for those who have received the Janssen vaccine will be the same as for those who receive mRNA vaccines. There will not be differences in how we define quarantine recommendations between products.

5. **Panelists mentioned one contraindication being a known allergy to a vaccine component. Are there any precautions to consider when using the Janssen vaccine, and is there any recommendation for a 30-minute observation period as opposed to a 15-minute observation period? What about guidance for people who have had a severe allergic reaction to the first dose of an mRNA vaccine?**
    - CDC has released clinical considerations for the Janssen vaccine: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
    - People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.
    - People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 vaccine. People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 vaccine.
    - People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy): Consideration may be given to mRNA COVID-19 vaccination. Of note, polysorbate allergy is no longer a contraindication to mRNA COVID-19 vaccination, it is a precaution.

6. **Do we have to bring the Janssen vaccine up to room temp before administration, or can vaccinators draw it up and administer directly?**
    - There is no mention in the EUA of the of a specific time frame the vaccine should be at room temperature or an administration temperature for this vaccine.
    - Once punctured the vials can be stored in the refrigerator between 2° and 6° C (36° and 46° F) for up to 6 hours and can be stored up to 25° C/77° F for up to 2 hours. Discard the vial if vaccine is not used within these times.

7. **After puncture, vials of Janssen vaccine are good for 6 hours in a fridge and 2 hours at room temperature, but if we pre-draw syringes do those have to be stored in the refrigerator? Does this count the same as if in the vial?**
    - Yes, the same time frames for storage apply to vaccine pre-drawn into a syringe.
    - In a large clinic it would be important to mark the vaccines that were prepared first so that they can be withdrawn and administered first.

8. **Once a vial of Janssen vaccine is punctured, can it be returned to the refrigerator and left to use for more doses, and if so for how long? Or once punctured does it have to be used immediately or discarded?**
    - A punctured vial can be stored for up to 6 hours in the refrigerator.
        i. If punctured and you would like to return it to the refrigerator you may do so, but the total amount of time remains 6 hours including any time out of the refrigerator. For example, if you have a punctured vial in a refrigerator for 1 hour, remove it to fill doses and leave it out of the refrigerator for an hour, it only has 4 hours left in the refrigerator.
    - Keep the vaccine stored where it has the longest viability time, 6 hours in the refrigerator vs 2 hours at room temperature when at all possible
    - If there is any residual vaccine after 6 hours, it should be discarded

9. **Are the Vaccine Prep and Administration Summary and Standing Orders for Administering Vaccines going to be available on CDC site soon?**
    - Can anticipate these items as well as an updated version of the pre-vaccination checklist after clinical guidance is released.
    - Will be posted on Johnson & Johnson's Janssen COVID-19 Vaccine Information | CDC

10. **How many mLs are in the Janssen vial and what is the dosage per vaccine?**
    - The Janssen vial holds 3.1mL, with a dosage of 0.5mL.
    - Dosage for Pfizer is 0.3 mL.
    - Dosage for Moderna is 0.5mL.

11. **Overage supply in vial has been mentioned. Has there been thought to allowing for additional doses depending on size of syringe utilized?**

- At this time there is no recommendation to draw additional doses. The likelihood that additional doses can be pulled up is low considering the amount of product in the vial and the quantity of each dose. We have not received any information on overfill of vials.

12. **Do we have any information about or contact information for what to do in the event of excursions with the Janssen vaccine?**
    - If there are temperature excursions with the vaccine you should contact the manufacturer for guidance. There is contact information in the EUA.

13. **Can you discuss the incidence of thromboembolic events during the Janssen trial?**
    - FDA did note a small imbalance in thromboembolic events between vaccine and placebo recipients (imbalance of 15 events in vaccinated persons vs 10 events amongst persons who received the placebo)
    - Noted that there was insufficient evidence to draw causal associations between the vaccine and those events
    - Will be included in post-approval safety monitoring

14. **Is there any recommended time to wait between the time when someone would get an inactivated flu vaccine and any of the three COVID vaccines?**
    - Current recommendation is that there should be an interval of 14 days between receiving a COVID vaccine and any other vaccinations.
    - If there are extenuating circumstances whereby the need for the two vaccines would be urgent, clinicians can choose to override that guidance.
    - We look forward to co-administration studies.

15. **Is there a response for those concerned about antibody dependent enhancement with adenovirus vaccines?**
    - There is no evidence to support this concern in either early phase Janssen clinical trials or the larger phase 3 trial.

16. **Do we know what long term effects we will see in terms of symptoms in those who showed mild clinical disease?**
    - Phase 3 clinical trial had medium follow up of 2 months
        - We will continue to learn as time goes on
    - Data showed a slight reduction for breakthrough cases in vaccine vs placebo groups, but further time and study is needed

17. **Since the Janssen vaccine is a viral vector vaccine, are there any concerns about interference of antiviral medications?**
    - No. We do not expect that any antiviral medication would impact the ability of the Janssen vaccine to work or to produce an immune response.

18. **A CDC summary on the COCA Call used slides that referenced a 28-day endpoint that were showing a higher range of efficacy than those seen at 14 days. How does that square up with the recommendation of 14-day full efficacy?**
    - Janssen had specified two primary endpoints – one at =>14 days, one at >=28 days
    - Janssen reported out on both, and evidence presented to ACIP looked at both primary endpoints
        - Subanalysis and resulting recommendations focused =>14 day data, which provided more follow-up time for those in trial (particularly elderly populations)

19. **Some data seemed to indicate there was perhaps a lower efficacy rate with Native American populations – is the Janssen vaccine something that shouldn't be distributed to tribal populations?**
    - The race data reported out at ACIP and VRBPAC, focused primarily on race and ethnicity categories of "non-Hispanic black," "non-Hispanic white," "Hispanic," and "other," where they had enough information to report estimates
    - Indigenous populations were included in the study worldwide (including some in South America and in the US)
    - When we pull out the estimate for efficacy it looks lower, but it represents a small proportion of the overall demographic study
        i. It's difficult to draw any specific conclusions when we look at any one small study population
    - CDC is actively engaging with manufacturer to determine when certain races were enrolled (Janssen's trial included rolling enrollment of persons with different ages, races, etc.)
        ii. The most likely answer is that when we look at small pieces of data it is likely to be an unstable estimate with wide confidence internals

20. **There was a report of several instances of severe allergic reaction after the Janssen study was completed – could panelists review those?**
    - We know of one instance that Johnson & Johnson reported out on, which happened **not** during the one-dose Phase 3 trial but rather in a 2-dose Phase 3 trial that is still active
    - This was a reported case of anaphylaxis, but we don't know any additional details

21. **Is there a recommendation for pregnant or breastfeeding patients?**
    - Recommendations for women to receive the Janssen COVID-19 vaccine are the same as the recommendations for both mRNA vaccines.
        i. Pregnant women can be offered the vaccine.
        ii. They are also at a higher risk for COVID-19 and should be included in the 1c vaccination phase.
    - There is language available about how receipt of a COVID-19 vaccine is the decision of the woman based on her individual potential risks and discussions with her providers.
        iii. This allows for the woman to choose whether or not she would like to be vaccinated.

22. **If you have a patient who received an IIV3 and 5 days later received a COVID vaccine, does that change anything as far as COVID vaccine efficacy?**
    - No. The COVID-19 vaccine should still be counted as a dose, and the subsequent dose (if an mRNA vaccine) should be given at the recommended interval
    - This guidance may be relaxed in the future as we obtain more data

23. **Community members are asking about the bioethical aspects of the Janssen vaccine. Do they use fetal or human cells as a part of the development or while investigating the safety of the vaccine?**
    - Some vaccines use fetal cell lines, often decades old, in the development of the vaccine but aren't used in the production of the vaccine
    - The reason why people are hearing there are more concerns about the Janssen vaccine is because of the adenovirus they are required to grow the viral vector. This is grown in fetal cell lines, but there are no fetal tissues or fetal cells in the vaccine.
    - CDC is developing talking points
    - If people are ethically opposed to the Janssen vaccine they should get a different product, but in terms of responding to questions: fetal lines are used in development, but there are no fetal tissues or cells in the vaccines themselves.

24. **What are recommendations or language around vaccine efficacy in older individuals, particularly those with comorbidities?**
    - The two endpoints that Janssen pre-specified in their study (>=14 days and >=28 days) had a significant impact on how many events they ended up observing in older adults with comorbidities
        - Staggered enrollment for the Janssen study
            - Started with younger, healthy people (18-59), later began enrolling older healthy people, and finally older adults with comorbidities
            - Older adults with comorbidities, because of when they were enrolled in the Phase 3 trial, had a shorter amount of time available for follow-up, and the data shows a wide confidence interval/estimates are much less stable

- The vaccine still had very high efficacy, even in the older population, when it comes to prevention of severe disease, including hospitalization and death
- From 28 days on (which is where people are most concerned about the 60+ population), no adults were hospitalized or died 28 days after receiving the vaccine, even in the older population with comorbidities
    - 100% efficacy against hospitalization, even when breakthrough cases occurred
- All evidence that we have at our disposal about how the vaccine performed in Phase 3 trials shows performance results in those 60 and older with comorbidities that are similar to the way the vaccine performed in other age groups
    - Once we continue to stratify by age and co-morbidities we will continue to see wider confidence intervals
    - If we look specifically at persons 65+, we see that there were 16 cases in the vaccinated group vs 68 events in the placebo group, giving an estimate of 76.5% VE for all

- When stratified by underlying conditions at the 14-day mark, efficacy much closer to overall estimate of 66%

25. **What can we say to community leaders and providers to reassure them that the Janssen vaccine is an effective vaccine for elderly populations with comorbidities?**
    - CDC recommends consistently returning to primary messaging that this vaccine has been recommended as safe for use in persons 18 years of age and older
    - Use the most robust estimates gleaned from Phase 3 trials
    - Prevention of severe disease outcomes is the greatest focus
        i. The vaccine still had very high efficacy, even in the older population, when it comes to prevention of severe disease and death
    - From 28 days on (which is where people are most concerned about the 60+ population), no adults were hospitalized or died 28 days after receiving the vaccine, even in the older population with comorbidities
        ii. 100% efficacy against hospitalization, even when breakthrough cases occurred
        iii. This study is still ongoing so we will continue to receive more data over time as the time for follow-up increases
            1. The original data cut off occurred when 50% or median of individuals who had received vaccine had been monitored for 2 months
            2. We will continue to reassess, and we expect additional data when Johnson & Johnson submits for full licensure to FDA
                a. We do not anticipate further FDA and ACIP review of the data until the vaccine is submitted for BLA

26. **What expiration dates will be loaded or populated into IIS when providers or jurisdictions upload VTrckS shipment file?**
    - When we started with other products, we used a placeholder. If we do not have the specific expiration date for your lot(s) in the file, you will see a placeholder.

27. **For the Pfizer vaccine, we know they store at their warehouse/distribution center at ultra-cold temperatures. After we receive vaccine, if we store it under the new guidelines for storage, do we have an additional 5 days in the refrigerator or just the 2 weeks in the freezer?**
    a. New guidance states that Pfizer vaccine may be stored in the freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks.
        i. The **total time** vials are stored at these temperatures should be tracked and should not exceed 2 weeks.
    b. After vaccine is thawed it is viable for 5 days at refrigerated temperatures.
        i. You cannot refreeze thawed COVID vaccine. Once in the refrigerator it cannot go back into ultra-cold storage or freezer storage.