ACIP Evidence to Recommendations for Use of Janssen COVID-19 Vaccine under an Emergency Use Authorization

Question: Should Janssen COVID-19 vaccine be recommended for persons 18 years of age and older in the U.S. under an Emergency Use Authorization?

Population: Persons 18 years of age and older

Intervention: Janssen COVID-19 vaccine (5×10^{10} viral particles, single 0.5 ml dose IM)

Comparison: No COVID-19 vaccine

Outcomes:

- Symptomatic laboratory-confirmed COVID-19
- Hospitalization due to COVID-19
- All-cause death
- SARS-CoV-2 seroconversion to a non-spike protein
- Asymptomatic SARS-CoV-2 infection
- Serious adverse events
- Reactogenicity grade ≥3

Background: The emergence of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), in late 2019 has led to a global pandemic with dramatic societal and economic impact on individual persons and communities. In the United States, more than 28 million cases and approximately 500,000 COVID-19-associated deaths have been reported as of February 25, 2021. Persons of all ages are at risk for infection and severe disease. However, the risk for severe illness from COVID-19 is higher in people aged ≥65 years, those living in long-term care facilities, and those with chronic medical conditions. Additionally, there is a disproportionate burden of COVID-19 infections and deaths among racial and ethnic minority communities. Non-Hispanic Black, Hispanic/Latino (Hispanic) and American Indian/American Native persons have experienced higher rates of disease, hospitalization and death compared with non-Hispanic White persons. This is likely related to inequities in social determinants of health that put racial and ethnic minority groups at increased risk for COVID-19, including overrepresentation among essential workers who have higher risk of exposure to COVID-19, lower incomes, reduced access to healthcare, or higher rates of comorbid conditions.

In the United States, the first vaccines to prevent COVID-19 received Food and Drug Administration (FDA) Emergency Use Authorizations (EUA): Pfizer-BioNTech on December 11, 2020 for persons aged 16 years and older and Moderna on December 18, 2020 for adults aged 18 years and older. On February 27, 2021, FDA issued an EUA for Janssen COVID-19 vaccine for prevention of COVID-19 in adults aged 18 years and older. The vaccine was found to be safe and highly effective in a randomized controlled clinical trial that included 43,783 participants randomized 1:1 to receive either vaccine or placebo.

Additional background information supporting the interim ACIP recommendation on the use of Janssen COVID-19 vaccine can be found in the relevant publication of the recommendation referenced on the ACIP website.

Problem

Criteria	Work Group Judgements	Evidence	Additional Information
Is the problem of public health importance?	Yes	COVID-19 is a major global public health threat that dramatically disrupted all sectors of society worldwide. In the United States, COVID-19 has important associated morbidity and mortality. **Incidence:** As of February 25, 2021, there were 28,212,548 COVID-19 cases reported in the United States for an incidence of 8,607 cases per 100,000 population.[1] **Hospitalization:** Among sites participating in population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations, the overall cumulative hospitalization rate between March 1, 2020 and February 20, 2021 was 452.2 per 100,000 population. Among those hospitalized, 25% required care in an intensive care unit and 11% died.[2,3] **Mortality:** As of February 25, 2021, there were 506,834 COVID-19-associated deaths reported in the United States.[1] Estimates of the SARS-CoV-2 infection fatality ratio range from 0.5% to 1.4%.[4,5] **Long-term disability:** While the natural history and long-term disability from COVID-19 are being studied, data on sequelae of COVID-19 and persistent symptoms in the first weeks and months after recovery are emerging.[6] Studies have also reported a clinically significant drop (44%-69%) in the quality of life when investigated up to 8 weeks after hospital discharge.[7,8]	**Consideration of Disparities:** Older adults (aged ≥65 years) and people with certain medical conditions such as obesity, diabetes, or chronic kidney disease are at increased risk for severe illness from COVID-19, including COVID-19-associated hospitalization and death.[9-11] Over 90% of persons hospitalized for COVID-19 have an underlying condition and 46% are aged ≥65.[3] Among persons who died with COVID-19, 76% had ≥1 underlying medical condition and 80% were aged ≥65.[12] As of February 25, 2021, approximately 5% of US COVID-19 cases and 35% of COVID-19-associated deaths were among long-term care facility (LTCF) residents and staff.[13] Additionally, a disproportionate burden of SARS-CoV-2 infections and COVID-19-associated deaths occurred among racial and ethnic minority communities.[14,15] **Seroprevalence:** The herd immunity threshold for SARS-CoV-2 is expected to range between 50% and 65%.[16] As of end of December 2020, seroprevalence in the US ranged from 3% to 24% by state.[17]

Benefits and Harms

Criteria	Work Group Judgements	Evidence	Additional Information

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How substantial are the desirable anticipated effects?	Large	Risk of symptomatic COVID-19, hospitalization due to COVID-19, and deaths were reduced among persons receiving one dose of the Janssen COVID-19 vaccine rather than placebo (GRADE Tables 3a, 3b, and 3c). The clinical trial for the Janssen COVID-19 vaccine demonstrated efficacy of the 1-dose regimen a median of 2 months after receipt of vaccine.[1,2] The overall efficacy* against symptomatic, laboratory-confirmed COVID-19[§] was 66.3% (95% Confidence Interval [CI]: 59.9%, 71.8%). Similar efficacy was observed in subgroup analyses by age group, sex, race[¶], ethnicity, and those with underlying medical conditions. Two persons in the vaccine group and 29 in the placebo group were hospitalized with COVID-19.[1] Vaccine efficacy against hospitalization due to COVID-19 was 93% (95% CI: 71%, 98%). For deaths related to all causes, 5 occurred in the vaccine group and 20 occurred in the placebo group. Vaccine efficacy against all-cause death was 75% (95% CI: 33%, 91%). There were no deaths attributed to COVID-19 among vaccinated persons, and 7 among placebo recipients. Preliminary data from serum collected at day 71 suggested a lower risk of seroconversion to a non-spike protein, i.e., marker of natural infection among persons who never had PCR-confirmed COVID-19 or symptoms of COVID-19[†] (vaccine efficacy 74%, 95% CI: 47%, 89%)[1] (GRADE Table 3d).	The Phase III randomized controlled trial was conducted on three continents during a time of high COVID-19 incidence while viral variants were emerging.
How substantial are the undesirable anticipated effects?	Small	Risk of serious adverse events was low and similar between the vaccine and placebo groups (GRADE Table 3e). Grade ≥3** reactogenicity was increased among persons receiving 1 dose of the Janssen COVID-19 vaccine rather than placebo (GRADE Table 3f). Adverse events classified as serious[§§] were reported in the same proportion among recipients of vaccine and placebo, overall (0.4%) and by system organ class; they represented medical events that occur in the general population at similar frequency as observed in the study. Solicited injection-site reactions and systemic reactions within 7 days after vaccination (i.e., reactogenicity) were frequent and mostly mild to moderate. Injection-site reactions were reported by 50.2% of participants; the most frequent symptom was pain at the injection site. The most common solicited systemic reactions were headache (38.9%), fatigue (38.2%), and muscle pain (33.2%). Systemic reactions were generally more frequent in the younger age group (18-59 years) compared with the older age group (≥60 years). Most reactions resolved after 1 to 2 days. Severe adverse reactions (grade ≥3) occurred more commonly with the vaccine (2.2%) compared with placebo (0.7%) based on the Phase III trial data. No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.	Safety data showed an acceptable safety profile.[1,2] Post-marketing surveillance will be critical to detect any rare serious adverse events which were not identified in the clinical trial.

Criteria	Work Group Judgements	Evidence	Additional Information
Do the desirable effects outweigh the undesirable effects?	Favors intervention		The Work Group decided that the desirable effects of the Janssen COVID-19 vaccine outweigh the undesirable effects.
What is the overall certainty of this evidence for the critical outcomes?	Effectiveness of the intervention is Level 2 (moderate) Safety of the intervention is Level 2 (moderate)	For the critical outcomes, the certainty of evidence was moderate for prevention of symptomatic COVID-19 and for prevention of hospitalizations due to COVID-19, and moderate for serious adverse events. For important outcomes, the certainty of evidence was moderate for prevention of all-cause death, low for prevention of seroconversion, and high for reactogenicity.	

Values

Criteria	Work Group Judgements	Evidence	Additional Information

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Does the target population feel that the desirable effects are large relative to undesirable effects?	Yes	In 46 national surveys among U.S. adults conducted between March 2020 and February 2021, for the scenario that a vaccine would be or had been approved in the United States, acceptability was moderate overall. The proportion intending to receive the COVID-19 vaccine ranged across the surveys between 42%-86%.[1] Acceptance over time has been relatively stable after COVID-19 vaccines became available in December. Surveys in February 2021 reported acceptance from 62-66%.[1,2,3,4] Common reasons for positive vaccine intentions included protecting self, family, and community from SARS-CoV-2 infection and severe illness, belief that COVID-19 vaccines are safe, and ability to resume social activities.[1,2] Common concerns or factors associated with vaccine hesitancy included vaccine side effects and uncertainty about vaccine safety. Many respondents reported concerns that COVID-19 vaccine approval was too fast.[5] In a survey conducted in February 2021, after two COVID-19 vaccines were authorized and recommended for use in the United States, 46% of participants reported that they would get the vaccine as soon as it is available, 27% would "wait and see," while 18% would definitely not get the vaccine.[6]	Most surveys were conducted prior to a vaccine being available, thus respondents stated intentions for unknown or hypothetical vaccine characteristics. Knowledge and attitudes may change with time, and intentions may not reflect uptake. The survey sample populations may not be representative, limiting the generalizability of the results to all adults in the U.S. Most surveys used convenience sampling, had limited representation of minority and priority populations (such as healthcare workers or essential workers), and low or unknown response rates.
Is there important uncertainty about or variability in how much people value the main outcomes?	Probably important uncertainty or variability	Vaccination intentions varied by race or ethnicity and socioeconomic status of respondents.[2,7,8,9,10,11,12,13] Younger adults, women, non-Hispanic Black adults, adults living in nonmetropolitan areas, and adults with less education and income, and without health insurance have the highest estimates of nonintent to receive COVID-19 vaccination.[10] Acceptance was lowest among Black respondents, highest among Asian and American Indian/Alaska Native respondents[1], and increased with higher socioeconomic status. Acceptance was also greater for higher efficacy vaccines and in cases where a healthcare provider recommendation was received. A survey among Black and Hispanic respondents found that trust in the safety and effectiveness of COVID-19 vaccine were important factors related to vaccination intentions.[14]	The Work Group determined that whereas there might be variability and uncertainty in how all populations value the vaccine, for most populations, the desirable effects probably outweigh the undesirable effects.

Acceptability

Criteria	Work Group Judgements	Evidence	Additional Information
Is the intervention acceptable to key stakehold-ers?	Yes	Pandemic vaccination response planning requires collaboration among a wide range of public- and private-sector partners. All health department jurisdictions are operationalizing their COVID-19 vaccination response within their jurisdictions according to their COVID-19 vaccine implementation plans. COVID-19 vaccination has been implemented in a variety of situations, including state and local health departments, healthcare sites and hospitals, mass vaccination clinics, Long Term Care Facilities and retail pharmacies. As of February 27, 2021, more than 72 million doses have been administered to more than 48 million people, including more than 7 million doses in LTCFs.[1] There were no published U.S. provider knowledge, attitudes, and practices surveys. In a CDC survey of state health officers conducted in October 2020, common concerns about vaccine administration included vaccine hesitancy (53%), vaccine safety (32%), and communications (26%) (CDC unpublished data). Jurisdictions have expressed concern regarding vaccine supply and unmet demand for vaccine in a recent letter to the President from the National Governors Association Executive Committee.[2]	The Janssen vaccine is a one dose vaccine with more convenient storage (stable for 3 months at refrigerated conditions) and does not require dilution which may make this vaccine more acceptable to a wide variety of stakeholders.

Resource Use

Criteria	Work Group Judgements	Evidence	Additional Information

Criteria	Work Group Judgements	Evidence	Additional Information
Is the intervention a reasonable and efficient allocation of resources?	Yes	The Work Group reviewed estimates of economic costs related to COVID-19 vaccinations, disease outcomes, and disease mitigation activities. Relative to other vaccines, the costs of vaccine doses are likely to be low for traditional payer systems such as private insurance, Medicare and Medicaid because the U.S. Government has committed to providing free COVID-19 vaccines.[1] While the vaccine dose may be provided by the U.S. Government, the costs of vaccine administration may be incurred by traditional payer systems. Vaccine administration fees range from $16.94 to $28.39 per dose in some Medicare programs[2] and average $27.86 per dose in the private sector.[3] Outside the traditional health care sector, the U.S. Government has committed over $10 billion to Operation Warp Speed for the provision of vaccines.[4] An effective vaccine combined with a successful vaccination program would be expected to reduce costs associated with COVID-19 disease outcomes and other COVID-19 mitigation activities. If 20% of the U.S. population gets COVID-19, the direct medical costs could be $163 billion.[5] Health-related costs (including premature deaths, long-term health impairment, and mental health impairment) have been estimated at $8.5 trillion and lost economic productivity has been estimated at $7.6 trillion.[6] A recent study not considering societal costs estimated the economic value of COVID-19 vaccinations to range from “cost-saving” for persons aged 65 years and over to over $94,000 per quality-adjusted life-year (QALY) for those with lower risk of COVID-19 hospitalization and death.[7]	The Work Group concluded that cost-effectiveness may not be a primary driver for decision-making on this policy question. In addition, the Work Group acknowledged that a precise estimate of cost-effectiveness and economic impact of vaccination would depend on a number of factors that remain unknown, such as: real-world vaccine effectiveness and duration of protection; vaccination coverage levels and speed of vaccination; and implementation costs associated with a large vaccination program. Vaccinations occurring prior to an increase in incidence are likely to avert more infections and deaths than vaccinations that occur during or after an increase in incidence.[8] One recent modeling study has concluded that there are relatively few situations that favor foregoing the first available COVID-19 vaccine(s) for a substantially higher efficacy vaccine that becomes available later on in the pandemic.[9] The Work Group concluded that use of all vaccines with acceptable vaccine efficacy is required during pandemic because it will save lives and resources.

Equity

Criteria	Work Group Judgements	Evidence	Additional Information
What would be the impact of the intervention on health equity?	Reduced Probably reduced Probably no impact **Probably increased** Increased Varies Don’t know	Several groups were identified with disproportionate COVID-19 morbidity and mortality. The Work Group considered that some of these same groups might also experience disproportionate barriers in relation to access and receipt of the Janssen COVID-19 vaccine. The Work Group noted that the federal Pharmacy Partnership for COVID-19 Vaccination in Long-term Care Facilities (LTCF) Program offers an opportunity to increase equitable access to the Janssen	Application of the PROGRESS-Plus Framework[6,7] assisted in the identification of factors that could be associated with inequities in COVID-19 morbidity and mortality. Groups disproportionately affected by COVID-19 morbidity and mortality include: • racial and ethnic minority populations and tribal communities[8]

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		COVID-19 vaccine for LTCF residents and staff. Vaccine access may be limited for LTCF residents and staff in facilities not enrolled in the Program (e.g., facilities electing not to participate or unable to participate because of remote location). Some Work Group members noted that healthcare facilities administering the vaccine to a broad range of healthcare personnel offer the potential to increase equitable distribution of the Janssen COVID-19 vaccine. Analysis of initial vaccine allocation plans showed 38% of states adopted use of a social vulnerability index to deliver vaccines more equitably, while 62% of states and half of states with the largest shares of disproportionately affected populations pursued such goals.[2] A large nationally representative survey (n=67,000) conducted in the first half of January 2021, showed Black persons were 52% less likely than White persons to be vaccinated or definitely plan to get vaccinated, after controlling for other factors.[3] As of February 21, Black and Hispanic persons had received smaller shares of vaccines relative to shares of population in many states.[4,5] The shipping, storage, handling, and administration requirements for the Janssen COVID-19 vaccine (as detailed in the feasibility domain) will allow for distribution and use in most community settings (e.g., community-based providers) and by mobile teams. The one-dose vaccination requirement will likely make it easier to reach some underserved groups such as those who are homeless, live in rural locations, justice-involved, disabled, or have no/limited access to healthcare. This will likely increase access of the Janssen COVID-19 vaccine to some groups who bear an unfair burden of COVID-19-related morbidity and mortality. Engaging communities in decision-making or allowing for individual choice in vaccines could improve acceptance.	• people living in poverty or with high social vulnerability [9] • essential workers: racial and ethnic minority populations are disproportionately represented in subsets of essential industries,[10-12] and almost one quarter of essential workers live in low income families[10] • residents in congregate settings such as LTCF,[13] corrections/detention facilities,[14] homeless shelters,[15] and group homes[16] • people with disabilities[17] • people with substance use disorders[18] In addition, sexual and gender minorities face social or structural inequities that can lead to health disparities.[19] The judgment of a majority of Work Group members was that the Janssen COVID-19 vaccine would increase or probably increase health equity; no member judged health equity to be reduced. The judgements of the remaining Work Group members were nearly equally distributed among the remaining four judgment options. The wide range of judgments also reflected concerns about differential acceptance of vaccines in general by groups that are disadvantaged and disparities in access to healthcare services including vaccination. To help ensure that inequities are reduced whenever possible and are not increased, the Work Group noted the critical importance of: 1) identification of groups disproportionately affected by COVID-19 or who face health inequities; 2) focused outreach and education tailored to specific groups, particularly those who experience inequities in the social determinants of health; 3) identification and resolution of barriers to vaccination (e.g., access to vaccination sites or appointment scheduling, vaccine confidence); and 4) monitoring equity in vaccination across groups

Criteria	Work Group Judgements	Evidence	Additional Information
			in vaccination across groups. Equity and vaccination program implementation are closely linked. The Work Group emphasized that equitable COVID-19 vaccine administration requires community engagement and focusing on groups with lower vaccine receipt to reduce existing health inequities and adequate resourcing for federal, state and local jurisdictions to ensure access and confidence.[20]

Feasibility

Criteria	Work Group Judgements	Evidence	Additional Information
Is the intervention feasible to implement?	Yes	Delivery of any adult vaccination can be challenging in the United States. Financial barriers to receiving the Janssen COVID-19 vaccine will be reduced because the vaccine is being provided free of charge to the U.S. population. However, health systems or health departments could incur costs for COVID-19 vaccination program planning, implementation, and administration. Personal investments in time and travel to obtain vaccine may be a barrier for some persons in groups disproportionally affected by COVID-19, though the cost of one dose would presumably less than for two vaccine doses. Access to vaccine could be limited for people who are underserved or live in rural or other hard-to-reach areas. The Federal Retail Pharmacy Program for COVID-19 Vaccination should increase access to COVID-19 vaccination across the US, as most Americans live within five miles of a pharmacy.[1] The Federally Qualified Health Center Program[2] and FEMA Community Vaccination Centers should further expand access.[3] The single-dose schedule and storage/handling requirements for the Janssen COVID-19 vaccine[4] should make it feasible to administer the vaccine across a range of providers and community locations: • the vaccine can be shipped and stored for 3 months at refrigerated conditions, • the vaccine does not require dilution at the vaccination site. The existence of multiple COVID-19 vaccines with different dosing schedules and conditions for storage and handling could increase the complexity of implementation.	Innovative solutions have been employed to overcome barriers to implementation. State and local health jurisdictions have created detailed microplans in preparation for complex implementation scenarios.[5] Differential access of various subpopulations needs to be considered when planning vaccination locations, communicating vaccine information, and scheduling appointments. Additional training and job-aids may be needed on different dosing schedules and storage and handling requirements, by product. There may also be emerging challenges related to managing choice/preferences of providers and consumers for different products.

Balance of consequences

Desirable consequences *clearly outweigh* undesirable consequences in most settings.
Is there sufficient information to move forward with a recommendation? Yes.

Policy options for ACIP consideration

ACIP recommends the intervention

Draft recommendation (text)

Janssen COVID-19 vaccine is recommended for prevention of coronavirus disease (COVID-19) for persons 18 years of age and older in the U.S. under the FDA's Emergency Use Authorization.

Additional considerations (optional)

Demand for COVID-19 vaccine is expected to exceed supply during the first months of the vaccination program. ACIP considered evidence related to SARS-CoV-2 epidemiology, vaccination program implementation, and ethical principles and issued an interim recommendation on allocation of the initial doses of COVID-19 vaccine. ACIP recommended that healthcare personnel and long-term care facility residents be offered vaccine in the initial phase of the COVID-19 vaccination program (Phase 1a) (http://dx.doi.org/10.15585/mmwr.mm6949e1). Updates to ACIP interim recommendation for allocating initial supplies of COVID-19 vaccine will be posted on the ACIP website (https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html).

Final deliberation and decision by the ACIP

Final ACIP recommendation

ACIP recommends the intervention.

The Janssen COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.

*Overall efficacy was calculated at ≥14 days after vaccination among persons without evidence of prior SARS-CoV-2 infection.

[§]Moderate to severe/critical COVID-19 is defined as PCR-positive (with or without confirmation at central laboratory) AND ≥1 of: respiratory rate ≥ 20 breaths/min, abnormal SpO2, pneumonia, DVT, shortness of breath/difficulty breathing OR ≥2 of: fever (≥100.4°F [38^{0}C]), heart rate ≥90, shaking chills, sore throat, cough, malaise, headache, myalgia, GI symptoms (nausea, vomiting, diarrhea, abdominal pain), olfactory/taste disorder, red/bruised toes.

[¶]Defined as White or Black race; numbers for other race groups were too small to produce reliable estimates.

[†]Asymptomatic SARS-CoV-2 infection is defined as (1) positive serology (non-spike protein), and (2) no prior SARS-CoV-2 positive PCR or COVID-19 symptoms during the study. Seroconversion to a non-spike protein can distinguish between natural infection and vaccine-induced immunity.

**Grade 3 reactions are defined as: use of a prescription pain reliever or those preventing daily routine activity, fever 102.1-104.0^{0}F (39°C–40°C); grade 4 reactions are defined as: requires emergency room visit or hospitalization, fever >104^{0}F (40°C).

[§§]Serious adverse events defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent disability/incapacity.

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