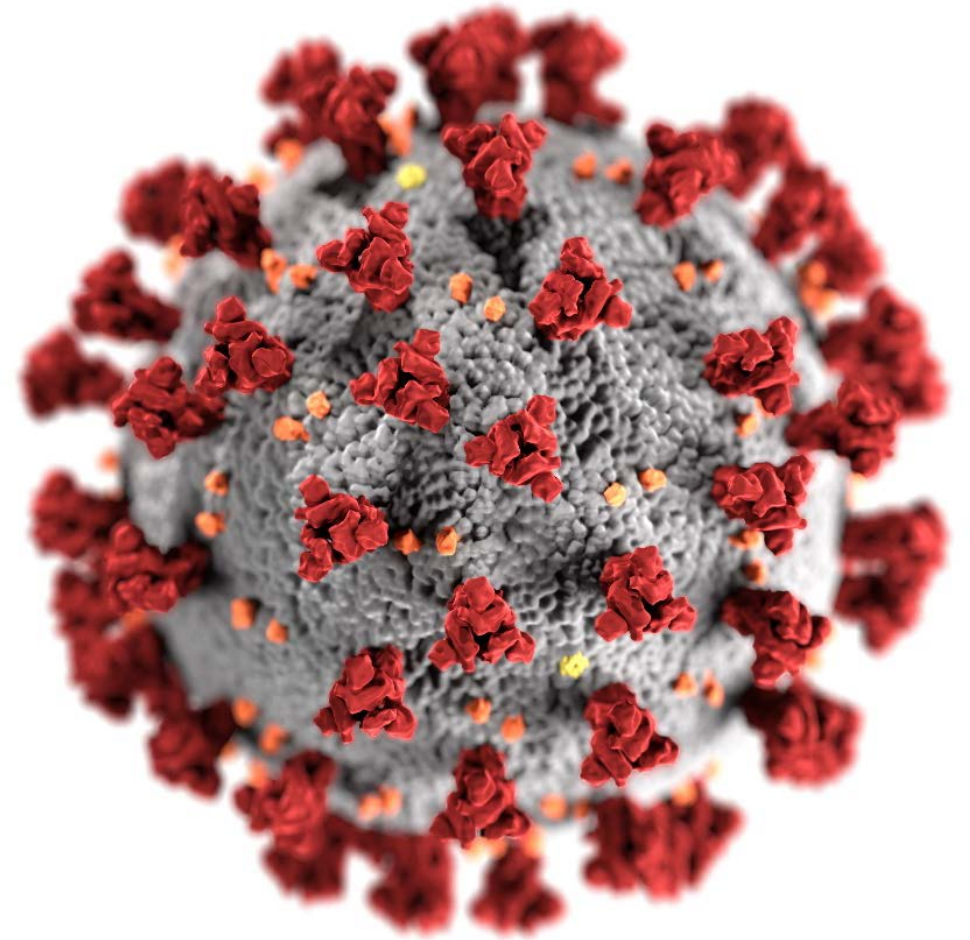


# Data and clinical considerations for additional doses in immunocompromised people

Sara Oliver MD, MSPH  
ACIP Meeting  
July 22, 2021

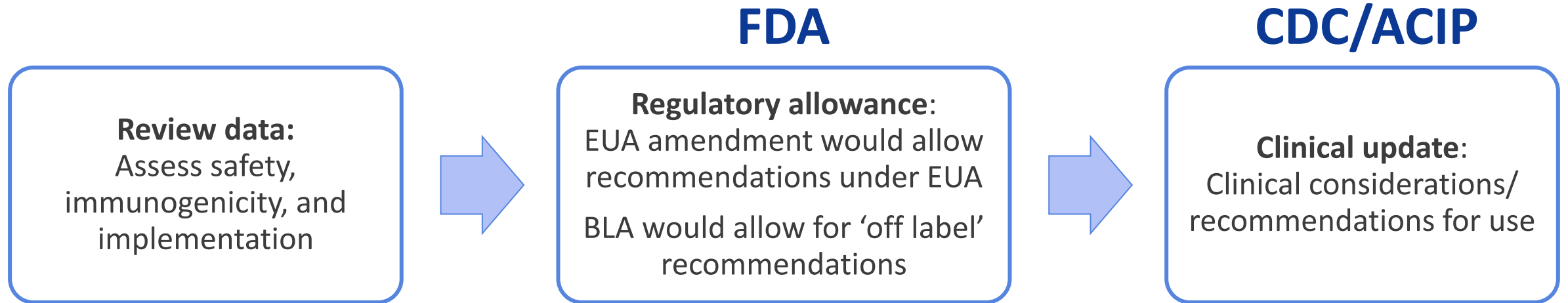


[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

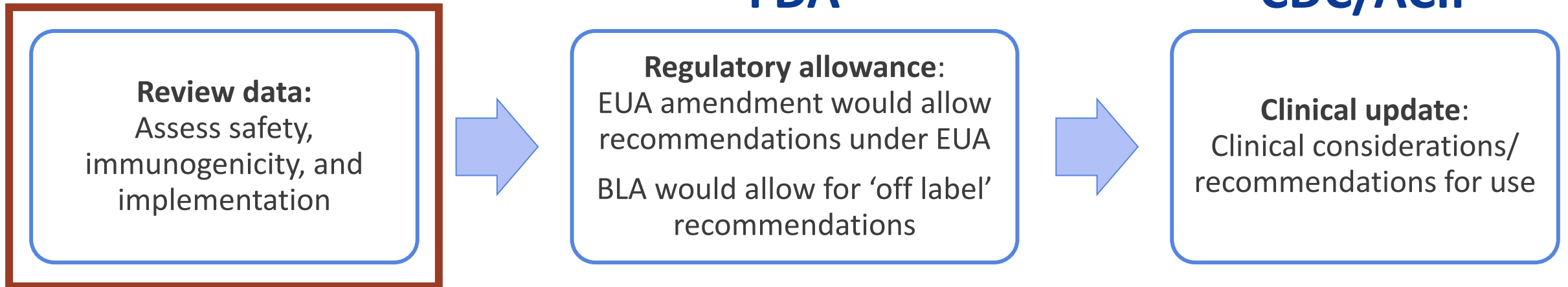
# Outline

- 1) **COVID-19 vaccine response among immunocompromised people**
- 2) **Response to an additional dose of COVID-19 vaccine among immunocompromised people**
- 3) **Frequently asked questions about vaccination of immunocompromised people**

# Additional doses in immunocompromised people



# Additional doses in immunocompromised people



# COVID-19 vaccine response in immunocompromised people:

## What do we know now?



# Immunocompromised people and SARS-CoV-2 infection

- Immunocompromised people comprise ~2.7% of U.S. adults<sup>1</sup>
  - Solid tumor and hematologic malignancies
  - Receipt of solid-organ or hematopoietic stem cell transplant
  - Severe primary immunodeficiencies
  - Persons living with HIV
  - Treatment with immunosuppressive medications such as cancer chemotherapeutic agents, TNF blockers, certain biologic agents (e.g., rituximab), and high-dose corticosteroids

# Immunocompromised people and SARS-CoV-2 infection

- More likely to get severely ill from COVID-19<sup>1,2</sup>
- Higher risk for:
  - Prolonged SARS-CoV-2 infection and shedding<sup>3-7 14-16</sup>
  - Viral evolution during infection and treatment (hospitalized patients)<sup>3,6,8-10,14,17</sup>
  - Low antibody/neutralization titers to SARS-CoV-2 variants<sup>12</sup>
- More likely to transmit SARS-CoV-2 to household contacts<sup>11</sup>
- More likely to have breakthrough infection:
  - **44%** of hospitalized breakthrough cases are immunocompromised people in US study<sup>13</sup>
  - **40%** of hospitalized breakthrough cases are immunocompromised people in Israeli study<sup>18</sup>

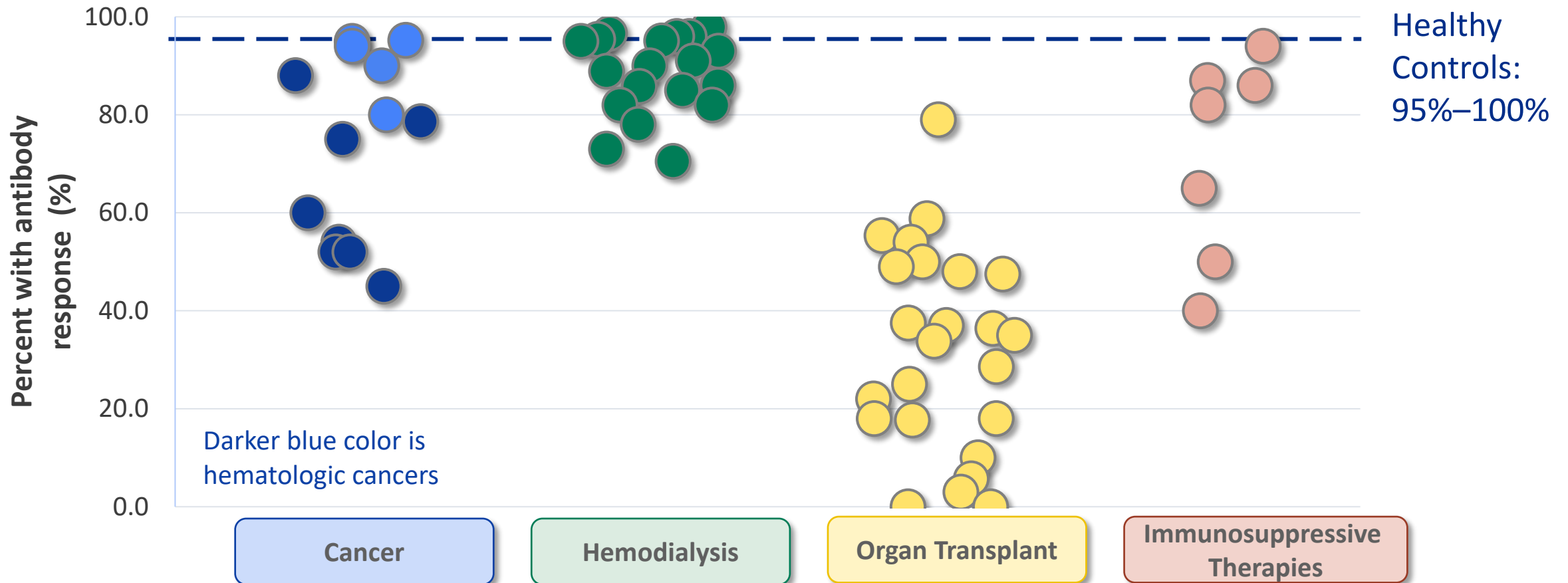
# mRNA vaccine effectiveness (VE) studies among immunocompromised populations

- VE: 7-27 days after 2nd dose of Pfizer-BioNTech vaccine<sup>1</sup>
  - **71%** (CI 37-87%) among immunosuppressed\* people vs. **90%** (CI 83-96%) overall: **SARS-CoV-2 infection**
  - **75%** (CI 44-88%) among immunosuppressed people vs. **94%** (CI 87-97%) overall: **symptomatic COVID-19**
- VE: ≥7 days after 2nd dose of mRNA vaccine<sup>2</sup>
  - **80%** among people with inflammatory bowel disease on immunosuppressive meds: **SARS-CoV-2 infection**
  - VE of **25%** was noted after 1st dose of mRNA vaccine for **SARS-CoV-2 infection**
- VE: ≥14 days after 2nd dose of mRNA vaccine<sup>3</sup>
  - **59%** (CI 12-81%) among immunocompromised people vs. **91%** (CI 86-95%) without immunocompromise: **COVID-19 hospitalization**<sup>3</sup>

\*Immunocompromised conditions (e.g., recipients of hematopoietic cell or solid organs transplant, patients under immunosuppressive therapy, asplenia, and chronic renal failure: advanced kidney disease, dialysis, or nephrotic syndrome)



# Percent of subjects with antibody response after two mRNA vaccine doses by immunocompromising condition and study (n=63)



- Studies that compared response after 1st and 2nd dose demonstrated poor response to dose 1
- Antibody measurement and threshold levels vary by study protocol

# Response to an additional dose of COVID-19 vaccine in immunocompromised people:

## The emerging data



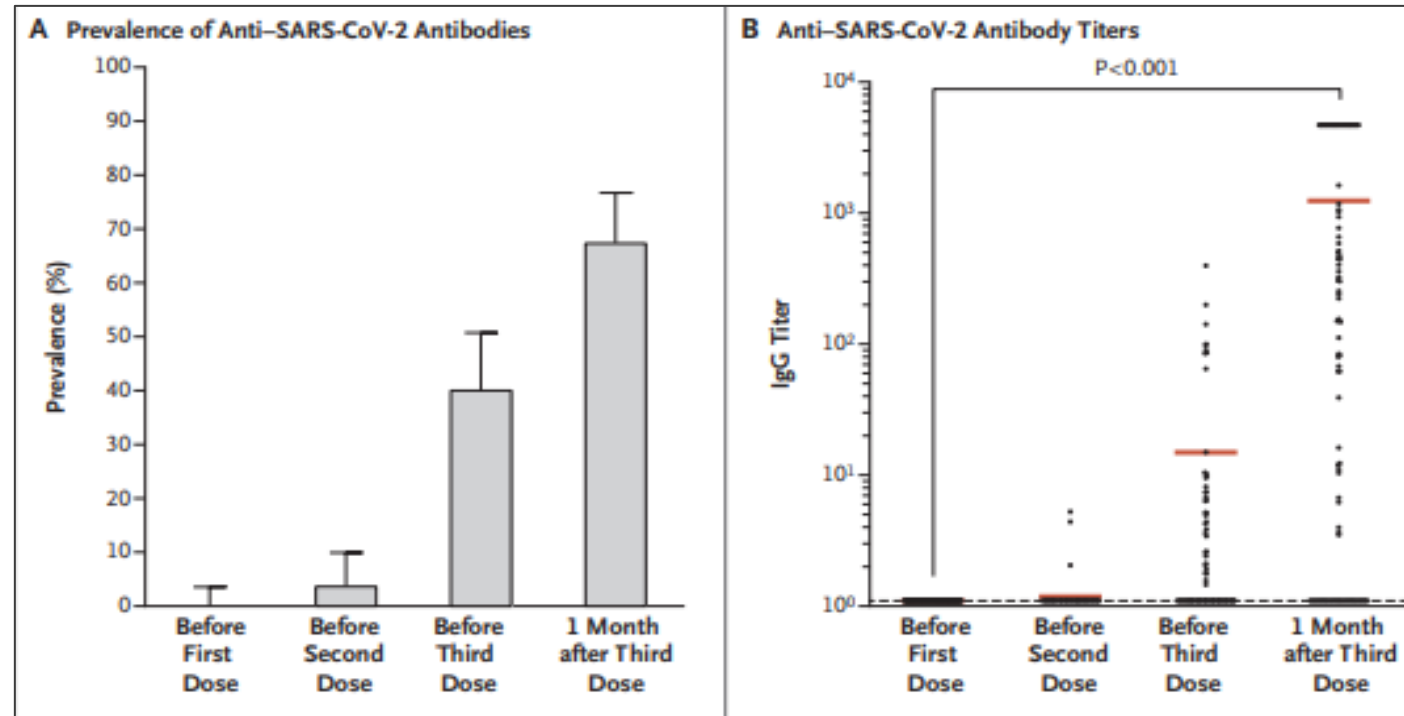
# Comparing evidence 3rd mRNA COVID-19 vaccine dose in immunosuppressed people with seropositive response

Study	Patient Population	2 <sup>nd</sup> Dose			3 <sup>rd</sup> Dose Seronegative after 2 <sup>nd</sup> dose		
		Sample Size	Seronegative N (%)	Seropositive N (%)	Sample Size	Seronegative N (%)	Seropositive N (%)
Kamar et al.	Recipients of solid-organ transplant	99	59 (60)	40 (40)	59	33 (56)	<b>26 (44)</b>
Werbel et al.*	Recipients of solid-organ transplant	30	24 (80)	6 (20)	24	16 (67)	<b>8 (33)</b>
Longlune et al.	Patients on hemodialysis	82	13 (16)	69 (84)	12	7 (58)	<b>5 (42)</b>
Maxime et al.	Patients on hemodialysis	106	66 (62)	40 (38)	12	6 (50)	<b>6 (50)</b>

\* Recipients received homologous mRNA prime followed by either a single Moderna, Pfizer, or Janssen boost

- Among those who had **no detectable antibody** response to an initial mRNA vaccine series, **33-50%** developed an **antibody** response to an additional dose

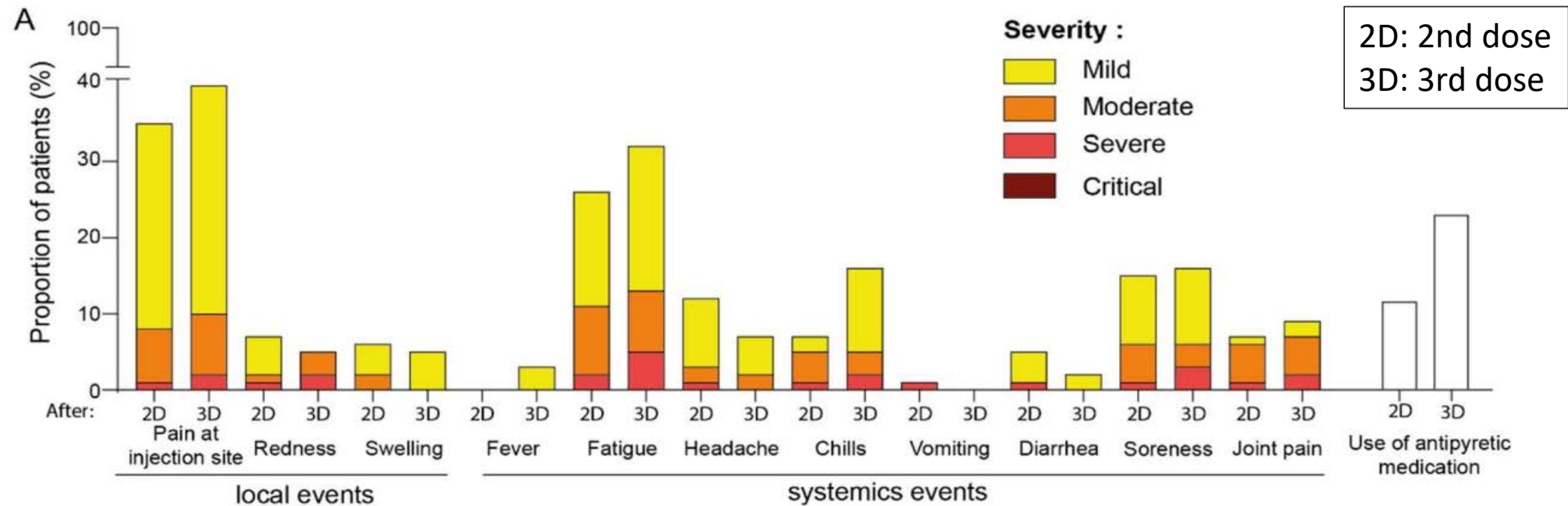
# Three doses of an mRNA COVID-19 vaccine in solid-organ transplant recipients



- No serious adverse events were reported after administration of the 3rd dose, and no acute rejection episodes occurred (n=99)

# Reactogenicity of 3rd mRNA vaccine dose in cohort of patients on hemodialysis (n=63\*)

- No patients developed critical side effects requiring hospitalization
- Symptoms reported were consistent with previous doses and the intensity of the symptoms was mostly mild or moderate



\*Sample included patients who had an optimal and suboptimal antibody response to primary mRNA series and chose to receive a 3rd dose

# International policies on additional doses for immunocompromised people

- France<sup>1</sup> (Announced April 11, 2021)
  - 3rd dose 4 weeks after the 2nd dose for patients who are “severely immunocompromised”
  - Could be extended at a later date to include a larger immunocompromised population
- United Kingdom<sup>2</sup> (Announced July 1, 2021)
  - Proposal for an additional dose for immunocompromised people  $\geq 16$  years (among others), to be implemented between 6 September and 17 December 2021
  - Decision pending
- Israel<sup>3</sup> (Announced July 11, 2021)
  - People living with organ or stem cell transplants, blood cancer, autoimmune disease and treatment with specific immunosuppressive medications
  - People with breast, lung, or colon cancer do not qualify

# Summary

- Immunocompromised people are at increased risk of poor outcomes from COVID-19
- Studies indicate a reduced antibody response in immunocompromised people following a primary vaccine series, compared to healthy vaccine recipients
- Emerging data suggest that an additional COVID-19 vaccine dose in immunocompromised people enhances antibody response and increases the proportion who respond
- In small studies, the reactogenicity of the 3rd dose of mRNA vaccine was similar to prior doses

# Frequently asked questions about vaccination of immunocompromised people





# Which immunocompromised groups should be considered for an additional dose as allowed by regulatory mechanisms?

- Conditions and treatments associated with *moderate to severe* immune compromise\*
  - Active or recent treatment for solid tumor and hematologic malignancies
  - Receipt of solid-organ or recent hematopoietic stem cell transplant
  - Severe primary immunodeficiency
  - Advanced or untreated HIV infection
  - Treatment with immunosuppressive medications such as cancer chemotherapeutic agents, TNF blockers, certain biologic agents (e.g., rituximab), and high-dose corticosteroids
- Chronic conditions associated with *varying* degrees of immune deficit, such as asplenia and chronic renal disease\*
- Different medical conditions and treatments can result in widely varying degrees of immunosuppression. A patient's clinical team is best able to assess the degree of altered immunocompetence and optimal timing of vaccination

\*General Best Practice Guidelines for Immunization and CDC Yellow Book can be consulted for detailed information

# Should immunocompromised people undergo antibody testing following COVID-19 vaccination?

- Utility of serologic testing or cellular immune testing to assess immune response to COVID-19 vaccination has not been established
- Exact correlation between antibody level and protection from COVID-19 remains unclear
- Commercial antibody and cellular immune testing may not be consistent across laboratories
- Serologic (antibody) testing or cellular immune testing outside of the context of research studies is **not recommended in the United States at this time**

# Are there data to support mixed-dose series in immunocompromised people: for example, Janssen followed by mRNA COVID-19 vaccine?

- Studies from Europe have assessed heterologous primary series (AstraZeneca and Pfizer-BioNTech) in the general adult population and found immunogenicity to be at least equivalent to homologous series<sup>1-5</sup>
  - Large UK trial (Com-COV) found that one dose of AstraZeneca + one dose of Pfizer-BioNTech resulted in superior immunogenicity compared with two doses of AstraZeneca vaccine but lower antibodies than 2 doses of Pfizer-BioNTech; increase in systemic reactogenicity observed with heterologous schedules<sup>5</sup>
- Evidence is needed regarding the safety and immunogenicity of using a mixed-dose approach for Janssen (FDA-authorized adenoviral vector vaccine) + mRNA vaccine in immunocompromised people

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# Following COVID-19 vaccination, what infection prevention measures should immunocompromised people maintain?

- Immunocompromised people should be counseled about potential for reduced immune responses to COVID-19 vaccination and need to follow prevention measures\*
  - Wear a mask
  - Stay 6 feet apart from others they don't live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider
- Close contacts of immunocompromised people should be encouraged to be vaccinated against COVID-19

\* <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>

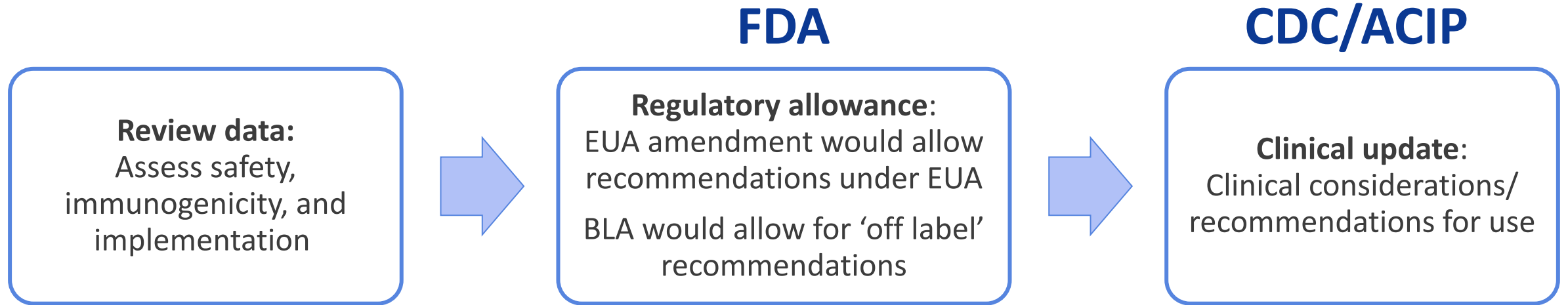
# Is there a role for monoclonal antibody use in immunocompromised people?

- Monoclonal antibodies are currently authorized by FDA for emergency use in persons with SARS-CoV-2 infection who are at high risk for progressing to severe COVID-19 and/or hospitalization
- Monoclonal antibodies are not yet authorized for SARS-CoV-2 infection prevention

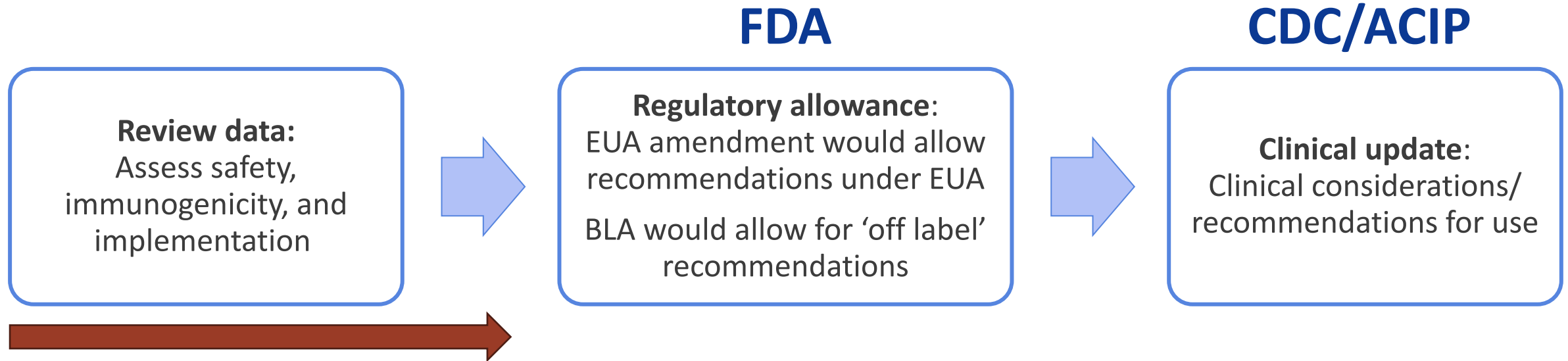
# What are the implications of the Emergency Use Authorizations (EUAs) for the COVID-19 vaccines, with respect to considerations for an additional dose in immunocompromised persons?

- FDA has authorized mRNA vaccines as a 2-dose series and Janssen COVID-19 vaccine as a single dose
- At this time, we are not aware of data submitted to FDA to support an amendment to the EUA for this population
- CDC/ACIP will closely monitor any updates to data and regulatory mechanisms

# Additional doses in immunocompromised people



# Additional doses in immunocompromised people



## Now:

Immunocompromised people should continue to **follow infection prevention measures:**

Wear a mask, stay 6 feet apart from others, avoid crowds and poorly ventilated spaces

**Close contacts** ( $\geq 12$  years) of immunocompromised people should be **vaccinated against COVID-19**

**Early treatment with monoclonal antibodies** may be beneficial in this population



# Additional COVID-19 vaccine dose in immunocompromised people: Next steps

- Assess additional studies of safety and immunogenicity of additional dose in immunocompromised people
- Assess additional studies and expert opinion regarding the subpopulations of immunocompromised people who may benefit most from an additional dose
- Determine acceptable intervals and mix and match schedules
- Await regulatory allowance (e.g. FDA amendment of EUA or BLA) for an additional dose of COVID-19 vaccine

# Questions for ACIP



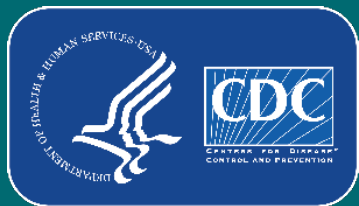
# Questions for ACIP

1. What additional data do ACIP need to inform these discussions?
2. Thoughts on the focus of “moderate to severe” immunocompromised populations, once authorized/approved?

# Acknowledgements

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- Hannah Rosenblum
- Monica Godfrey
- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

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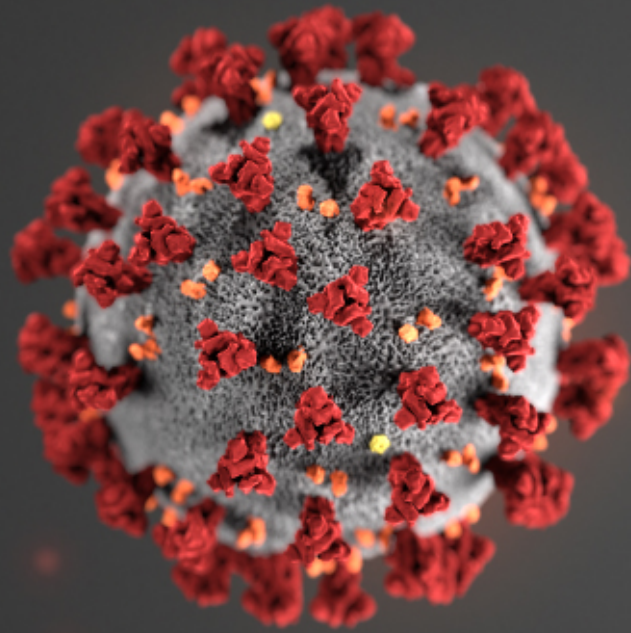
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## References for slides 10: Comparing evidence 3rd for mRNA COVID-19 vaccine dose in immunosuppressed people with suboptimal response

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