COVID-19: Who should not get vaccinated?

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I declare no conflict of interest

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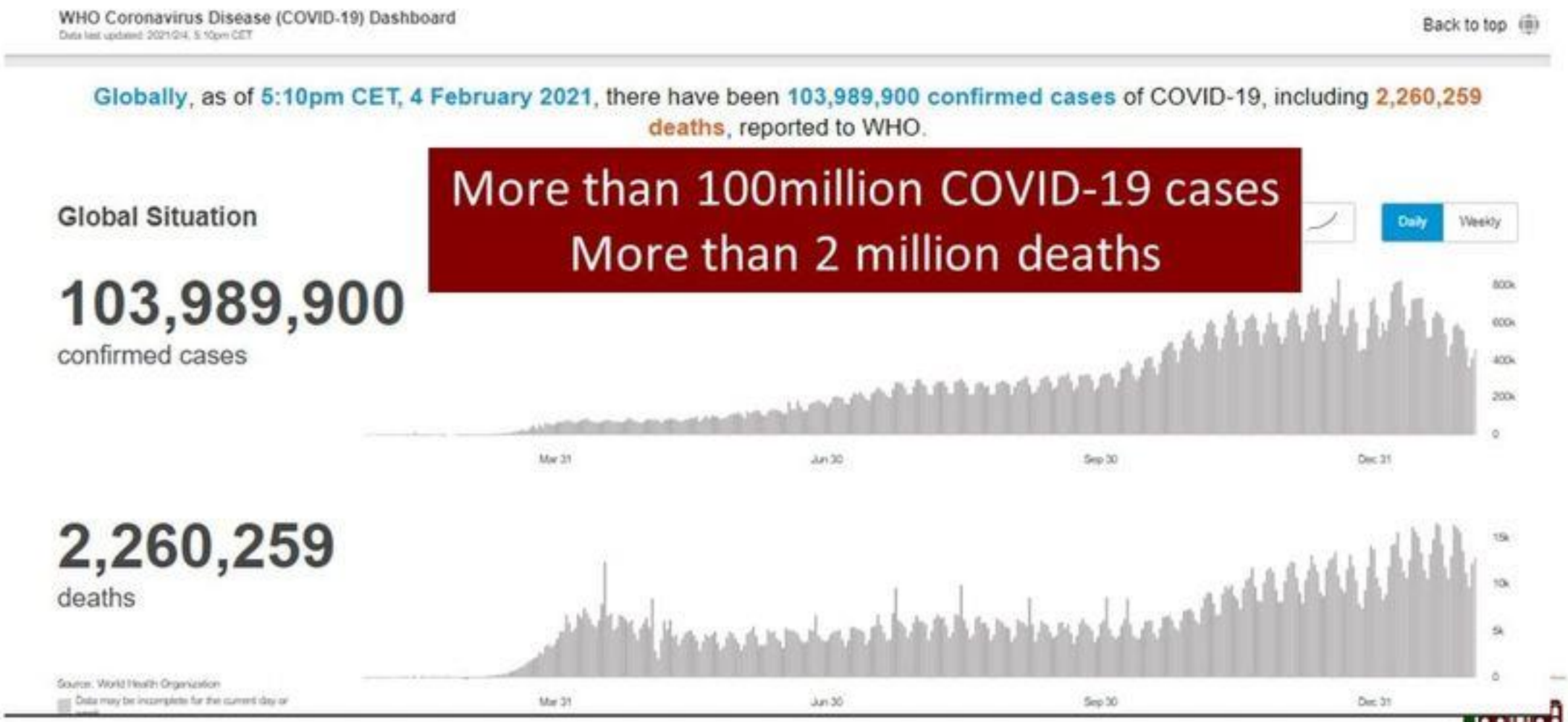
Are the COVID-19 vaccines really necessary?

- We continue to be in the midst of a pandemic!
- So far: “health protocols” have allowed us to cope with the pandemic
  - social distancing, handwashing, and wearing masks
- BUT perhaps the best way to stop this COVID-19 virus is to build enough SARS-CoV-2-specific immunity.
- No virus has ever eliminated itself by inducing natural immunity (getting a large enough percentage of the population infected).
- Only **herd immunity induced by vaccination was able to** eliminate viruses in past (i.e.smallpox)

Are the COVID-19 vaccines really necessary?

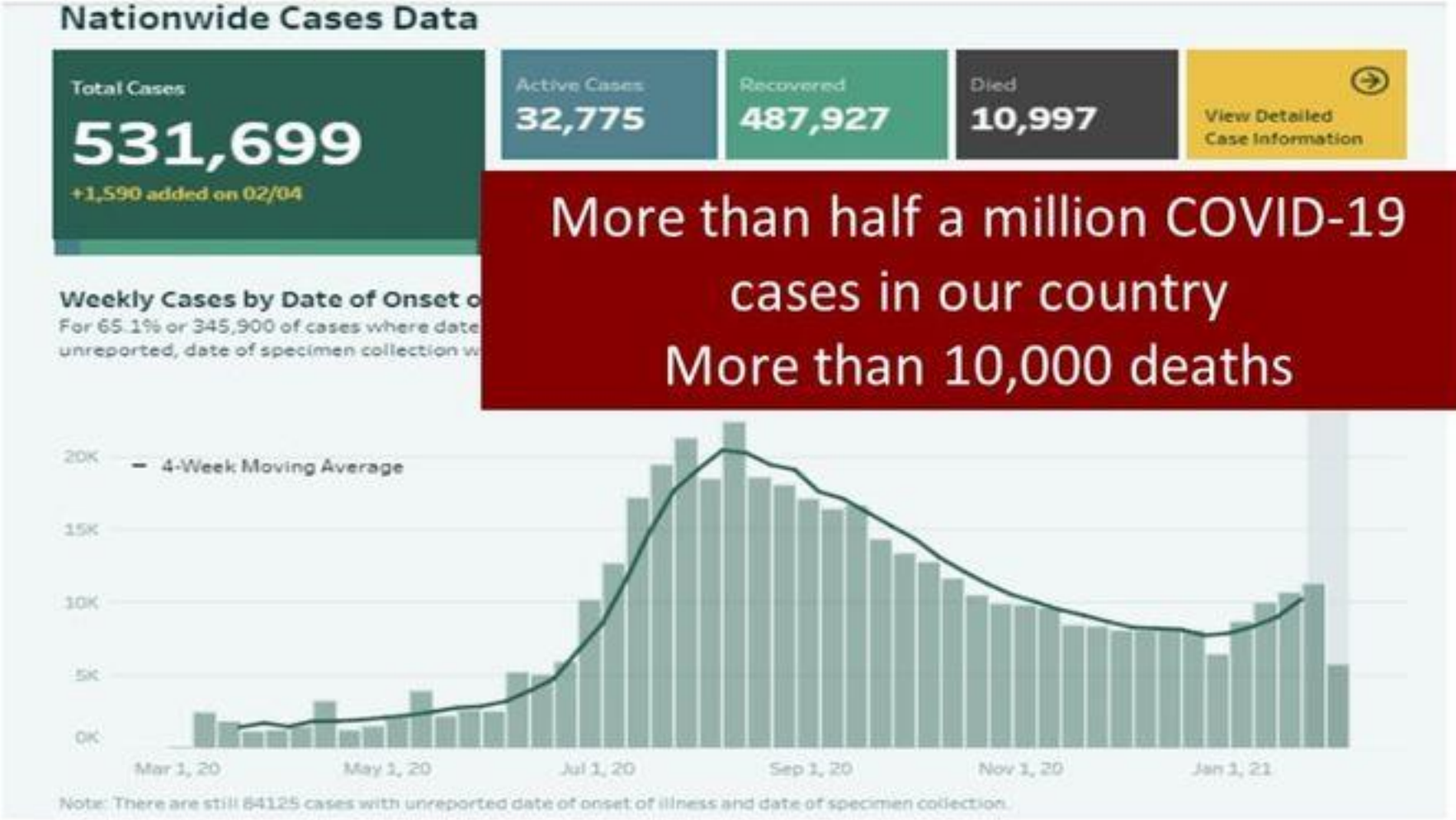
The answer is YES,
The vaccines offer one of the ways we may be able to end the pandemic.

GLOBAL COVID-19 DATA



https://covid19.who.int/

Philippine Data (02/04/2021)



https://doh.gov.ph/covid19tracker

Who needs to be prioritized in the Philippines?

PRIORITIZATION: We need to protect our essential health and non-health workforce to secure our frontliners. We also need to protect the vulnerable populations.

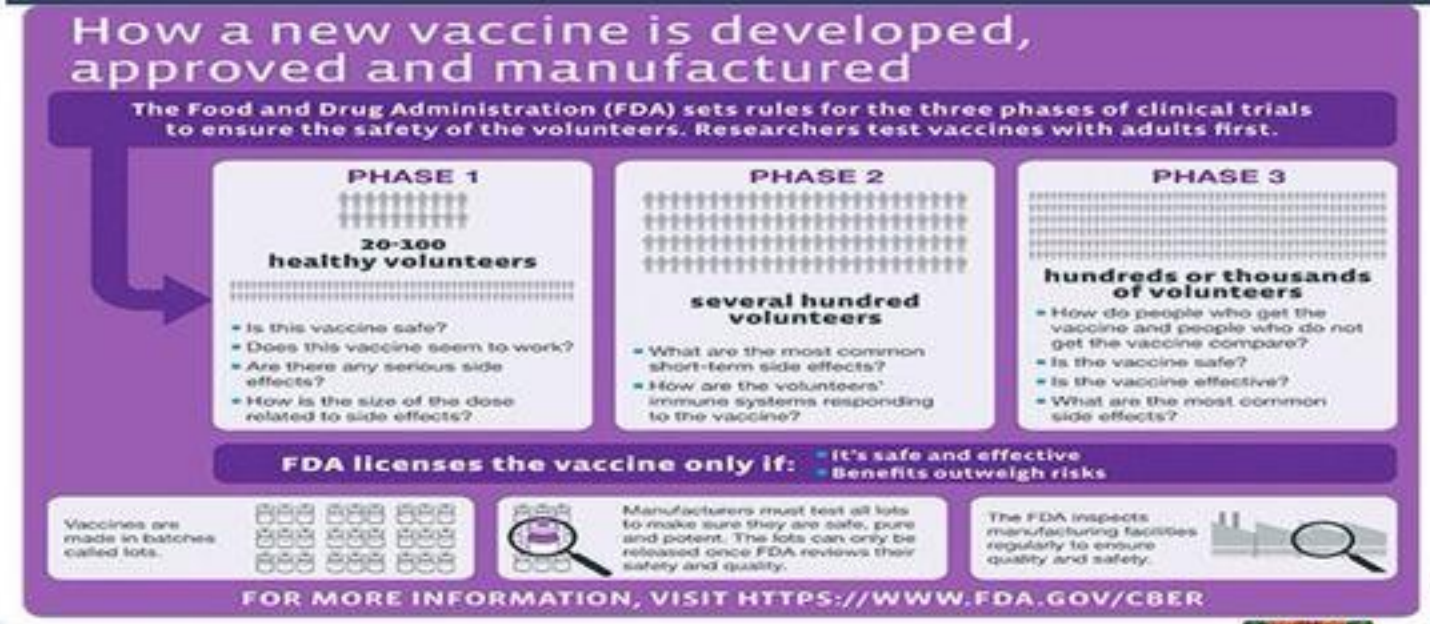
How are we sure that the vaccines are SAFE?

- Understandable to be concerned about their safety issues
- Phase III trials for COVID-19 vaccines have been as large as those for other vaccines
  - trials were large enough to detect any major safety concerns.
- The data from these large phase III vaccine trials underwent extensive review by several groups
  - Published data
  - Global groups: “stringent bodies” WHO, FDA, Advisory committees of governments
  - Independent scientists and experts
- Same stringent protocols are followed in the Philippines

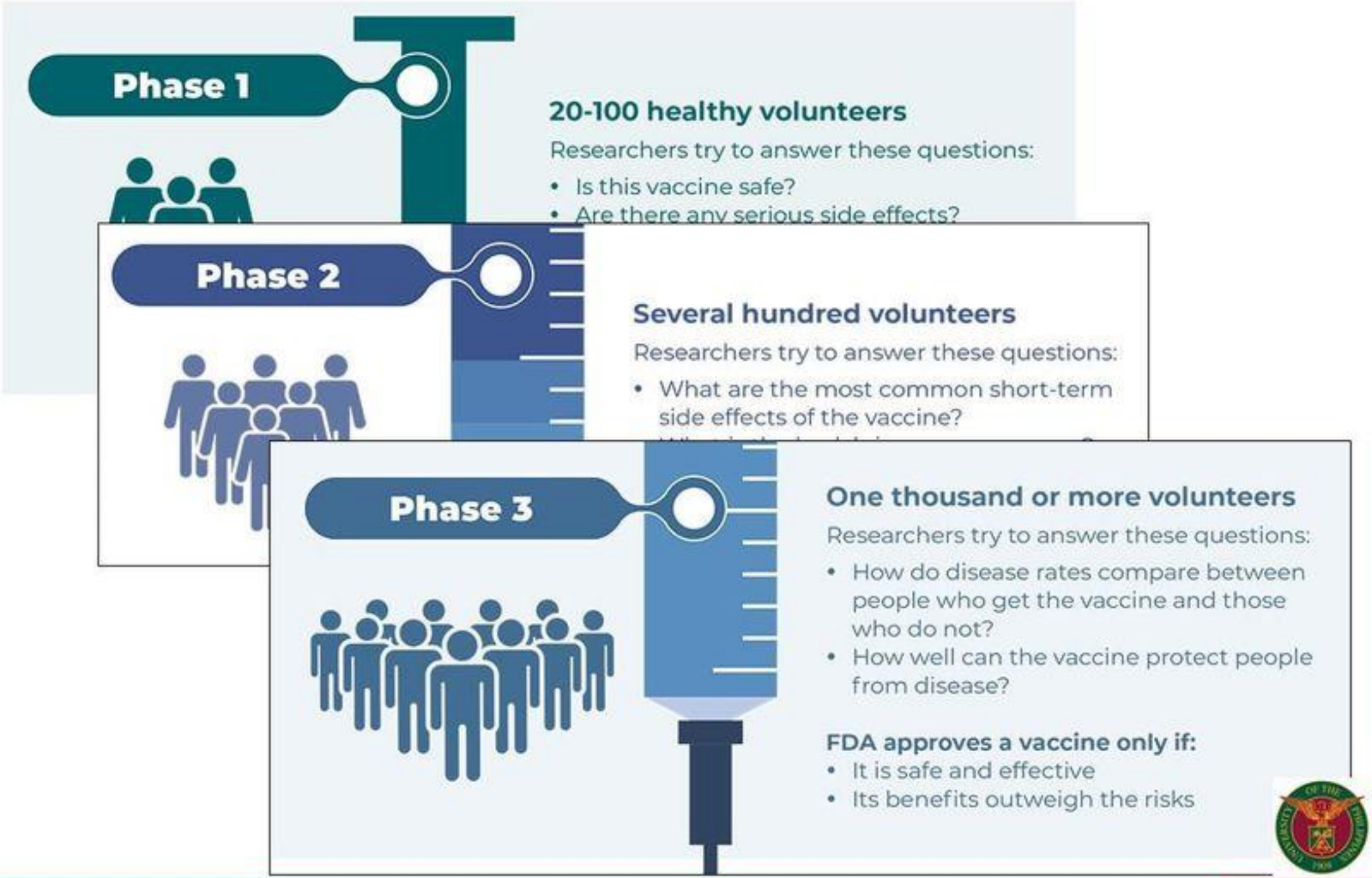
The Journey of a Vaccine

How a new vaccine is developed, approved, and manufactured

The U.S. Food and Drug Administration (FDA) sets rules for the four phases of clinical research so that researchers can learn about the effects of new therapies while keeping volunteers safe. This includes trials of new vaccines to protect against infection; researchers always test vaccines with adults first.



Gogglieb & McClellan https://www.wsj.com/articles/how-emergency-use-can-help-roll-out-a-covid-vaccine-11600029


Phase 1
20-100 healthy volunteers
Researchers try to answer these questions:
• Is this vaccine safe?
• Are there any serious side effects?
Phase 2
Several hundred volunteers
Researchers try to answer these questions:
• What are the most common short-term side effects of the vaccine?
Phase 3
One thousand or more volunteers
Researchers try to answer these questions:
• How do disease rates compare between people who get the vaccine and those who do not?
• How well can the vaccine protect people from disease?
FDA approves a vaccine only if:
• It is safe and effective
• Its benefits outweigh the risks

Current ongoing monitoring of AEs

cdc.gov

Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness of information
- Lack of unvaccinated comparison group
- Not designed to assess causality

- VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

BASIC PREMISE: Vaccine to be made available to the public are SAFE

- **Careful testing**. All vaccines go through clinical trials to test safety and effectiveness.
- **Authorization for emergency use**. Country EUA will be granted ONLY is the vaccines met Philippine FDA safety and effectiveness standards.
- **Continuous monitoring for problems and side effects**. DOH will have system for short term and continuous monitoring for one year.

TRUST

That if the FDA grants a vaccine brand the EUA:

it is safe and effective

OVERALL THE COVID-19 VACCINES SHOULD BE SAFE and EFFECTIVE FOR MOST OF US!

BUT THERE ARE SPECIFIC POPULATIONS FOR WHOM VACCINE SHOULD NOT BE GIVEN DUE TO:

- **Contraindication**
- **Lack of sufficient data**
- **Issue of vaccine supply**

WHO SHOULD NOT BE VACCINATED BECAUSE IT IS CONTRAINDICATED?

ANSWER: THE ONLY ABSOLUTE CONTRAINDICATION IS ALLERGY TO THE VACCINE.

What kind of allergic reactions would make one NOT ELIGIBLE for the COVID-19 vaccine?

Position Statements of the
Philippine Society of Allergy, Asthma, and Immunology
On COVID-19 Vaccines and their Adverse Reactions

February 1, 2021

se statements were developed by the COVID-19 Vaccine Adverse Reaction Task Force
Philippine Society of Allergy, Asthma, and Immunology (PSAAI).

PSAAI 02/01/2021 Statement http://bit.ly/COVIDvaccinereaction

WHO SHOULD NOT BE GIVEN THE VACCINE?

- The ONLY current contraindication to COVID-19 vaccination is an allergy to a previous dose of COVID-19 vaccine and any of its components. (Statement 3)

PSAAI 02/01/2021 Statement http://bit.ly/COVIDvaccinereaction

Those who SHOULD NOT receive COVID-19 vaccines: (Allergic response)

1. Patients who have experienced an immediate allergic reaction, whether mild (e. g. rashes) or severe (e. g. anaphylaxis) to COVID-19 vaccine after the first dose should not receive the second dose
2. Patients who have a history of allergic reaction or anaphylaxis to certain vaccine excipients such as
   a. polyethylene glycol (PEG) found in colonoscopy preparation or laxatives
   b. polysorbate (which can be found in vascular graft materials, surgical gels, PEGylated medications) should not receive the COVID-19 vaccines.

*PEG 2000 is an ingredient of the mRNA vaccines

*polysorbate 80 can be found in non-replicating adenovirus vector vaccines and protein subunit vaccines.

There are no reliable diagnostic tests to confirm allergic reactions to PEG or polysorbate

These patients may be referred to an allergist for further evaluation

How often did allergic reactions occur in other countries?

- During December 14–23, 2020, US VAERS detected
  - 21 cases of anaphylaxis after administration of 1,893,360 first doses of the Pfizer-BioNTech COVID-19 vaccine
  - 11.1 cases per million doses
  - 71% of these occurred within 15 minutes of vaccination

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm (Jan 15, 2021)

- Rare but may occur
- Therefore: IT IS IMPORTANT that the facility is able to address the potential reactions. The hospitals will observed vaccinees for 30 to 60minutes.

MAHALAGA:

- Kung sa unang (1st) bakuna ay may ALLERGIC REACTION (kahit mild katulad ng rash) :
  - i-report sa vaccination facility
  - **HUWAG NA** ibigay ang pangalawang (2nd) dose

- Kung noon ay nagka reaction sa mga components ng COVID Vaccines katulad ng:
  - Allergy sa laxative na ginamit sa nakaraang "Colonoscopy"
  - Allergy sa mga graft materials or surgical gels na may polysorbate
  - I-report sa vaccination facility sa Screening
  - **HUWAG NA** magpabakuna kahit ng 1st dose

If a person has allergic reactions to food or medication, can they get the vaccine?

- Those who **need further evaluation**:
  - Patients who have experienced an immediate allergic reaction, such as urticaria, angioedema, difficulty of breathing, regardless of severity, to any **OTHER vaccine or injected therapy** must be evaluated by an allergist to assess possible allergic reactions to PEG or polysorbate.

  - All vaccinated patients with the above history should be observed for at least 60 minutes after vaccination.

PSAAI 02/01/2021 Statement http://bit.ly/COVIDvaccinereaction

If a person has allergic reactions to food or medication, can they get the vaccine?

Special Groups who **can receive** the vaccines:

- Patients with allergic reactions (of any severity) to food, inhalant/ environmental allergens, insects, latex, oral medications, not related to vaccines and their components, **can receive** COVID-19 vaccines.
- Patients with immunodeficiency and autoimmune disease (e.g. Guillain-Barre Syndrome, Bell's palsy) may **also get vaccinated** but they should be informed that there is still not enough data available to establish vaccine safety and efficacy in these conditions.
- Patients with well-controlled asthma and on inhaled corticosteroids, and those with allergic rhinitis on intranasal corticosteroids **can receive** the COVID-19 vaccine.

PSAAI 02/01/2021 Statement http://bit.ly/COVIDvaccinereaction

MAHALAGA: Konsulta muna sa Allergy specialist para makatulong sa desisyon

- Lahat ng SEVERE REACTION sa nakaraan ay dapat i-konsulta sa Allergy specialist para makatulong sa desisyon

- Lahat ng REACTION (kahit mild) dahil sa ibang bakuna (katulad ng flu shot o tetanus shot) ay dapat i-konsulta sa Allergy specialist

MAHALAGA: Ok magpabakuna nguni't obserbahan nang MAS MATAGAL

- Nguni't kung ang allergy ay mild at hindi naman kaugnay sa COVID Vaccine katulad ng:
  - Ibang pagkain (halimbawa- seafoods)
  - Ibang gamot (halimbawa – ibuprofen)
  - Mga bagay sa paligid (halimbawa – pollen)
  - Mga gamit (halimbawa – sa gloves)
- Maaari pa rin magpabakuna
- Nguni't ipaalam sa doctor sa screening stage upang masiguradong kayo ay mababantayan ng 15 minutos

Will the COVID-19 vaccines sensitize us and cause ADE?

- Antibody-dependent enhancement (ADE) **has not** been identified as a concern related to SARS-CoV-2 infection or following COVID-19 vaccination.

  - ADE seen in Dengue viruses is NOT a concern with COVID-19 vaccines
  - Most of us have been infected with other coronaviruses in our lifetime and ADE has not been observed
  - In human studies of documented COVID-19, NO reports of ADE.
  - No biological basis to worry about ADE in COVID-19

Halstead and Katzelnick. J Infect Dis 2020 Nov 13;222(12):1946-1950. doi: 10.1093/infdis/jiaa518.

Do COVID-19 vaccines have side effects? Are these side effects BAD?

ANSWER: YES, vaccines have side effects and they are not necessarily BAD.

- Side effects from COVID-19 vaccines are caused as part of the immune response to the vaccines.
- In some ways, the more vigorous the immune response, the more common the side effects.
- Side effects occurred during the first week after vaccination, but most likely one or two days after receipt of the vaccine.
- Side effects were
  - more frequent after 2nd dose;
  - more likely to be experienced by younger than older recipients

Side effects have been seen to have frequently occurred during the Phase III trials. But most are mild & transient

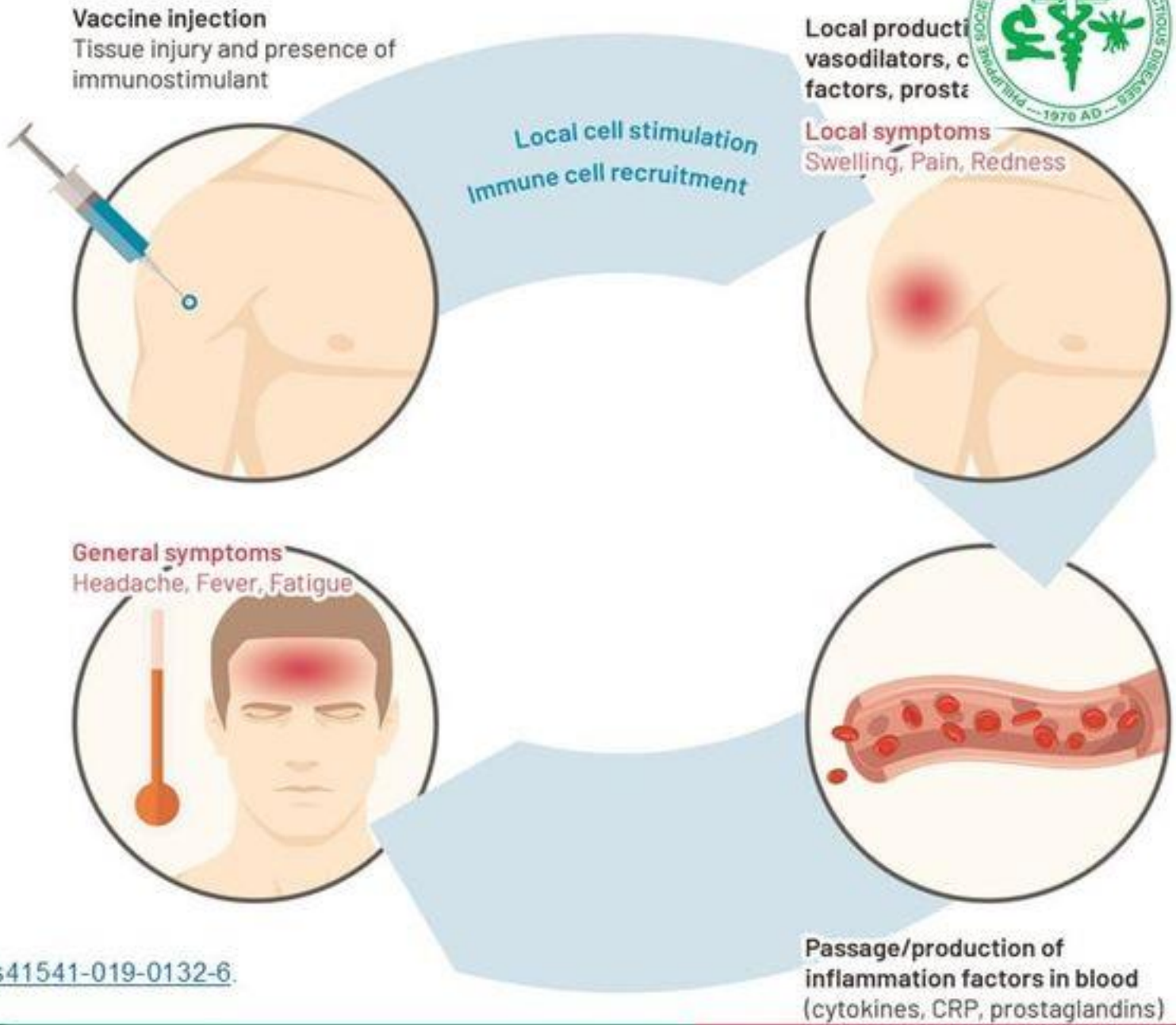
Vaccinees should know about what to expect and be prepared post vaccination.

The side effects are because of Vaccine REACTOGENICITY.

Reactogenicity

Definition

- Subset of reactions occurring soon after receipt of a vaccine
- Physical manifestations of the inflammatory response to vaccination



From Slide Set of PSMID COVID-19 Vaccines
Herve, C. et al. npj Vaccines (2019)4:39 https://doi.org/10.1038/s41541-019-0132-6.

Ongoing monitoring of post-vaccination in the US

Most commonly reported adverse events to VAERS after COVID-19 vaccines*

Pfizer-BioNTech COVID-19 vaccine (N = 7,307)

Adverse event†	N (%)
Headache	1,550 (21.2)
Fatigue	1,192 (16.3)
Dizziness	1,113 (15.2)
Nausea	1,014 (13.9)
Chills	983 (13.5)
Pyrexia	962 (13.2)
Pain	958 (13.1)
Injection Site Pain	716 (9.8)
Pain In Extremity	610 (8.4)
Dyspnoea	536 (7.3)

Moderna COVID-19 vaccine (N = 1,786)

Adverse event†	N (%)
Headache	430 (24.1)
Pyrexia	333 (18.6)
Chills	315 (17.6)
Pain	290 (16.2)
Dizziness	289 (16.2)
Fatigue	287 (16.1)
Nausea	281 (15.7)
Injection Site Pain	208 (11.6)
Pain In Extremity	189 (10.6)
Dyspnoea	172 (9.6)

* Reports received through January 18, 2021; †Adverse events are not mutually exclusive

WHAT TO DO WITH SIDE EFFECTS OF VACCINE while onsite?

- Mild allergic reactions such as urticaria and rhinitis can be managed with antihistamines.
- Anaphylaxis should be recognized and treated immediately with EPINEPHRINE (1mg/mL) 0.3-0.5 mL intramuscularly at the mid antero-lateral thigh.
- Anaphylaxis may increase the risk of mortality if not treated promptly.

http://bit.ly/COVIDvaccinereaction

Ensuring Safety for COVID-19 Vaccines

Vaccine Providers must make sure the following are available

Medications and Supplies for Assessing and Managing Anaphylaxis

Should be available at all sites	If feasible, include at sites (not required)
Epinephrine prefilled syringe or autoinjector	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine)	Oxygen
Blood pressure apparatus	Bronchodilator (e.g., albuterol)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device to assess pulse	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (CPR mask)

From PSMID Vaccine Primer

WHAT TO DO WITH SIDE EFFECTS OF VACCINE after you have left the vaccination facility?

- **After you have gone home and the reactions occur:**
  - You are likely to experience a side effect post vaccine so BE PREPARED.
  - Plan for a light day during your vaccination days.
  - Common side effects on the arm where you had the shot: Pain and swelling
  - Common side effects throughout the rest of the body: Fever, chills, headache, fatigue
  - Reactogenic reactions are often mild and subside within a few days with supportive care (paracetamol, NSAIDs, cold compress).
  - To reduce pain and discomfort where you got the shot:
    - Apply a clean, cool, wet washcloth over the area.
    - Use or exercise your arm.
  - To reduce discomfort from fever:
    - Take paracetamol.
    - Drink plenty of fluids.
    - Dress lightly.

WHAT TO DO WITH SIDE EFFECTS OF VACCINE after you have left the vaccination facility?

- **When to contact your doctor or vaccine provider:**
  - If the redness or tenderness where you got the shot increases after 24 hours
  - If your side effects are worrying you or do not seem to be going away after a few days

  - NOTE: Cough, shortness of breath, sore throat, runny nose, loss of taste or smell ARE NOT side effects of the vaccines
    - If these occur, get tested for COVID-19

MAHALAGA:

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

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
MAAARING MARANASAN			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
PWEDE PA BA MAGPABAKUNA MULI (2nd dose?)	No Hindi	Yes Oo	Yes Oo

WHAT IF I DON'T GET SIDE EFFECTS DOES IT MEAN the VACCINE DIDN'T WORK?

ANSWER: NO

- Many more people will get the vaccine and not experience side effects. **This does not mean that the vaccine did not work for them.**

- In the clinical trials side effects occurred at varying rates
  - i.e wide range: only about 1 to 20 of every 100 people had a fever
  - but efficacy seen for > 90 of every 100 people

IF I GOT A RECENT VACCINE (i.e anti- PNEUMONIA) HOW LONG DO I NEED TO WAIT BEFORE GETTING A COVID VACCINE?

ANSWER: at least 14 days

Co-administration with other vaccines

- There should be a minimum interval of 14 days between administration of the COVID vaccine and any other vaccine against other conditions
  - regardless of the order in which they are received.
  - until data on co-administration with other vaccines become available.

https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1-eng.pdf

DOES A VACCINATED PERSON PRESENT A RISK TO THE REST OF AN UNVACCINATED HOUSEHOLD?

- **ANSWER: NO**

- The COVID-19 vaccines are **not composed of live viruses**, so there is no infectious virus to spread from a vaccinated person to others in the home who did not get their shots yet.
- Given that families will not all get vaccinated at the same time, those who have been vaccinated should continue to practice same health protocols.

Is it okay to get different types of COVID vaccines?

ANSWER: NO, VACCINE BRANDS ARE NOT INTERCHANGEABLE AT THIS TIME. (no data)

- WHO recommends that the same product should be used for both doses.
- If different COVID-19 vaccines are inadvertently administered in the 2 doses, no additional doses of either vaccine are recommended at this time.

https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1-eng.pdf

- US CDC gives stronger statement: mRNA COVID-19 vaccines **are not interchangeable with each other or with other COVID-19 vaccine products**. The safety and efficacy of a mixed-product series have not been evaluated.
- Both doses of the series should be completed with the same product

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

Can pregnant women get the COVID-19 vaccine?

ANSWER: DISCUSS WITH YOUR DOCTOR

- WHO **does not recommend** vaccinating pregnant women at this time
- Very limited data on effect of vaccine on pregnant women and their babies
  - Although the COVID-19 vaccines are not live vaccines
  - In the small group of women included in trials and in animal studies no safety concerns

- Because pregnant mothers are at higher risk for severe COVID than non pregnant, selected pregnant women who are at high risk for getting infected or have severe complications **MAY BE GIVEN** the vaccine (*benefit may outweigh risk)* such as in:
  - Pregnant women at high risk for COVID-19, such as healthcare workers with high risk exposures
  - Pregnant women with comorbidities which place them at increased risk of developing complications when infected with COVID-19.

- Discuss with Obstetrician/Health provider

POGS statement 01/29/2021. https://pogsinc.org/practice-bulletins/

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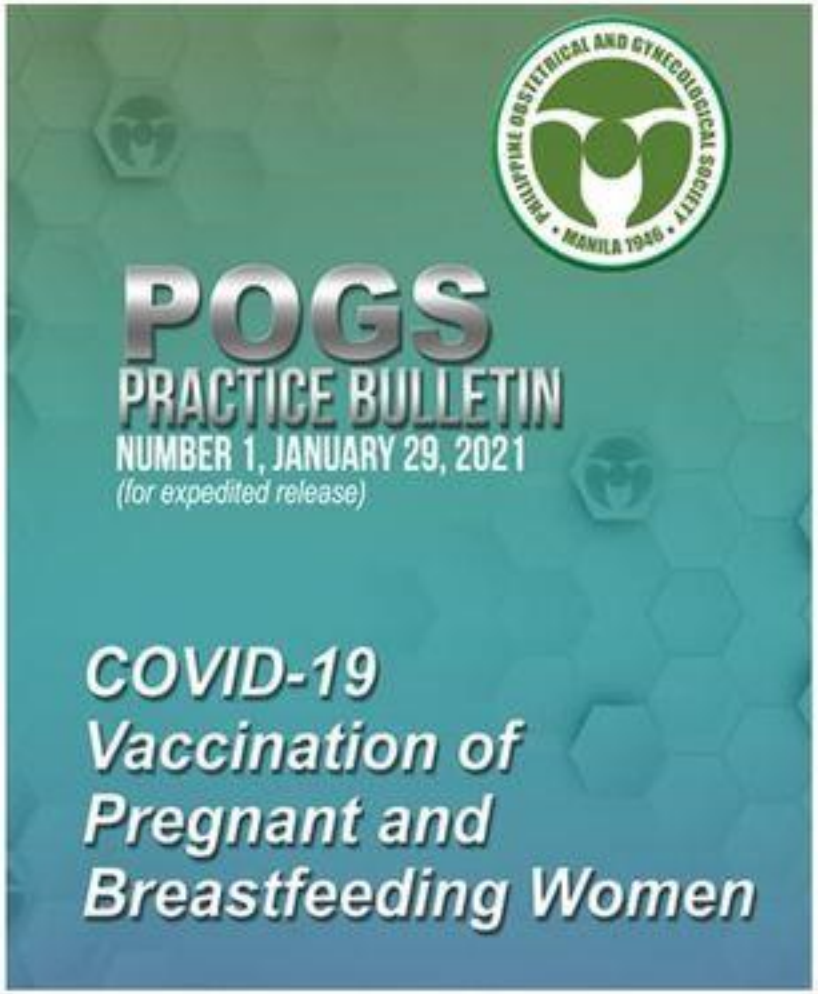
Can pregnant women get the COVID-19 vaccine? POGS statement



The mRNA COVID-19 vaccines should be offered only to pregnant and breastfeeding women classified to be in the high-risk group recommended for priority vaccination.

A. The Philippine National Government identified the following Priority Eligible Population:

1. Frontline Health Workers: All health workers from the PRIVATE and PUBLIC sectors, currently on ACTIVE practice/service, whether they are permanent, contractual, job-order and/or outsourced employees or staff
   - Public and private health facilities
   - Public health workers in public primary care facilities
   - Barangay Health Workers including Barangay Health Emergency Response Teams
   - Relevant Personnel in National Government Agencies (NGAs)
2. Uniformed Personnel: All enlisted uniformed personnel in active services under the:
   - Armed Forces of the Philippines
   - Philippine National Police
   - Philippine Coast Guard
   - Bureau of Fire Protection
   - Citizen Armed Force Geographical Unit

Pregnant and breastfeeding women with comorbidities which add to their risk of severe disease, may be vaccinated in consultation with their health care provider.

1. Those with significant congenital or acquired heart disease
2. Those with severe respiratory conditions including cystic fibrosis and severe asthma
3. Those receiving immunosuppression therapies sufficient to significantly increase risk of infection
4. Those receiving dialysis or with chronic kidney disease (stage 5)
5. Those who have homozygous sickle cell disease
6. Solid organ transplant recipients

POGS statement 01/29/2021. https://pogsinc.org/practice-bulletins/

Can a breastfeeding mother get vaccinated?

ANSWER: Yes discuss benefit vs risk with your doctor

- WHO says: Breastfeeding offers substantial health benefits to lactating women and their breastfed children.
- Vaccine efficacy is expected to be similar in lactating women as in other adults.
- Limited data but the vaccine is not a live virus unlikely to pose a risk to the breastfeeding child.
- A lactating woman who is part of a group recommended for vaccination, e.g. health workers, **should be offered** vaccination.
- WHO does not recommend discontinuing breastfeeding if the mother is vaccinated.

WHO https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1-eng.pdf

Can a breastfeeding mother get vaccinated? (POGS Statement)

There are no data on the safety of COVID-19 vaccines in breastfeeding women or on the effects of mRNA vaccines on the breastfed infant or on milk production/excretion.

A. A woman who is breastfeeding and is part of the Priority Eligible Population group recommended to receive a COVID-19 vaccine, such as a frontline healthcare worker or a frontline essential care worker with an unavoidable high risk of exposure, may choose to be vaccinated.

B. For women administered with the Pfizer BioNTech COVID-19 vaccine, the World Health Organization (WHO) does not recommend discontinuing breastfeeding after vaccination.

POGS statement 01/29/2021. https://pogsinc.org/practice-bulletins/

Can persons with immunocompromised states get vaccinated?

ANSWER: YES unless with contraindications

- People with immune-compromised conditions may get the COVID-19 vaccine as long as they are not in one of the following categories:
  - Severe allergy to a vaccine component
  - History of severe allergy to any vaccine or injectable medication
  - It is recommended that individuals with compromised immune systems discuss their personal risks and benefits with a healthcare provider to determine whether to receive the vaccine.

WHO https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-[illegible]ng.pdf

Can persons with immunocompromised states get vaccinated?

ANSWER: YES unless with contraindications

- Immunocompromised persons are at higher risk of severe COVID-19.
- The possibility that the weakened immune response of patients may cause them not to have a good response to the vaccine
- The available COVID vaccines are not of live virus
- Immunocompromised persons who are part of a group recommended for vaccination **may be** vaccinated.
- Discuss benefit–risk assessment with your doctor.
- Discuss that DATA not sufficient yet

WHO https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-...ng.pdf

Can persons with cancer get vaccinated?

Answer: Yes since cancer patients are at high risk for worse outcome; as long as no contraindication

- Cancer patients had a higher risk from COVID-19 of
  - death (odds ratio [OR], 2.34; 95% CI, 1.15-4.77
  - ICU admission (OR, 2.84; 95% CI, 1.59-5.08]
  - at least 1 severe complication (OR, 2.79, 95% CI; 1.74-4.41; *P* <.01)
- Common cancers: lung (death rate 18%), gastrointestinal, breast, thyroid, and hematological malignancies (death rate 33%)
- The sole US FDA warning for immunocompromised patients, including those undergoing immunosuppressant therapy (i.e. chemotherapy) is the possibility that response to vaccine is not as good as desired.
- CDC statement: immunocompromised patients may receive the vaccines so long as they have no contraindications to vaccination
- Patients need to be counseled that data is insufficient.

Dai M, Lie D, Liu M, Cancer Discov April 2020
McNutty 2021 https://www.ajmc.com/view/covid-19-vaccine-considerations-for-the-immunocompromised

Additional notes on severely immunosuppressed patients

Keep in mind the general recommendations on vaccination of very immunocompromised patients from ACIP

- Severe immunosuppression is expected in leukemia, lymphoma, generalized malignancy or therapy with alkylating agents, antimetabolites, radiation, or large amounts of corticosteroids
- DO NOT GIVE live or live attenuated-virus vaccines
- When cancer chemotherapy or immunosuppressive therapy is being considered (i.e, for patients with Hodgkin's disease or organ transplantation), vaccination ideally should precede the initiation of chemotherapy or immunosuppression by greater than or equal to 2 weeks.
- Vaccination during chemotherapy or radiation therapy should be avoided because antibody responses are suboptimal.
- Patients vaccinated while on immunosuppressive therapy or in the 2 weeks before starting therapy should be considered unimmunized and should be revaccinated at least 3 months after discontinuation of therapy

https://www.cdc.gov/mmwr/preview/mmwrhtml/00023141.htm

Can a person receiving steroids receive the COVID19 vaccine?

ANSWER: In general, YES

- High doses of steroids may reduce a person's response to the vaccine.
- Discuss with your physician to determine whether the quantity of steroids that you are receiving is suppressing your immune system. Consider adjustment in timing when best to receive the vaccines.

Can a person with Autoimmune disease receive the COVID vaccine?

ANSWER: Yes unless with other contraindications (allergy)

- No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials.
- Also there were NO observed occurrence of symptoms consistent with the development of autoimmune conditions or other inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo.
- More data to determine whether immunosuppressant medications or unchecked disease activity may reduce vaccine effectiveness. Most expert groups believe the vaccines will provide protection for the vast majority of patients with arthritis and rheumatic diseases.
- Persons with autoimmune conditions who have no contraindications to vaccination **may** receive an mRNA COVID-19 vaccine.

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

Can a person with History of Guillain-barre receive the COVID vaccine?

ANSWER: YES unless with contraindication (allergy)

- To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials.
- With few exceptions, ACIP's general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination.
- Persons with a history of GBS **may** receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination.
- Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to VAERS.

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

Can a person who was given other types of passive antibody treatment receive the COVID vaccine?

ANSWER: YES unless with contraindication (allergy)

- For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of mRNA COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response.
- Thus, there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination.

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

Can a person living with HIV infection get receive the COVID-19 vaccine?

ANSWER: It depends. HIV-positive persons who are well controlled on antiretroviral therapy can be vaccinated. (CD4 > 200)

- Persons living with HIV (PLHIV) may be at higher risk of severe COVID-19.
- Among the phase 2/3 clinical trial participants with well controlled HIV, there were no reported differences in safety signals.
- Insufficient data for HIV patients who are not well controlled on therapy.
- The vaccine is not a live virus so PLHIV may be vaccinated if CD4 > 200.
- Best to seek counselling about vaccine safety and efficacy with HIV doctor.
- No need to test for HIV infection prior to vaccine administration

Can patients on anticoagulation receive the COVID Vaccine?

Answer: YES but with precautions

- Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination.
- A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes
- The individual patient should be informed about the risk of hematoma from the injection.

BMJ 2020;371:m4759
https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

Can patients with comorbidities get vaccinated even if they are not yet senior citizens?

ANSWER: YES unless with contraindications (Allergy)

- Adults **of any age** with the following **underlying medical conditions** have been shown to be at increased risk for severe illness from the virus that causes COVID-19. Severe illness from COVID-19 is defined as hospitalization, admission to the ICU, intubation or mechanical ventilation, or death.
  - Cancer
  - Chronic kidney disease
  - COPD (chronic obstructive pulmonary disease)
  - Down Syndrome
  - Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
  - Immunocompromised state (weakened immune system) from solid organ transplant
  - Obesity (body mass index [BMI] of 30 kg/m^2 or higher but < 40 kg/m^2) and Severe Obesity (BMI ≥ 40 kg/m^2)
  - Sickle cell disease
  - Smoking
  - Type 2 diabetes mellitus
- They are among the persons to whom the COVID-19 vaccination is recommended and prioritized.

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Can patients with chronic infections get vaccinated?

ANSWER: YES unless with contraindication (allergy)

- Persons who are being treated for chronic infections like TB can be vaccinated. These patients must continue taking their medicines/antibiotics before, in between first and second doses, and after the vaccination.

- Persons who will come to the vaccination facilities with an acute fever or currently treating a current acute infection (i.e.dengue, pneumonia) will be asked to come back when they have fully recovered from their illnesses

Can a person with active COVID-19 infection get injected with the vaccine?

ANSWER: NO NOT RIGHT AWAY

- People who currently have COVID-19 should wait until they have recovered.
  - Recovery of Mild to Moderate COVID-19: 14 days
  - Recovery of Severe to Critical COVID-19: 21days
- If a person had antibody therapy (monoclonal antibodies or plasma convalescent) as part of a trial for their treatment, they should wait additional 3 months before getting the vaccine.

https://apps.who.int/iris/handle/10665/338484

Should persons who had COVID-19 in the past still get vaccinated?

ANSWER: YES IT IS RECOMMENDED

- People who have already had COVID-19 or tested positive may still benefit from getting the COVID-19 vaccination.
- There is not enough information to say if or for how long people are protected from getting COVID-19 after they have had it (natural immunity).
- Early evidence suggests natural immunity from COVID-19 may not last very long (may only be 3 to 6 months) and experts hope that vaccination will offer a more durable immunity.
- But longer period still needed to measure response to vaccines

https://apps.who.int/iris/handle/10665/338484

WHO SHOULD NOT GET VACCINATED?

People who should NOT get the COVID-19 vaccine

- Anyone with a previous severe or immediate allergic reaction (i.e., one that causes anaphylaxis or requires medical intervention) to a COVID-19 vaccine dose, a vaccine component – PEG or polysorbate
- Those younger than 16 years of age
- People currently isolating or experiencing symptoms of COVID-19; these people can get vaccinated once they are finish their isolation and their primary symptoms have resolved.

People who MAY get the vaccine after considering risks vs benefits and/or consulting with their healthcare provider

- Individuals with a history of severe or immediate allergic reaction to any other vaccine or injectable medications
- Pregnant women
- People with certain immune-compromising conditions
- Breastfeeding women
- People on anticoagulants

People who should follow special procedures

- Someone with a history of severe or immediate allergic reaction (requiring medical intervention) to anything other than a vaccine or injectable medication can get the vaccine, but they should remain at the vaccination location for medical observation for 30-60 minutes after receipt of the vaccine.
- People who recently had COVID-19 and were treated with antibody-based therapies (e.g., monoclonal antibodies or convalescent plasma) should wait until 90 days after treatment to be vaccinated.
- People with a known COVID-19 exposure should wait until their quarantine is over before getting vaccinated.
- People who received another vaccine (non-COVID-19 vaccine) should wait at least 14 days before getting COVID-19 vaccine and vice versa

Final Messages: the bottomlines

- We are trying to fight the COVID-19 pandemic, a **global crisis which has caused** with devastating health, social and economic impacts. COVID-19 can cause severe disease and death.

- We now have EUA-approved vaccines which have been evaluated to be safe and effective vaccines for COVID-19.
  - We need to be vaccinated to protect us from becoming ill.
  - This is particularly important for healthcare professionals and vulnerable populations such as older people and people with long-term diseases.

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus

Oliver, garano et al ACIP The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?

Final Messages: the bottomlines

- Whereas there might be uncertainty/incomplete data in how all populations value the current vaccines, **for most populations**, the desirable effects outweigh the undesirable effects.

- For special populations, most **MAY** receive the vaccines except if with contraindications (see previous slides). Discuss with your doctor!

- But vaccines alone will not end the pandemic. People need to remain vigilant and continue to adhere to basic preventative measures that include physical distancing, wearing masks and handwashing.

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus
Oliver, garano et al ACIP The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — L s, December 2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?
https://reliefweb.int/report/world/covid-19-vaccines-alone-will-not-end-pandemic-warns-ifrc

MAHALAGA:

- Sa Pilipinas sinasabing kailangan umabot sa lampas sa 70% sa ating mga barangay ang dapat mabakunahan upang ating marating ang “herd immunity” – yan ang sitwasyon na mahihirapan na ang COVID virus na manghawa pa ng iba kung marami na sa atin ang bakunado.

- Kung EUA approved ay panatag ang ating loob na ligtas at epektibo ang mga bakuna.

- Hanggang sa maaari at lalo na kung mabigyan tayo ng pagkakataon na mabigyan ng bakuna ay pumayag tayo na magpabakuna.
- Mas marami sa atin ang dapat magpabakuna.
- Aralin mabuti ang mga impormasyon na kalakip dito

Thank you/ okay to share these slides/ and email queries to rpberba@up.edu.ph