























Objectives

- 1. Difference between Influenza and COVID-19
- 2. Vaccines: Benefits for a Preventive Approach
- 3. Address Vaccine Concerns
- 4. In-depth: The Johnson and Johnson "Pause"
- 5. Challenge to our Audience: Finding your Reason and Being an Advocate









What is *herd immunity* and why is it important?

- Transmission is reduced when more of the population has immunity because the virus cannot travel as easily⁵⁵
- When the population does not have immunity or protection, viruses travel easily55
- Herd protection: Doesn't provide immunity to everyone. Rather, protects vulnerable members like those who are immunocompromised^{57,59}
- Estimates range from 60-80% (herd immunity for COVID-19); large outbreaks are expected in areas where vaccination is low⁵⁸⁻⁶⁰
- Herd immunity successes through vaccination:
 - Measles, mumps, rubella, pertussis, chickenpox, polio, etc.^{56,61}
- Skipping vaccination and relying on herd immunity "naturally" is dangerous and has never successfully been accomplished^{49,59}
 - Leads to loss of life; disability













	Polio	Hepatitis B	HPV (Human Papilloma Virus)	COVID
Released	1955 ¹⁷	1981 ¹⁹	2006 ²²	2021, clinical trials began 2020 ²⁹
Efficacy	99-100% (completion of series) ¹⁸	80-100% (declines with advanced age) ¹⁹	99-1 00% ^{15,20}	Pfizer: 95% Moderna: 94% J&J: 66-67% ^{16,34}
Prevents	Paralysis; death ¹⁷	Liver disease; death ¹⁹	HPV-caused cancers including cervical, penile, anal cancers; genital warts; death ²⁰	Symptomatic COVID disease including serious illness, hospitalizations,death ^{30,35}
Age	Infanthood ²³	Birth and infanthood; Note: Incidence was <i>unchanged</i> until universal vaccination of babies/children took place (series of 3 shots) ²¹	Childhood starting at age 11-12 (early as age 9) ²³ Important to start <i>before</i> sexual debut but ASAP if already sexually active	16 and over (Moderna); 18 and over (Pfizer, J&J) ²⁶ : Clinical trials ongoing for children ²⁷
Noteworthy	United States has been Polio-free since 1979 because of vaccines ³¹	Required for school entry in most states including California (amongst many other vaccines) ²⁴	Avoidance of HPV vaccines linked with concerns somewhat similar to COVID including: beliefs the vaccine is unnecessary (lack of perceived susceptibility/seriousness); hesitancy also linked to concern about instigating sexual behavior; low uptake results in low population effect/still circulates/spreads/causes disease ^{26,32}	Many do not believe they are susceptible to serious outcomes of COVID nor believe they will transmit (even asymptomatically) to others leading to serious illness in vulnerable populations



Will I HAVE to have a COVID vaccine?

- Once vaccines are fully approved, they may be required at locations including:
 - School entry
 - CSU/UC's starting Fall 2021²⁵
 - Employment
 - Travel (example: Europe may open for vaccinated Americans starting this Summer)42
 - Sporting events⁴³
- Other benefits for vaccinated people⁶⁹:
 - $^{\circ}$ Visit inside a home or private setting without a mask with other fully vaccinated people of any age
 - Visit inside a home or private setting without a mask with one household of unvaccinated people of any age who are not at risk for severe illness
 - $\circ\,$ Travel domestically without a pre- or post-travel test
 - Travel domestically without quarantining after travel
 - Travel internationally without a pre-travel test depending on destination
 - Travel internationally without quarantining after travel



Concerns over pain of injection; side effects

Smaller needles used

- $\circ\,$ Many injections and vaccines cause anxiety and pain
- COVID vaccines use smaller needles (smaller than a pencil point!)⁵¹
- Many who have been vaccinated have been surprised at the lack of pain with injection

• Side effects vary

- More common in younger populations (but not a guarantee)
- Some report no symptoms and others report flu-like symptoms
 - 10-12 hours after second injection is common
- Although it feels icky, much less painful than COVID especially hospitalization, ventilation, etc.
- Symptoms resolve quickly
- Some worry that a *lack* of side effects means it didn't work. This is false! They vary for everyone!^{52,53}

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Concerns over breakthrough cases

- Breakthrough cases occur when someone was diagnosed with COVID-19 after vaccination
- Vaccines are not 100% effective in preventing a person from getting COVID-19; they are effective in preventing *most serious cases* of COVID^{38,39}
- SO important to avoid contact with others until after *two weeks* from your final COVID vaccination (to allow the body to build the strongest immunity)
- Incredibly important to vaccinate the population (those that can) as variants are a cause of breakthrough cases³⁹

COVID-19 vaccine breakthrough inf of April 20 As of April 20, 2021, more than 87 million people in the United States h	ections reported to CDC as
Total number of vaccine breakthrough infections reported to CDC	7,157
Females	4,580 (64%)
People aged ≥60 years	3,265 (46%)
Asymptomatic infections	2,078 (31%)
Hospitalizations*	498 (7%)
Deaths+	88 (1%)
*167 (34%) of the 498 hospitalizations were reported as asymptomatic †11 (13%) of the 88 fatal cases were reported as asymptomatic or not r	or not related to COVID-19. related to COVID-19.





Why masks and social distancing if vaccinations are effective?



If the airbags work, then why the seatbelt? If the seatbelt works, then why the airbags? If both work, then why the brakes?

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Concern over long-term effects of a vaccine?

- · Historical data can help us understand long-term issues with vaccines
- Long-term effects of prior vaccines including MMR, Polio, etc. were not really long-term issues
- Adverse events with previous vaccines occurred within 8 weeks
- Because of the knowledge gained with other vaccines, the FDA required companies making COVID-19 vaccines to follow trial participants for a minimum of eight weeks before they could submit their data for approval⁴⁷
- Scientists and public health officials carefully analyze and continually monitor the data related to every vaccine before, during and after it becomes available
- Example: Pfizer
 - Began July 27, 2020 enrolled 43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate as of November 13, 2020
 - · Five months since last injection with no new adverse conditions reported
 - Pfizer clinical trials will follow participants for two years and report any adverse outcome⁴⁸





Concern over cost of getting vaccinated?

• All people eligible for the vaccination need to know that the vaccine is FREE!

- You may be asked for insurance, but this is not to bill you
- You may be asked for an ID or SSN; you may be able to decline (pharmacies, etc.)
- If you've had COVID previously, you still need to get vaccinated:
 - Although you have antibodies, the amount of protection is unknown
 - Reinfection is possible, but symptoms should be less severe
 - Discuss this with your care provider IF you had any treatment for COVID-1968
- Where can you get vaccinated?
 - Santa Clara County has mobile vaccination sites in vulnerable communities
 - Most pharmacies including Walmart, Walgreens, Rite-Aid, CVS, etc.
 - Schedule an appointment when convenient for you:
 - myturn.ca.gov
 - vax.sccgov.org
 - Find a Shot: findashot.org
 - Vaccine Spotter: vaccinespotter.org







What exactly happened?

- Rare *autoimmune* response to J&J/Janssen Vaccine (*CVST*: clot in the brain plus *thrombocytopenia*: low levels of blood platelets)⁴
- Out of 6.8 million doses, 6 rare/severe of a stroke-like illness occurred⁶
- Outcome: 1 fatal case, 5 treated/monitored
- Any specific subpopulations of women?
 - Too few cases to make that determination in this case with this particular vaccine. IF there are more, they will look further into it. Not able to single out subgroup/make generalizations (common in small sample sizes)
 - AT THIS TIME there is no clear association with oral contraceptives and these individuals with blood clots⁶





When/how often is this occurring after vaccination?

- Usually about 1 week after, and not longer than 3 weeks after median 9 days after vaccination⁶
- Note: Flu-like symptoms and headache are common after vaccination⁶
- Symptoms for concern:
 - Severe headache
 - Pain in legs
 - Pain in abdomen severe enough for medical attention
 - What a medical provider would determine:
 - Blood clots
 - Low platelets⁶

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Should you be worried if you were vaccinated?

- If you received the Pfizer or Moderna vaccine, this has NOT been reported (different type of vaccine mRNA vs. Adenovirus)⁶
- For those that received the Johnson & Johnson/Janssen vaccine:
 - If it's been more than 1 month, very low risk
 - Within the last few weeks, monitor yourself for any symptoms:
 - Severe headaches, abdominal pain, leg pain, or shortness of breath,
 - What to do? Contact your healthcare provider and seek medical treatment.
 - Note: These symptoms are different from the mild flu-like symptoms, fever and so forth that many people experience in a couple days after receipt of the vaccine which are *expected* to occur⁶

Why did these events cause a signal to the FDA/CDC?

- Analysis from CDC and FDA found that the pattern of CVST and low platelets occured *together* similar to what was seen in Europe with the AstraZeneca vaccine (also an adenovirus vaccine)
- As a precautionary measure, the FDA and CDC paused the vaccine to ensure they understood the complications
- In addition, revising clinical guidelines was necessary to ensure appropriate treatments were provided to prevent dangerous or fatal outcomes with the traditional treatment (Heparin).⁶

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Are PAUSES common in vaccinations? Clinical Trials?

- This is the first pandemic in our lifetime
- Previous pauses for COVID-19 vaccinations/meds:
 - 2020: Johnson & Johnson, Eli Lilly/NIH's ACTIV-3, AstraZeneca¹¹
- Varying views; some say it's common, others say it's not (due to safety, phase III)¹¹
- Clinical Trial Phases:
 - Phase I trials: Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.
 - **Phase II trials:** The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
 - **Phase III trials:** The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.
 - Phase IV trials: Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.¹⁵

Why was this a PAUSE and not a STOPPAGE

- Not a mandate; recommendation out of an abundance of caution
- Individual healthcare provider were still able to administer the vaccine if the provider felt it WAS beneficial for that individual.
- Update: April 23: "Following a thorough safety review, including two meetings of the CDC's Advisory Committee on Immunization Practices, the U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention have determined that the recommended pause regarding the use of the Johnson & Johnson (Janssen) COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume."⁷²
- Additionally, the Western States Scientific Safety Review workgroup recommended resuming use of Johnson & Johnson Vaccine. California will resume use of the vaccine.^{73,74}











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