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April/May 2021 Report

COVID Vaccine Updates

Interchangeability of Vaccines

- The National Advisory Committee on Immunization (NACI) has provided new recommendations on vaccine interchangeability saying that COVID-19 vaccines types should remain consistent
- They have however stated that if a second dose of the Oxford-AstraZeneca vaccine is unavailable, it could be supplemented with the single-dose Johnson and Jonson's Janssen vaccine
- There is currently no data on the interchangeability of COVID-19 mRNA vaccines although the committee states there is no reason to believe that mRNA vaccine series completion with a different authorized mRNA vaccine product would result in any additional safety issues or deficiency in protection
- In Ontario, public health officials have announced that they will offer the province's remaining inventory of AstraZeneca COVID-19 vaccine to those awaiting their second dose of the shot, however, they will not offer AstraZeneca shots to anyone else as a first dose
- Preliminary results from a study in the U.K. suggest that interchanging vaccines is safe, however, could be more likely to lead to mild side-effects such as a headache, chills, or a fever
    - The study looked at more than 800 adults aged 50 and over who had received mixed vaccine doses at a four-week interval
    - They looked at 2 mixed schedules - Pfizer followed by AstraZeneca and AstraZeneca followed by Pfizer
        - Both results in more frequent side-effects after the second dose when compared to 'non-mixed' schedules
        - This included increase in temporary problems, including fever and fatigue after receiving the shot
        - These adverse reactions ranged from mild to moderate, but were short-lived and no major safety concerns were found
    - There are no results yet on how effective the vaccines are when administered in this way
    - Data on efficacy is expected to arrive next month

Vaccine side-effects

- Data from the U.S. Centers for Disease Control and Prevention has shown that more women than men have reported side effects, such as blood clots and allergic reactions
- During the first month of vaccine administration in the US, 61% of the doses were given to women, but 72% of the side effects were reported by them

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- However, not all countries had drawn a link between gender, age, and the coronavirus vaccine
- Possible reasons for this are that women are more likely to report side effects and that estrogen produces a stronger immune reaction against the shot
- Swollen lymph nodes seem to be a more common side effect in women
    - For women, the side effect of a enlarged lymph node near the breast may resemble a sign of breast cancer and can lead to false red flags
- For both the AstraZeneca and Johnson & Johnson vaccines, there are reports that involve extremely rare clotting, including a type of blood clot called cerebral venous sinus thrombosis, which was seen in combination with low levels of blood platelets, called thrombocytopenia
    - With AstraZeneca, most of the cases so fat have been reported by women under 60 years of age within 2 weeks of vaccination
    - Among possible causes being invested are that the vaccine triggers an unusual antibody in rare cases
- There is however, some voices that suggest it is too early to link gender to the vaccine
    - In countries where blood clots happened the most and the earliest (Europe), healthcare workers were being vaccinated with AstarZeneva and healthcare workers tend to be women
    - This could meant that the vaccine did not necessarily cause more blood clots in women but simply that more women were getting inoculated

Pfizer-BioNTech

- The study found that approximately 72% of individuals experienced a local side effect after the first dose and 69% of individuals experienced a local side effect after their second dose
    - The most common side effect = feeling tenderness at the site of injection
- 13.5% of people reported experiencing systemic side effects after the first dose and 22% of people reported experiencing this after the second dose
    - The most common side effect was headaches and fatigue
- 1.1% of people experienced an allergic reaction in the form of burning of skin after the second dose

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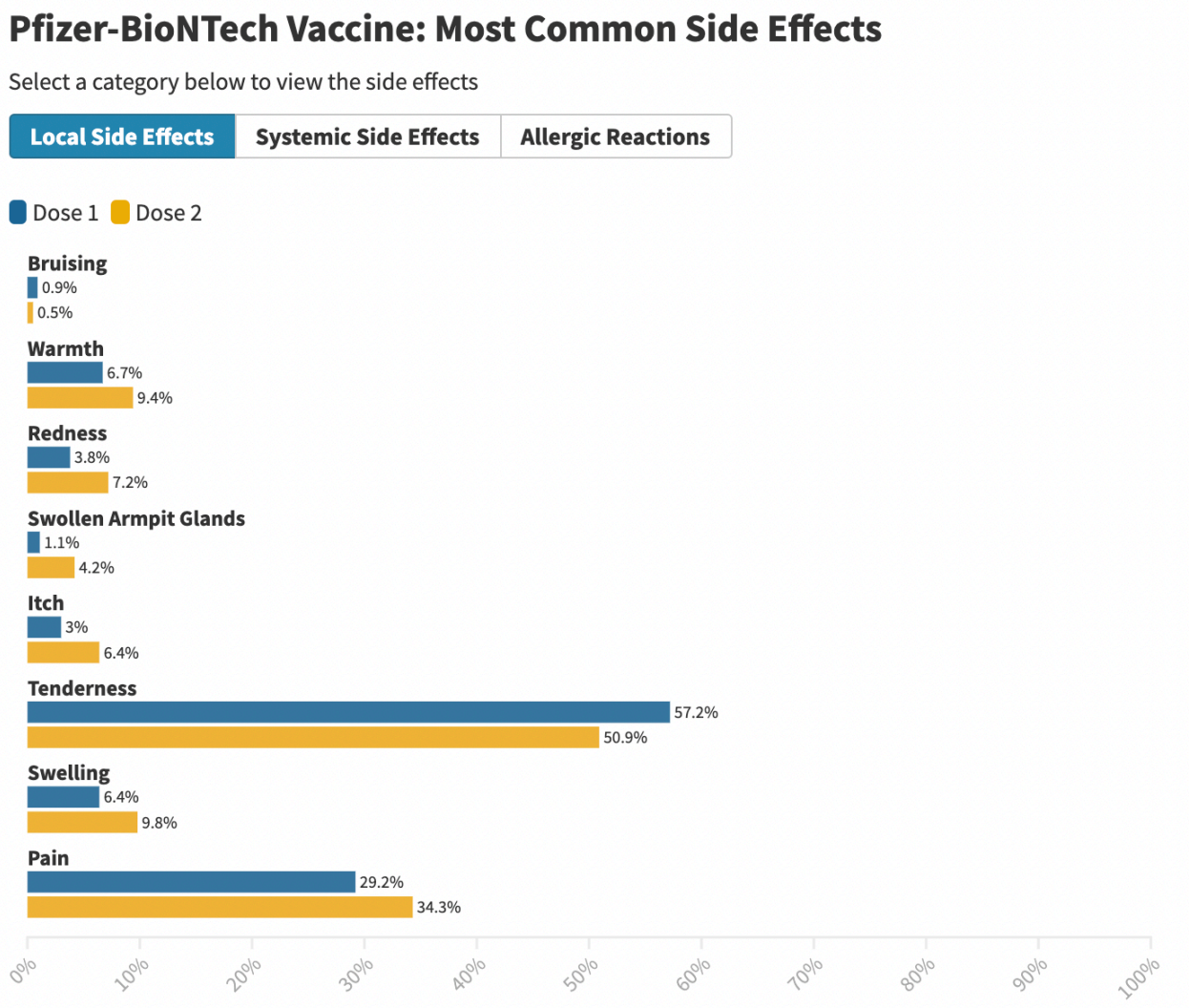

AstraZeneca

- Nearly 59% of people reported having a local side effect with tenderness being the most common outcome
- About 34% of people experienced systemic side effects after the first dose of the AstraZeneca vaccine, with headaches and fatigue as the leading symptom, followed by chills and shivers
- Allergic reactions were rare and less than 2% of people reported skin burning and less than 1% reported rashes and red welts on their face and lips

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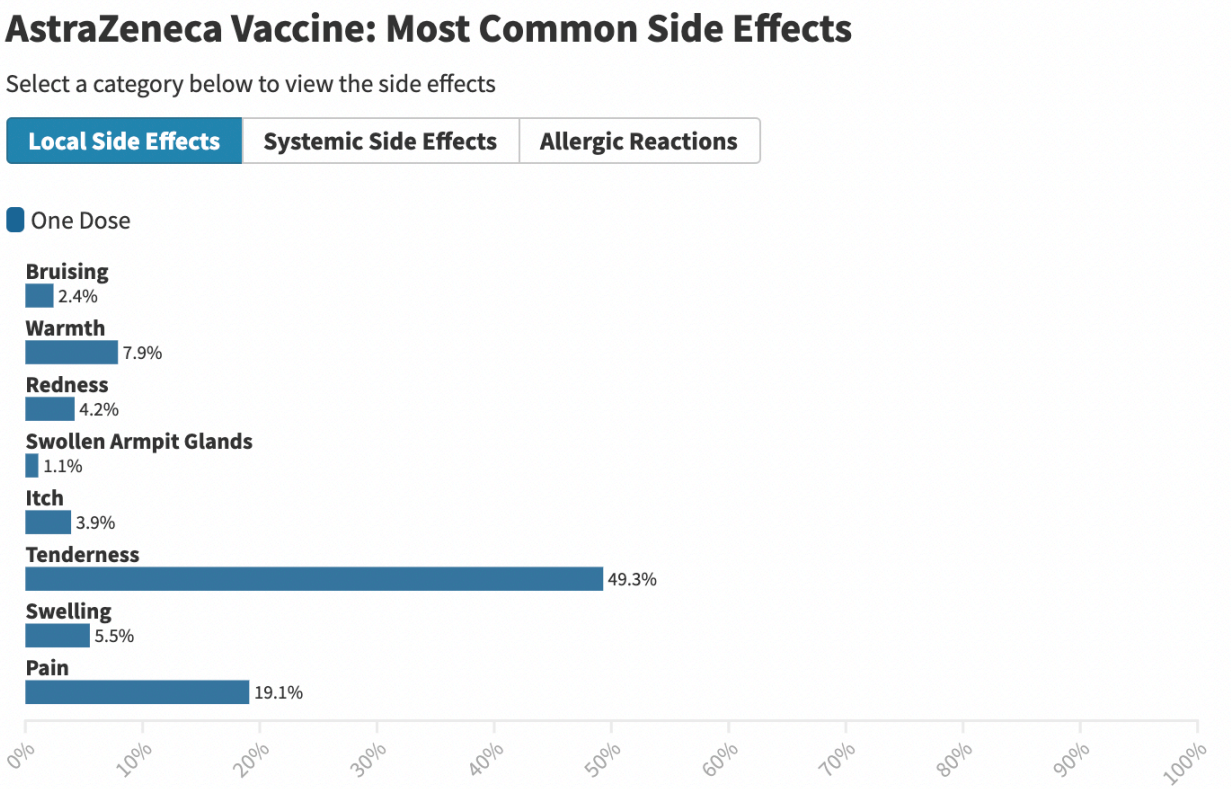

Efficacy of COVID-19 Vaccines

- If researchers have a well-defined correlate of protection, they can predict from early trial data how effective a vaccine will be
    - This alleviates the need to do larger, more expensive and time- consuming phase III trials
- Data from seven vaccination trials were examined to help identify a blood marker for protection against COVID-19
    - They found a strong link between participants' antibody levels recorded in early-stage trials and vaccine-efficacy results from late-stage trials
    - The researchers estimate that a vaccine has an efficacy of 50% even if it induces antibody levels 80% lower than those found, on average, in a person who has recovered from COVID-19
    - Vaccines that generated the strongest neutralizing responses, such as the mRNA-based vaccines made by Moderna and Pfizer-BioNTech were the most protective
- The researchers predict that because antibody levels wane over time, booster shots might be needed in about a year, but protection against severe disease could last many years even without them
- A study published in the New England Journal of Medicine, following the outcomes of nearly 40,000 people tested for COVID-19 in Qatar, found that 1 shot of the Pfizer vaccine was only 29.5% effective in preventing infection

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    - 1 shot of the Pfizer was found to be 54.5% effective in preventing “severe, critical pr fatal” outcomes due to infection by the B.1.1.7 variant
    - However, officials in this study followed the dosing direction that the second dose should be given no more than 21 days after the first, so this one dose estimate that was provided was the efficacy in the first 3 weeks immediately after the first dose
    - Among those who received both doses, the study found that the vaccine’s efficacy against infection by B.1.1.7 with or without symptoms, was 87%, increasing to 90% 14 days after the second dose
        - It was 100% effective against severe symptoms or death
- Other studies cited by NACI found a single dose of a coronavirus vaccine to be 65 to 80% effective in preventing a severe outcome
- In Britain, doses have been spaced out by 12 weeks
- The WHO has recommended a maximum spacing of 6 weeks, but only in critical circumstances
- In Ontario where the first and second dose have been spaced out around 16 weeks, health officials have said that they have seen great results from the one-dose only regimen, with 70% efficacy against infection overall and more than 90% efficacy against severe outcomes
- The province has seen good levels of immunity starting at 14 days after injection, steadily increasing up to 28 days after injection
- Between mid-December 2020 to late April 2021, nearly 6800 people were infected with COVID-19 after receiving 1 dose of a vaccine
    - Among these, 4515 cases were reported within 14 days of their first vaccine dose and 2274 cases were reported at a minimum of 14 days
- For the B.1.351 variant first discovered in South Africa, the Qatar study saw poorer results from one dose
    - It was found t one 17% effective in preventing infection and 0% effective in preventing hospitalization or death due to B.1.351
- The Public Health England research found that those who became infected 3 weeks after receiving their first Pfizer-BioNTech or AstraZeneca vaccines were between 38 and 49 percent less likely to pass the virus on to their household contacts compared to others who were unvaccinated
- The shorts also stop pa vaccinated person developing symptomatic infection to start with, reducing the risk by about 60-65% from 4 weeks after 1 dose of either vaccine
- Moderna has announced that its COVID-19 vaccine
- was powerfully effective in 12 to 17 year old and plans to apply for FDA authorization
    - This is based on a clinical trial that enrolled 3,732 people ages 12 to 17, 2/3rds of whom received 2 vaccine doses
    - There were no cases on symptomatic COVID-19 in fully vaccines adolescents, which translates to an efficacy of 100%
        - This is the same figure that Pfizer and BioNTech reported in a trial of their vaccine in 12 to 15 year old

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- Federal regulators authorized the Pfizer-BioNTech vaccine this month for 12-15 year old
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Sanofi and GlaxoSmithKline

- An experimental COVID-19 vaccine developed by Sanofi and GlaxoSmithKline showed a robust immune response in early-stage clinical trial results
    - This has enabled them to move to a late-stage study
    - A global Phase III trial will start in the coming weeks and involve more than 35,000 adults
        - This Phase II study will assess the vaccine against various strains including a virus lineage known as B.1.351 first detected in South Africa
- Sanofi and GSK last December, were forced to restart their trial when the vaccine showed a low immune response in older adults as a result of a weak antigen formulation
- The Phase II interim results showed 95% to 100% seroconversion following a second injection in all age groups and across all doses, with acceptable tolerability and no safety concerns
    - Seroconversion is the vaccine's ability to prompt the body to produce antibodies against the coronavirus, as measured by blood readings
- They also observed that the vaccine generated a higher antibody response in those with precious COVID-19 infection
    - This is being analyzed further as it may suggest that the vaccine can serve as a potential booster
- The GSK and Sanofi vaccine candidate uses the same technology as one of Sanofi's seasonal influenza vaccines and it will be coupled with an adjuvant - a substance that acts as a booster to the shot
- So far, Sanofi has purchasing agreements with the U.S, the EU, Britain, and Canada, as well as with the WHO-backed COVAX facility
- Sanofi is also working on a mRNA candidate with U.S. company, Translate Bio for which it has started clinical trials

COVID-19 Vaccine Protection Period

- Pfizer and BioNTech has stated that data from their Phase 3 trial showed high levels of protection against COVID 6 months after 2nd doses
- There is other research backing up the claim that the Moderna vaccine offers protected against COVID-19 for at least 6 months
- These reports were based on follow-up tests in dozens of people who received the shorts during studies that led to the vaccines' use
    - These were done before troubling new variants or versions of the coronavirus, had emerged and started to spread
- The FDA's top vaccine regulator has stated that a COVID-19 booster shot could be needed for fully vaccinated people within a year

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- Pfizer-BioNTech is testing a third booster shot of its vaccine on fully vaccinated people
- Moderna is also testing a potential third dose of its current vaccine and a possible booster shot specifically targeting the South Africa variant
- There is less data available for the AstraZeneca vaccine, however, when looking at the effectiveness of the vaccine after giving the 2 doses at different intervals, studies have shown that the vaccine efficacy reached 82.4% after a second dose for those who had a dosing interval of 12 weeks or more
    - This means that it is reasonable to think the protection will last at least a further 3 months after the second dose, although more data is needed
- While it is possible that vaccine-induced protection will last longer than the 6 months being proposed by these findings, many experts believe that the antibodies created by vaccines will wane over time and booster shots will be required
- If vaccines need to be tweaked to be more effective against new variants manufacturers have said that these will be easy to do and can be done in less than 3 months

General COVID-19 News

- WHO director general Tedros Adhanom Ghebreyesus has warned that the world reminds in a very dangerous situation where more cases have been reported so far this year than in the whole of 2020
- According to current trends, the number of deaths will overtake last year's total within the next 3 weeks
- More than 75% of all vaccines have been administered in just 10 countries
- WHO is urging countries to donate vaccine doses to COVAX to enable 10% of the populations of all countries to be inoculated by September and 30% by year's end
- In Europe, British scientists say that sniffer dogs trained using smelly socks worn by people infected with the SARS-CoV-2 virus could soon be used yo pick up the "corona odour" of those infected with the virus
    - They say that these dogs can screen a line of several hundred people coming off a plane within half an hour, and detect with up to 94.3% sensitivity those infected
    - These researchers presented results of an early-stage study which involved some 3500 odour samples donated in the form of unwashed socks or T-shirts
    - They say these dogs were even able to sniff out asymptomatic or mild COVID-19 cases, as well as cases caused by a variant that emerged in the U.K. last year
- While India is currently at the epicentre of the global coronavirus pandemic, it is not the only country with a worsening COVID-19 outbreak
    - Argentina, Bahrain, Taiwan, and Nepal, as well as many other countries have reported record increases in cases in the last few weeks
    - These are generally countries that are lagging in vaccinating their populations due to limited supply of shots
- Federal health official have stopped investigating breakthrough coronavirus infections in vaccinated people unless the cases cause serious disease that lead to a hospitalization or a death

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- They will continue to gather data about mild breakthrough cases that are reported to the agency but will only investigate the most serious cases
- Until May, the agency was monitoring all cases
- Although they will continue to carry out vaccine effectiveness studies, it will focus on specific populations like health care workers, essential workers, the elderly and residents of long-term care facilities
- Some criticize this move saying it is wasting an opportunity to learn about the real-world effectiveness of different vaccines, gather information on when vaccine protection begins to wane, whether variants play a significant role in breakthrough infections, and if some patient are more susceptible than others to the post-vaccine infection
- Others understand that they need to prioritize and focus on understanding the cases associated with severe disease