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February/March 2021 Report

Pfizer- BioN Tech Vaccine Updates

Vaccine Side effects

- The most commonly reported side effects have been - typically last for several days:
    - Pain at the site of infection
    - Tiredness
    - Headache
    - Muscle pain
    - Chills
    - Joint pain
    - Fever
- More people experienced these side effects after the second dose than after the first dose
- A study of 40,000 mainly health workers who had received the Pfizer vaccine found that one in three reported minor side effects
    - None was serious and all were short lived
- It is hypothesized that younger people are more likely to report side effects from vaccine when compared with older people due to them having a more robust immune system
- One study found that someone is more likely to suffer side effects from the vaccine if they have already had coronavirus (https://covid.joinzoe.com/post/vaccine-after-effects-more-common-in-those-who-already-had-covid)
    - 33% of people in this group reported "mild whole-body" side effects such as fatigue, headache and shivers after their first dose, compared with 19% of patients who had not had COVID
    - Researchers suggest this may be the effect of a favourable immune response among the group who have already had COVID-19, however, they stress more research is needed

Changes in 2nd dose administeration

- With some countries experiencing low supplies, some researchers say that the second dose of the Pfizer vaccine could be delayed in order to cover all priority groups as the first one if highly protective
    - The vaccine had an efficacy of 92.6% after the first dose
    - They do however caution that there may be uncertainty about the duration of protection with a single dose
- Pfizer however states that alternative dosing regimens of the vaccine have not been evaluated yet and that the decision resides with the health authorities
- Some argue that the urgency of the pandemic requires flexibility while others oppose abandoning data-driven approaches for the sake of expediency
- In Britain, authorities have said that data supported its decision to move to a 12-week dosing schedule for Pfizer's vaccine

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    - Both Pfizer and BioNTech have warned that they have no evidence to prove it
    - Pfizer's vaccine is authorized to be taken 21 days apart
- In clinical trials, Pfizer couldn't accurately determine the efficacy of a single shot because participants had already received their second dose after 3 weeks and there was no comparative one-dose study done
    - Pfizer reported an efficacy of 52% for 1 shot, compared to the more commonly cited 95% after the second shot
    - Danuta Skowronski, the epidemiology lead at the British Columbia Centre for Disease Control realized that the company had included in its analysis, the 2 week time period immediately after vaccination - before the body's immune response typically kicks in
    - She states that they were underestimating the efficacy of the 1st dose, and rather than the efficacy being 52%, that it was actually 92%
    - Longer intervals between the first and second dose of a vaccine are generally preferred because shorter intervals can interfere with the immune boost response, however, clinical trials on COVID-19 vaccines ran with the shortest time frame possible so they could get data out quickly
    - Skowronski states that the second dose is still needed eventually to have as much protection from COVID-19 as possible
- This finding led the National Advisory Committee on Immunization (NACI) to change the recommended time between doses of COVID-19 vaccines from 3 weeks to an unprecedented 4 months
    - Following this change, B.C. Canada announced that it would be delaying second doses early this week
    - Ontario, Quebec, Alberta, Manitoba, and Newfoundland and Labrador quickly followed suit
- This will allow close to 80% of Canadian over 16 to get at least 1 shot of the Pfizer-BioNTech or Moderna vaccine by the end of June
- No other country that Canada has delayed second doses up to 4 months
- There is no evidence yet on the long-term effect it could have on immunity to COVID-19
- NACI states that its decision to delay second doses is based on emerging real-world data from Quebec, B.C, Israel, the U.K, and the U.S. that showed "good effectiveness" of between 70 and 80% from a single dose of the vaccines "for up to 2 months in some studies"
    - They do make clear that these studies have not yet collected 4 months of data on the long-term effectiveness of a single dose, meaning NACI is betting on the "high levels of protection" shown so far
- NACI will continue monitoring vaccine effectiveness data as it comes out around the world to determine if its needs to further alter its recommendations

Changes in storage temperature

https://globalnews.ca/news/7651176/pfizer-covid-vaccine-storage-temperatures/ - February 19, 2021

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- Pfizer and BioNTech asked the U.S. health regulator to relax requirement for their COVID-19 vaccine to be stored at ultra-low temperature
- The companies submitted new temperature data to the FDA to support an update to the current label that would allow vials to be stored at -25 to -15 degrees Celsius for a total of 2 weeks, instead of between -80 and -60 degrees Celsius
- This can greatly expand the ability to use the vaccine in many parts of the world that do not have the capacity for deep freeze storage
- On Wednesday March 3, Health Canada announced that Pfizer's COVID-19 vaccine can be stored for up to 2 weeks and transported at temperatures between -25 and -15˚C
- The long-term storage requirements remain the same
- Vaccine vials stored at -15 to -15˚C can be returned one time to the approved storage of -80 to -60˚C.

Moderna Updates

- Moderna's vaccine is already cleared for stage at -25 to -15 degrees Celsius
- Moderna increased the low end of this vaccine production target for this year to 700 million doses from 600 million doses and indicated that it plans to make at least 1.4 billion doses of the short in 2022
- They also indicated that it was projecting sales of about $18.4 billion from its COVID-19 vaccine shot this year
    - This is higher than Pfizer, which has forecast that its share of COVID-19 vaccine revenues would stand at roughly $15 billion in 2021
- While South Africa stopped administering AstraZeneca's vaccine, after trials showed that it only provided minimal protection against a strain spreading across the country, Moderna has said that its shot will provide protection against the South African strain
- On February 23, 20201, Moderna announced that they are developing a booster shot for new coronavirus variants - mRNA-1273.351
    - They are working with U.S. government scientists
- They have produced raw material for a booster short aimed at addressing the virus variants first found in South Africa that may be more resistant to existing vaccines
- They have shipped the vaccine tp the U.S.' National Institutes of Health for additional study
- They are experimenting with several potential ways to combat new variants of the virus such as:
    - An additional booster shot that targets the variant now prevalent in South Africa and spreading globally
    - A combined booster shot that mixes its current COVID-19 vaccine with the experimental show
    - And extra booster shot on top of its current 2-dose vaccine

General COVID-19 updates

General public's confidence in vaccine growing

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https://www.theguardian.pe.ca/news/world/covid-19-vaccine-confidence-grows-as-side-effect-worries-fade-559912/

- A 14-country survey shoed that confidence in COVID-19 vaccines is growing, with people's willingness to have the shots increasing
    - The latest survey involved more than 13,500 people in Australia, Britain, Canada, Denmark, France, Germany, Israel, Italy, Japan, The Netherlands, Norway, Singapore, South Korea, Spain, and Sweden
- Co-led by Imperial College London's Institute of Global Health Innovation (IGHI) and the polling firm YouGov, the survey found trust in COVID-19 vaccines had risen in 9 out of 14 countries including France, Japan, and Singapore, which previously had low levels of confidence
- The latest update of the survey, which ran from Feb. 8 to Feb. 21 found that people in the UK are the most willing, with 77% saying they would take a vaccine designed to protect against COVID-19 if one was available that week
    - This is up from 55% in November
- People in France, Singapore, and Japan remained among the least willing to have the vaccine, at 40%, 48%, and 48% respectively
    - However, all three have seen confidence rising since November when only 25%, 36%, and 39% of people were positive
- The sever also found that worries over vaccine side effects have faded in the majority of countries, with fewer than half (45%) of all respondents currently reporting concern

Women should consider getting mammogram before COVID-19 Vaccine

https://www.ketv.com/article/covid-19-vaccine-side-effect-could-look-similar-to-infection-breast-cancer-in-mammogram/35727535# - March 5, 2021

- The Society of Breast Imaging recently put out a recommendation that patients should schedule their mammograms around their COVID-19 vaccines
    - Either before the vaccine or getting it 4-6 weeks after the second dose
- An SBI report noted that a significant amount of patients who participated in both the Pfizer and Moderna vaccine clinical trial noticed lymph node swelling in their armpit
    - The vaccine can create a lymph node response- which is good as it it a sign that the lymph node is pumping antibodies to COVID-19
    - Report shoed that between 11-16% of patients who received the second dose of the Moderna shot had swollen or tender lymph nodes - results were similar for Pfizer
- This side effect can impact mammogram screening - if a doctor is unaware of recent vaccine, that may think it is more malignant
    - Infection the patient is fighting can cause this but so can breast cancer and lymphoma

New research

https://www.gov.uk/government/news/people-with-learning-disabilities-had-higher-death-rate-from-covid-19 - November 12, 2020

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- The report, Deaths of people identified as having learning disabilities with COVID-19 in England in the Spring of 2020 examined data from the English Learning Disabilities Mortality Review and NHS England's COVID-19 Patient Notification Systems (CPNS_ which records deaths in hospital settings
- The report found 451 per 100,000 people registered as having a learning disability died with COVID-10 between March 21 and June 5
    - This death rate is 4.1 times higher than the general population after adjusting for other factors such as age and sex
- Since not all deaths in people with learning difficulties are registered on these databses, researchers estimate that the real rate may have been as high as 692 per 100,000 = 6.3 times higher
- Deaths were also spread much more widely across the age spectrum among people with learning disabilities
- There was far greater mortality rates in younger adults, compared to the general population
- The death rate for people aged 18 to 34 with learning disabilities was 30 times higher than the rate in the same age group without disabilities
- Among people with learning disabilities, the rate of COVID-19 deaths for adults in residential care was higher than the rates of COVID-19 deaths of adults with learning disabilities generally
    - This difference is likely in part to reflect the greater age and disability in people in residential care
- People with learning disabilities are more likely to have other physical health problems such as obesity and diabetes and certain kinds of learning disability, such as Down's syndrome , can make people more vulnerable to respiratory infections, which can increase their risk of dying from COVID-19
- A learning disability also reduces ones ability to understand new or complex information and learn new skills - consequently, those with learning disabilities may find it harder to recognize symptoms of COVID-19 or follow government advice about getting tested, self-isolation, social distancing, and infection prevention and control
    - It may also be more difficult for people caring for them to recognize the onset of symptoms if these cannot be communicated

Vaccine for children

https://www.nihr.ac.uk/news/first-childrens-covid-19-vaccine-trial-open/26870 - February 15, 2021

- The National Institution for Health Research (NHIR) has funded a study which will be run by Oxford University, trialling the Oxford-AstraZeneca vaccine in young people aged 6 to 17
- They will be studying its effects on 240 young volunteers
- Half of the children will be given the Oxford-AstraZeneca vaccine and half a placebo vaccine

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- They will be monitored for their immune responses and any side effects

Johnson & Johnson Vaccine

https://www.smithsonianmag.com/smart-news/fda-authorizes-johnson-johnson-vaccine-heres-why-every-covid-19-vaccine-helps-180977122/ - March 2, 2021

- On February 27, the U.S. FDA issued emergency use authorization for the Johnson & Johnson COVID-19 vaccine in adults 18 years of age and older
- The vaccine is now the 3rd approved for use in the U.S.
- This vaccine does not use mRNA
    - It uses more stable DNA carried in the shell of a common cold virus which promotes the body to make coronavirus' spike proteins
    - The immune system then recognizes the protein and makes antibodies, which then allow the body to fight against attack from the same virus if exposed in the future
- Only one dose is needed instead of two
- It does not require super-cold storage - remains stable in regular refrigeration for 3 months
- In the U.S. clinical trials, Johnson & Johnson's vaccine was 100% effective at preventing hospitalization and death related to COVID-19 and boasts a 72% efficacy rate at preventing cases of COVID-19 after 28 days
    - Efficacy dropped to 66% when averaging results from other global trials, including a South African study that factored in more transmissible variants of the COVID-19 virus
    - The FDA also reported that effectiveness appeared to be lower (42.3% after one month) in people over 60 with comorbidities such as diabetes or heart disease
- Johnson & Johnson's clinical trial involved over 43,000 volunteers in South Africa, Mexico, the U.S, and several South American countries
- The vaccine was less effective in South Africa, where the variant of the coronavirus called B.1.351 is prevalent, than in the U.S.
    - It was 64% effective in preventing infection in South African about a month after the vaccines were administered
- The FDA noted the most common reported side effects were headache and fatigue, followed by muscle aches, nausea, and fever
- Johnson & Johnson expects to supply about 4 million doses this week, 20 million doses by the end of March and 100 million by the end of June

COVID-19 Variant

- Europe recently recorded 1 million new COVID-19 cases at the end of February - an increase of 9% from the previous week and a reversal that ended a 6-week decline
- The so-called U.K. variant is spreading significantly in 27 European countries monitored by WHO and is dominant in at least 10 by the agency's count
    - This includes Britain, Denmark, Italy, Ireland, Germany, France, the Netherlands, Israel, Spain, and Portugal

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- This variant is 50% more transmissible than the virus that surged last spring and again in the fall
- The South Africa variant is also predominant in a district of Austria that extends from Italy to Germany
- The South Africa variant is now present I n26 European countries and is a source of particular concern because of doubts over whether the current vaccines are fully effective against it
- The Brazilian variant, which appears capable of reinfecting people, has been detected in 15 Euroepan countries
- WHO and its partners are working to strengthen the genetic surveillance needed to track variants across the continent
- The CDC is pledging $200 million to track coronavirus variants
    - The White House says that the investment could result I na significant increase in the number of positive virus samples that labs could sequence
- Public Health laboratories, universities, and programs run by the Centers for Disease Control and Prevention sequenced more than 9,000 genomes in mid February and the agency hopes to increase its own contribution to 25,000 genomes a week

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- Experts believe it is critical to increase sequencing efforts - however, at the moment, efforts are too small and uncoordinated to adequately track where variants are spreading and how quickly