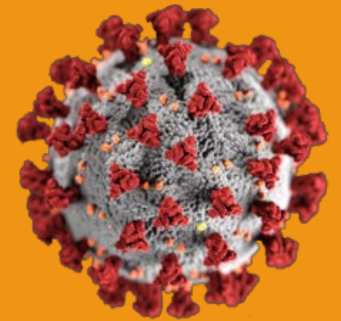


COVID-19 Vaccines

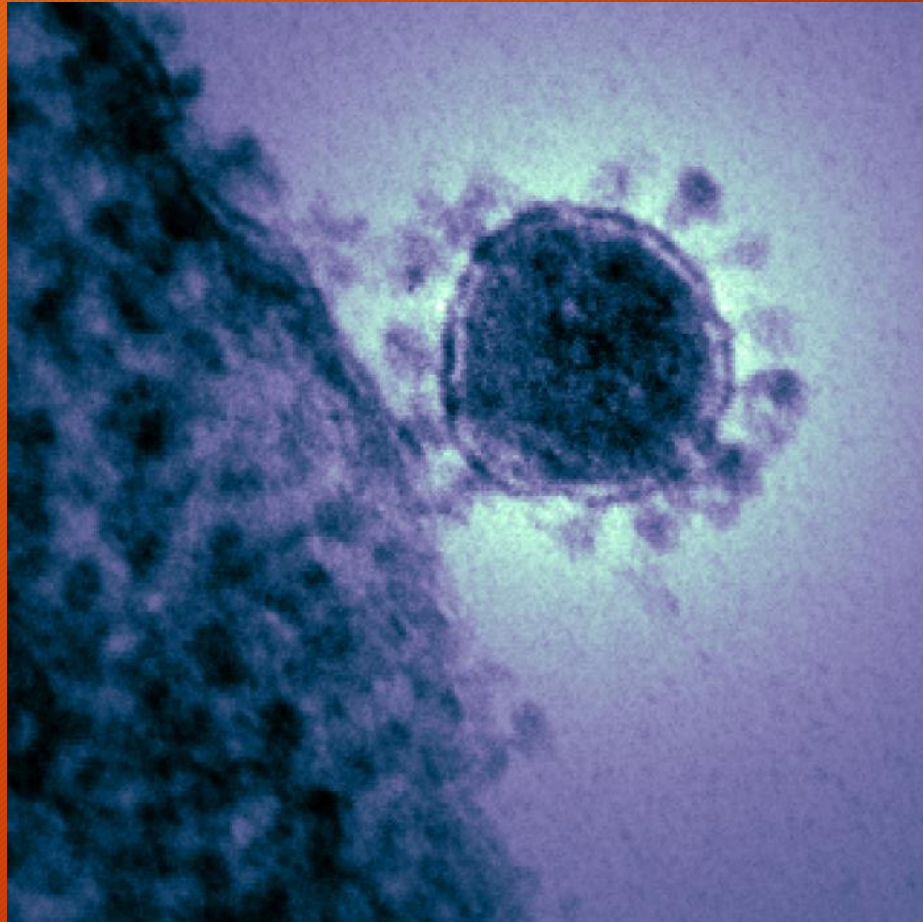
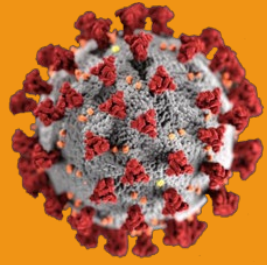


Presentation for UNITE HERE - April 6, 2021

Kevin T. Kavanagh, MD, MS
Chris Pontus, MS, RN, COHN-S/CCM

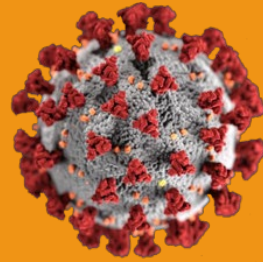
How The Virus & Vaccines Work

How a Virus Works



Clinical Trials

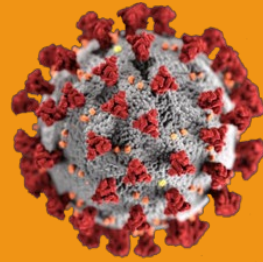
Clinical Trials



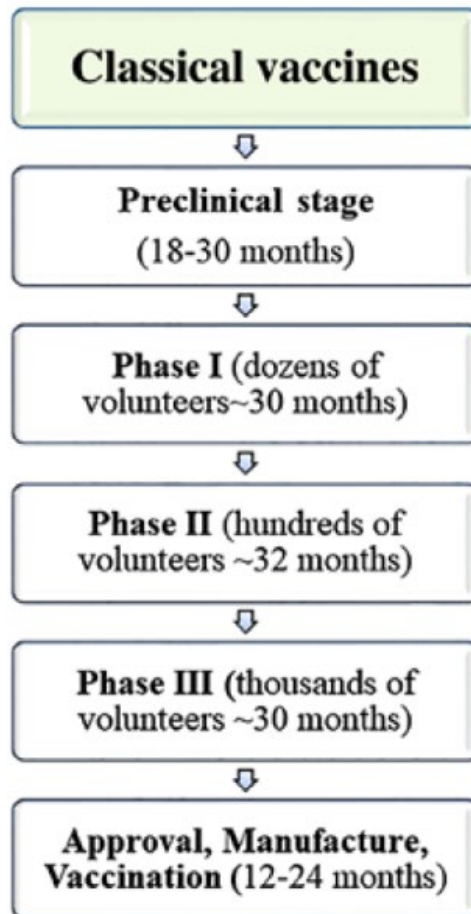
- In **Phase I**, the vaccine is given to approximately 10 to 100 healthy volunteers. The goal is to determine if the vaccine is safe and will not cause severe side effects.
- In **Phase II**, the vaccine is given to approximately 100 to 1000 subjects, and in **Phase III**, to 1,000 to 100,000 subjects. The goal is to determine safety and efficacy.
- During a pandemic, these studies may be overlapped, But before approval it is important to test tens of thousands of subjects and follow them from 2 to 6 months.

Towards effective COVID-19 vaccines: Updates, perspectives and challenges (Review) Int J Mol Med. 2020 Jul;46(1):3-16. doi: 10.3892/ijmm.2020.4596. Epub 2020 May 6.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7255458/>

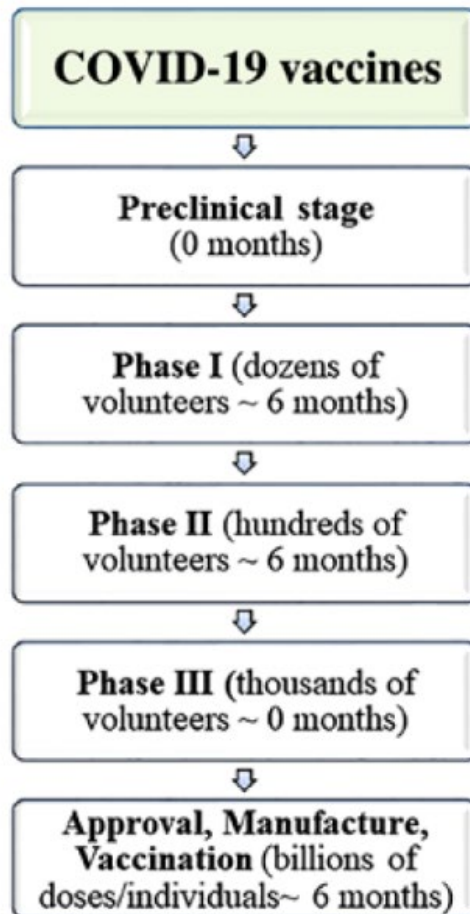
Clinical Trials



Classical vaccines

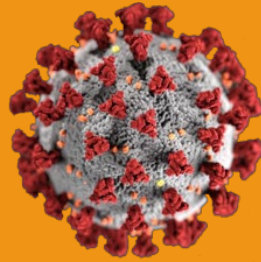


COVID-19 vaccines



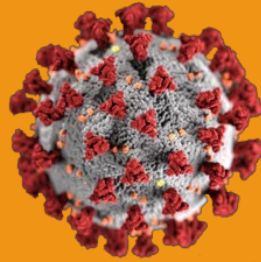
Towards effective COVID-19 vaccines: Updates, perspectives and challenges (Review) Int J Mol Med. 2020 Jul;46(1):3-16. doi: 10.3892/ijmm.2020.4596. Epub 2020 May 6. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7255458/>

COVID-19 Clinical Trials



- All have run Stage III Trials for at least 2 months before EUA was granted.
- The vast majority of vaccine complications occur within the first 2 months after vaccination.
- Currently there is 6 months of safety and efficacy data.
- Patients will be followed for at least 2 years.

COVID-19 Clinical Trials



- **Pfizer/BioNTech – 40,000 subjects in trial**
- **Moderna – 30,000 subjects in trial.**
- **Johnson & Johnson – 44,000 subjects in trial.**
J&J ran their trial last and in countries which had variants.

In South Africa, the trial enrolled 6,000 individuals.

-- 64% effective in South Africa and 95% of the subjects who had COVID-19 had the South African Variant.

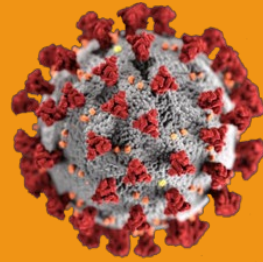
-- Across the entire study's population, 31 people were hospitalized from COVID-19: 29 had received the placebo and two received the J&J's vaccine. There were seven deaths, all were in the placebo group.

<https://www.businessinsider.com/jj-single-dose-covid-19-vaccine-full-study-results-2021-2>

<https://www.reuters.com/article/us-health-coronavirus-vaccines-johnson-j-idUSKBN2B31UV>

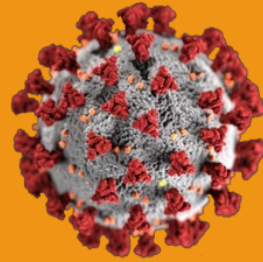
Dangers of COVID

Post COVID-19 Medical Problems



1. There is a huge risk of persistent side effects and Long-Hauler's syndrome. This can affect 15% to 20% of those with mild to moderate infections. This virus affects every organ in the body.
2. Even more serious side effects are seen in those hospitalized.
 - Approximately, 20% will have heart disease (heart attacks, myocarditis)
<https://jamanetwork.com/journals/jamacardiology/fullarticle/2763524>
 - 80% reported to still have trouble breathing
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7896197/>
3. Many COVID patients who were hospitalized develop new medical problems post-discharge. Approximately, 29% of COVID patients were readmitted and 12% died after discharge (mean follow-up of 140 days).
<https://www.medpagetoday.com/infectiousdisease/covid19/91890>
<https://www.bmj.com/content/372/bmj.n693>
4. How COVID-19 Affects the Brain
"Respiratory and gastrointestinal symptoms are accompanied by short and long-term neuropsychiatric symptoms (NPs) and long-term brain sequelae. Some patients present with anosmia, cognitive and attention deficits (ie, brain fog), new-onset anxiety, depression, psychosis, seizures, and even suicidal behavior. Post-COVID-19 NPs in 20% to 70% of patients, even in young adults, and lasting months after respiratory symptoms resolved, suggesting brain involvement persists."
<https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2778090>

Post COVID-19 Medical Problems

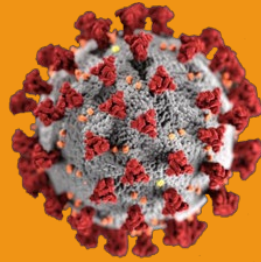


Symptoms lasting longer than 6 months in hospitalized patients. Lancet, Jan. 8, 2021.
1733 hospitalized patients were enrolled. Follow-up time was 6 months.

1. -- **Fatigue and muscle weakness 63%**
2. -- Sleep difficulties 26%
3. -- Anxiety or depression 23%
4. -- **Would not walk as far as expected for age 24%-29%**
5. -- Hair Loss 22%
6. -- Smell Disorder 11%
7. -- Heart Palpitations 9%
8. -- **The proportion of participants with lung diffusion impairment was 22% to 56%.**

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32656-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32656-8/fulltext)

Post COVID-19 Medical Problems



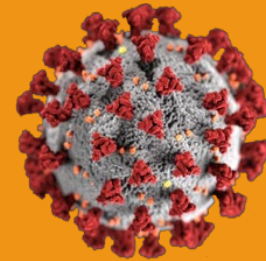
30% Still Having Symptoms at 9 Months – JAMA Network Open

- 14 (8%) participants, including 9 nonhospitalized individuals, reported negative impacts on activity of daily living after infection.
- 49 (32.7%) of non-hospitalized patients and 5(31.3%) of patients with severe disease reported having at least 1 persistent symptom in follow up.
- The most common persistent symptoms were
 - fatigue (24 of 177 pts. [13.6%]) – Approx. 15% in mild cases.
 - loss of sense of smell or taste (24 pts. [13.6%]) – Approx. 17% in mild cases.
- Among the 16 hospitalized patients,
 - Greater than 80% reported trouble breathing.
 - Greater than 80% reported still having a cough.
 - Greater than 80% reported feeling feverish.

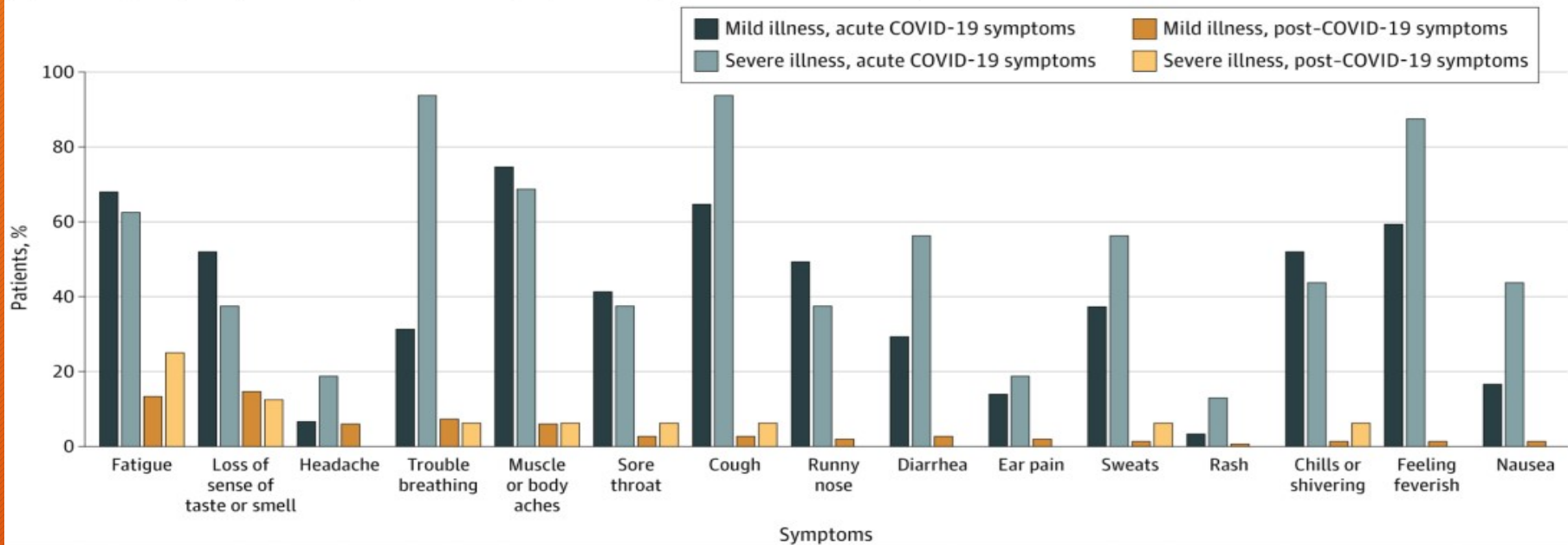
Of the 177 patients followed, 150 (84.7%) were never hospitalized and considered to have mild illness and 11(6.2%) were asymptomatic. 23 out of the 177 also had hypertension.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7896197/>

Post COVID-19 Medical Problems



B Percentage of participants who reported COVID-19 symptoms during acute illness and at follow-up

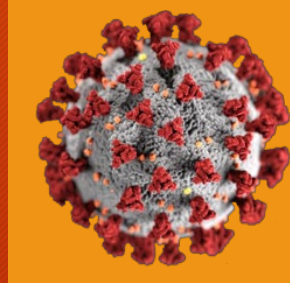


Logue JK, Franko NM, McCulloch DJ, et al. Sequelae in Adults at 6 Months After COVID19 Infection. JAMA Network Open. Feb. 19, 2021. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776560>

Of the 177 patients followed, 150 (84.7%) were never hospitalized and considered to have mild illness and 11(6.2%) were asymptomatic. 23 out of the 177 also had hypertension.

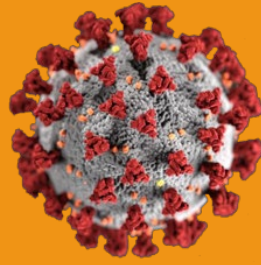
Variants

COVID-19 Variants



- Wild Type Virus – Wuhan Variant
- D614G
- UK Variant B117
- EeeK variants with the E484K mutation.
-- New York, South African, Brazilian
- California Variant L452R
- Indian Double Mutation Variant E484Q and the L452R

Double Mutant In San Francisco



- A "double mutant" coronavirus variant with features of the so-called California variant plus a mutation found in Brazil and South African variants has been detected in the San Francisco Bay Area. (*San Francisco Chronicle*)

<https://www.medpagetoday.com/infectiousdisease/covid19/91930>