

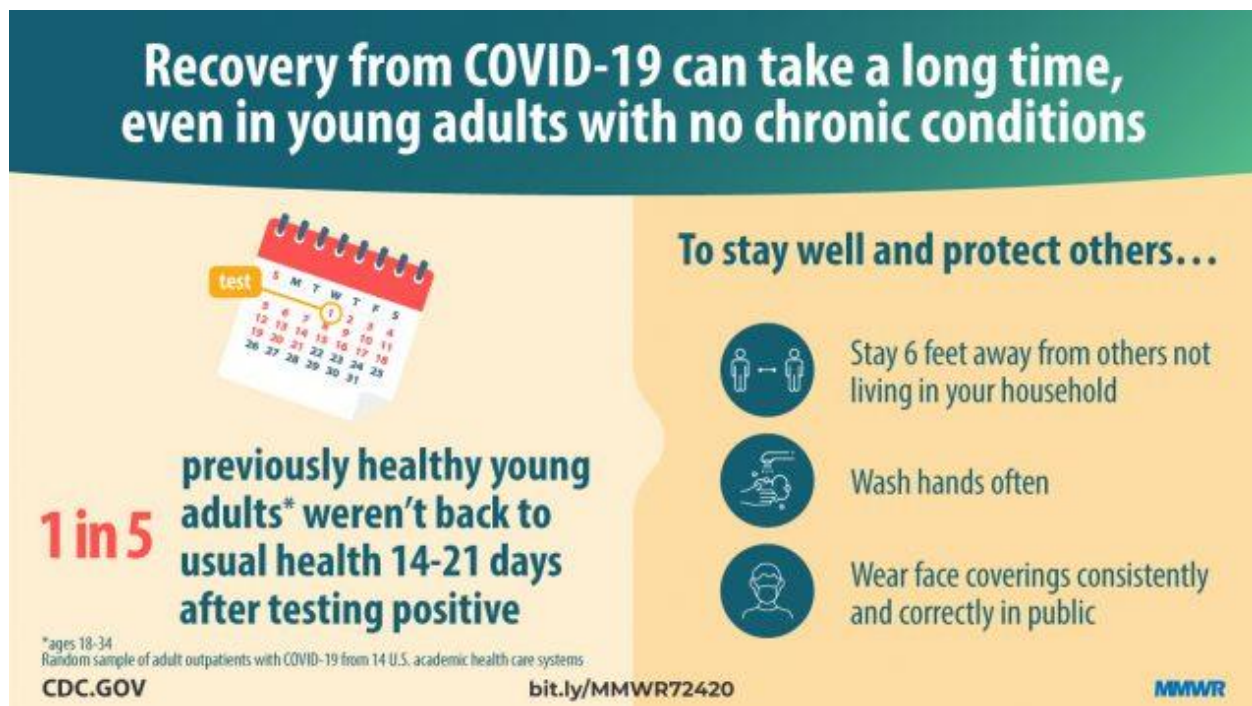
Covid-19 Sequelae (more)

FDA (Food and Drug Administration) Clinical Trials

Vaccines

More Covid Sequelae:

- 1) *Long term effects of Covid, even in young, CDC report*



<https://www.cdc.gov/mmwr/volumes/69/wr/mm6930e1.htm>

2) *Length of pandemic*

Google to Keep Employees Home Until Summer 2021 Amid Coronavirus Pandemic

<https://www.wsj.com/articles/google-to-keep-employees-home-until-summer-2021-amid-coronavirus-pandemic-11595854201>

3) *Child Care*

How the Child Care Crisis Will Distort the Economy for a Generation

The economic toll of the collapse of the child system will be felt for 20-30 years

<https://www.politico.com/news/magazine/2020/07/23/child-care-crisis-pandemic-economy-impact-women-380412>

FDA Clinical Trials: Goals and Phases



Charge:

- Responsible for protecting public health by ensuring safety, efficacy and security of **Drugs, Biologic products & Medical devices** AND Ensuring safety of nation's food supply, cosmetics and radiation emitter

Mechanisms:

- Drug Safety and Efficacy demonstrated through **Clinical Trials**

Remember:

Clinical Trials Goal of Effectiveness

1. Does the drug do what it says it will do?
(in Covid example **increase antibodies** to Covid)
2. Does this effect result in decreased disease?
, i.e. **decrease Covid 19 infection**

These can be 2 disparate goals and achievements, but one does not necessarily mean the other is accomplished AND

Is decreased infection:

- Decreased overall incidence of infection?
- Decreased infection causing hospitalization?
- Decreased severe, ICU requiring infection?

Bottom Line: Complicated

Clinical Trial Phases:

- Phase 0
 - Very first trial in small group of people, study drug affects
- Phase I
 - Goal is to find optimum dose in people with fewest side effects, generally tested in small groups of 15-30 people
 - Primary goal is to test drug's safety
- Phase II
 - Further assessment of safety and efficacy in larger groups of people
 - To date, clinical trials with Covid drugs have been in this stage
- Phase III
 - Drug evaluation in large groups of people (> 100, many times, thousands)
 - Generally, evaluation is through randomization of people,
 - Randomized to 2 groups, treatment group, no treatment group
 - Identify of treatment, no treatment, not known until conclusion of trial
 - This results in most accurate determination of drug's effects
 - Randomized trials are the Is the GOLD Standard of drug, that is results of the trial are due to drug's effects, not something else
- Phase IV
 - Tests drugs already approved by FDA, post approval analysis and review

Alternative to drugs to decrease Covid infection

- Another way to decrease infection is through infusion of plasma from people who have recovered from Covid infection
- Essentially infusion antibodies from recovered patient
- Another complicated issue...

Vaccines:

Definition:

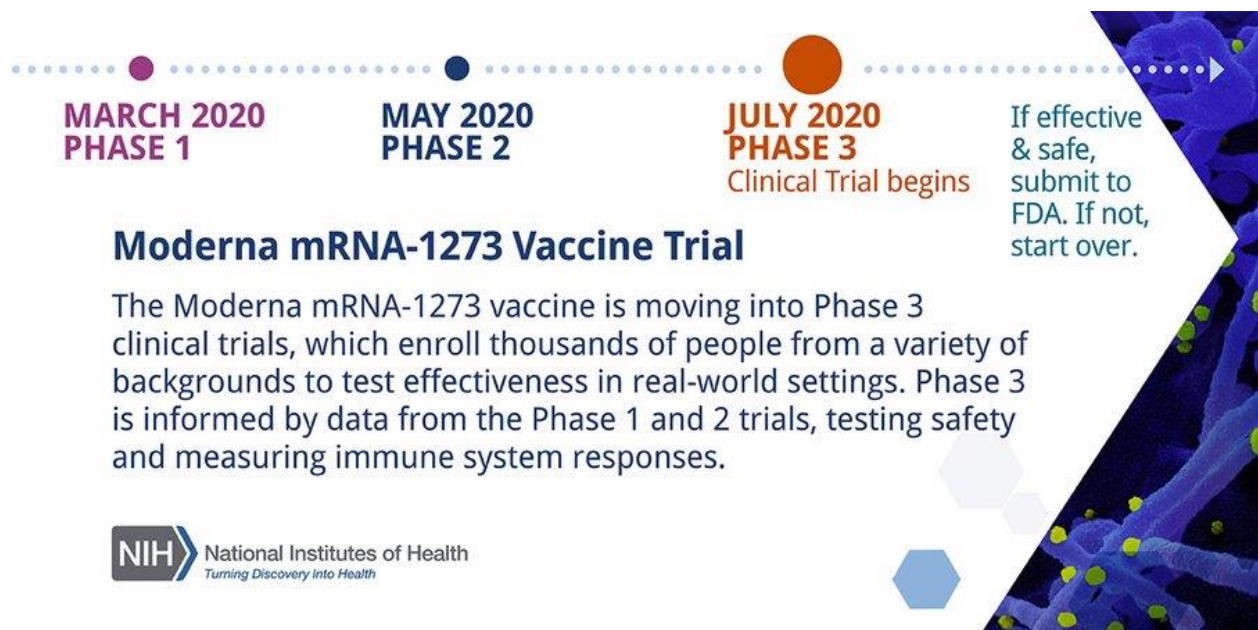
- Biological preparation that provides active acquired immunity to an infectious disease
- A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins, or one of its surface proteins.
- The agent stimulates the body's immune system to recognize the agent as a threat, destroy it, and to further recognize and destroy any of the microorganisms associated with that agent that it may encounter in the future
- VACCINES ARE, in essence, a way to activate the immune system without disease.
 - They can be made with
 - weakened viruses,
 - inactivated viruses,
 - the proteins from a virus,
 - a viral protein grafted onto an innocuous virus (some Covid vaccines combine with adenovirus)

Issues/Problems: “A Vaccine Reality Check”

- The technology works and a vaccine/vaccines will be developed BUT another huge task lies ahead:
 - Distribution
 - When vaccines are approved, 300 million doses will not be available all at once, and a system is needed to distribute limited supplies to the public. This is exactly the sort of challenge that the U.S. government has proved unprepared for in this pandemic.
 - Logistical challenges
 - Storage, ie storage (refrigeration?)
 - One dose/two doses?

- Prioritization of recipients
 - Age, prior conditions
 - Racial disparities, etc.
- Conspiracy theories?
- Anti-vaxxers?
 - <https://www.theatlantic.com/health/archive/2020/07/covid-19-vaccine-reality-check/614566/>

Current Status of one Vaccine



Virus vaccine put to final test in thousands of volunteers

https://apnews.com/d9150647d677cd036c03b8d0ab52358b?utm_campaign=SocialFlow&utm_source=Twitter&utm_medium=AP