

"To vaccinate or not? Should I get the COVID vaccine?"

Hear from a former ('recovering') drug-discovery scientist about the basic logistics of vaccine development.

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My background in science:

- ▶ PhD in Medical Physiology from University of Maryland Medical School.
 - ▶ Specialty in Neuroendocrinology/Neuroscience.
- ▶ Twenty years experience with University and Medical School teaching and research.
 - ▶ Culminating with 3 years experience working at private drug-discovery company.



We are beyond COVID-19 Rescue Dogs
with the pandemic....



COVID-19 Vaccinations

- ▶ Major questions/concerns:
 - ▶ It was rushed so how good and safe can it be?
 - ▶ It will change my genetics.
- ▶ To address concerns, helpful to understand:
 - ▶ How/why pharmaceutical companies develop products, in general.
 - ▶ How vaccines are developed and approved.



Pharmaceutical Companies are Businesses

- ▶ Develop products to make money.
- ▶ Cost-benefit analysis done to minimize financial risk/maximize financial return.
 - ▶ Sequential steps of product development, testing, and data analysis.
 - ▶ Successful products continue with broader testing and data analysis.
- ▶ With COVID-19 Vaccine: US Federal Government Covered Development Costs.
 - ▶ NO financial risk.
 - ▶ All development steps could be done combined and/or simultaneously with much larger commitment of resources.



General Phases of Vaccine Development

- ▶ Preclinical phase.
 - ▶ Does the vaccine particle trigger an immune response?
- ▶ Phase I.
 - ▶ Is the vaccine safe?
- ▶ Phases 2 & 3.
 - ▶ What is the vaccine's efficacy?
 - ▶ Major difference between phases is the number of patients in the study.
- ▶ Phase 4.
 - ▶ Post FDA-approval phase.
 - ▶ Continue to examine safety, efficacy, including long term efficacy.



Vaccine Development – Classic Method

- ▶ Grow large quantities of the virus.
- ▶ Inactivate the virus and inject into people.
- ▶ Your immune system mounts attack on the virus, produces antibodies, and 'memory' immune cells.

- ▶ **Benefits:**
 - ▶ Proven method for developing vaccine.
- ▶ **Drawbacks:**
 - ▶ With viral mutations vaccine can become less effective.

- ▶ Chinese COVID vaccines.



Vaccine Development – mRNA

- ▶ Synthesize large quantities of mRNA (with COVID – spike protein mRNA).
- ▶ mRNA Vaccine is injected into people.
- ▶ mRNA causes cells to make this foreign spike protein.
- ▶ Your immune system mounts attack on the foreign protein, produces antibodies, and ‘memory’ immune cells.

- ▶ **Benefits:**
 - ▶ Based on decades of molecular biology and virology research.
 - ▶ More rapid development.
 - ▶ COVID mRNA vaccines are more efficacious than classic vaccines.
 - ▶ Can pivot faster to develop vaccine against new mutations.
- ▶ **Drawbacks:**
 - ▶ Relatively newer technology.
 - ▶ Current vaccines require two shots for maximal effectiveness.

- ▶ Pfizer and Moderna vaccines.



Vaccine Development – other Methods

- ▶ These vaccines are not as far along in development as the COVID mRNA vaccines.
- ▶ Adenovirus-based.
 - ▶ Uses harmless virus to deliver spike protein DNA.
 - ▶ J&J and Oxford/Astra-Zeneca vaccines.
- ▶ Protein-based.
 - ▶ Vaccine is the spike protein in nanoparticles.
 - ▶ Novavax vaccine.



Vaccine Approval

- ▶ The Approval Process was NOT rushed.
 - ▶ Each step reviews data for efficacy and safety of the vaccine, and manufacturing process.
 - ▶ Ask questions, request more information.
 - ▶ Makes recommendations to the next group in the review process.
- ▶ Process steps:
 - ▶ Panel of scientists independent from both pharmaceutical company and FDA.
 - ▶ FDA Scientists and Public Health Officials.
- ▶ EUA – Emergency Use Authorization.
 - ▶ Occurs when benefits far out weigh side effects.
- ▶ Ongoing checks – every batch tested for quality and safety.
- ▶ Phase 4 Clinical Studies.



How do we encourage people to take the vaccination?



Communication, communication, communication

- ▶ Pool our collective experience.
 - ▶ What do you think?
- ▶ My thoughts:
 - ▶ Involve respected and knowledgeable health professionals to develop message.
 - ▶ Have consistent message delivered by multiple district and community leaders.
- ▶ Useful links:
 - ▶ <https://www.vaccines.gov/basics/types>
 - ▶ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html>
 - ▶ <https://www.nytimes.com/interactive/2021/health/how-covid-19-vaccines-work.html?action=click&module=Well&pgtype=Homepage§ion=Health>



The end is in sight.

