

Covid Vaccines Q&A with Paul Offit M.D., Pediatrician and Scientist

By Maria Kootsikis, Pharm.D.

I recently diagnosed myself with “medical information overload.” I know that self-diagnosis is not a smart thing to do, but my cytokines storm every time I hear things in the news like “take hydroxychloroquine” or “inject a disinfectant” to prevent COVID-19. To calm myself, I first turned off the T.V. and then turned to Medscape, an excellent free resource for medical updates and opinions. I was most interested in learning more about the current status of COVID-19 vaccines. Having worked in R&D for pharma, I knew from past experience that it takes time to bring a vaccine to market. A very informative Q&A by Eric. J. Topol, M.D. and Paul A. Offit, M.D. greatly helped clarify a few points.¹ To be fully transparent, I do listen to the news, especially when someone of Dr. Topol’s credentials (he is an internationally known cardiologist and researcher) speaks. Remember, he is the doctor who recently tweeted about the misrepresentation of data by Dr. Han from the Centers for Disease Control and Prevention regarding the exaggerated benefit of treating COVID-19 with convalescent plasma.²



Medscape recently published a discussion with Dr. Topol and Dr. Offit³, a pediatrician who co-developed the rotavirus vaccine and published over 130 papers in medical and scientific journals. From a high-level view, Dr. Offit commented that “it’s all happening at warp speed,” which can be scary, especially if “timelines are being truncated or, worse, that safety guidelines are being ignored.” To put our minds at ease, he does say that as long as phase III trials are not truncated, and as long as results are not oversold because of lack of data, we’re okay. Right now, there are “eight companies in the midst of phase III trials—large, prospective, placebo-controlled trials—to prove efficacy...and safety.” In response to Dr. Topol’s question about his thoughts on the mRNA vaccines (which are being tested in two of the three phase III trials in the U.S., see the chart to the right), Dr. Offit commented that the lack of commercial experience with mRNA vaccines leaves us with a learning curve.

Dr. Offit doesn’t see how it will be possible for results from two phase III vaccine trials to be available by the end of October. This was stated in response to Dr. Topol, who pointed out that there are “two 30,000-participant, placebo-controlled trials with Pfizer and Moderna vaccine candidates, which are expected to complete enrollment by the end of this month. Both of these have a two-dose program. After the first dose, there’s a booster a month later, and then it will take time to before you will see the full expected immune response.” And to add more to the mix, according to a statement in *The New York Times* on September 14, 2020, Pfizer is planning to expand their trial to 44,000.⁵ Dr. Offit agrees with Moncel Slaoui, an immunologist who formerly headed vaccine development at GlaxoSmithKline (GSK) and is now the head of operations to bring a vaccine to market, who thinks “the best-case scenario would be the end of the year, most likely the beginning of next year.”*

We can learn from history as we wait for results-based safety and efficacy data. We do not need another vaccine fiasco as was experienced in 1976 when hundreds of soldiers at Fort Dix, New Jersey, contracted a new strain of the H1N1 virus that seemed to be a descendant of the one responsible for the 1918 flu pandemic. As it turns out, the virus never left the confines

of Fort Dix and was less virulent than originally thought. Unfortunately, the vaccine was fast-tracked for a broad distribution and of the 45 million vaccinated against the swine flu, an estimated 450 people developed the paralyzing syndrome Guillain-Barré and of those, more than 30 died before halting the mass vaccination program.⁴

As we continue learning more and more about COVID-19, I believe we will come through this stronger and better. Since we know that COVID-19 and cancer involve mRNA, we will learn a lot regarding potential prevention, diagnosis, and treatment not only for COVID-19 but also cancers, and all at “warp speed.”

Currently enrolling COVID-19 studies in the U.S. as listed on [ClinicalTrials.gov](https://clinicaltrials.gov)

ClinicalTrials.gov 9/13/20				
Title	Intervention	Population	Notes	Sponsor
CROWN CORONATION: COVID-19 Research Outcomes Worldwide Network for CORONAvirus prevenTION	•Drug: MR or M-M-R II • vaccine •Drug: Placebo	Enrolllent: 3000	Limited to health-care workers	•Washington University School of Medicine •COVID -19 Therapeutics Accelerator
A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19	•Biological: mRNA-1273 •Biological: Placebo	Enrollment: 30000		•ModernaTX, Inc. •Biomedical Advanced Research and Development Authority •National Institute of Allergy and Infectious Diseases (NIAID)
Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Adults	•Biological: BNT162b1 •Biological: BNT162b2 •Other: Placebo	Enrollment: 29481		•BioNTech SE •Pfizer

Note: As of September 14, 2020, clinical trials for the AstraZeneca/Oxford University coronavirus vaccine, AZD1222, have resumed in the UK and Brazil.^{5,7} AstraZeneca stated that the trial volunteer who experienced an adverse reaction, resulting in the halting of the AZD1222 vaccine trial for coronavirus, has recovered from severe inflammation of the spinal cord and is no longer hospitalized.⁶

*Update since the time of this interview posting: On September 16, 2020, Dr. Robert Redfield, Director of the CDC, stated “there will be a vaccine that will initially be available sometime between November and December, but in a very limited supply and will have to be prioritized. If you’re asking me when is it going to be generally available to the American public so we can begin to take advantage of vaccine to get back to our regular life, I think we’re probably looking at late second quarter, third quarter 2021.”⁸

1. www.medscape.com/viewarticle/936937
2. www.kpbs.org/news/2020/aug/25/fdas-hahn-apologizes-for-overselling-plasmas/
3. en.wikipedia.org/wiki/Paul_Offit
4. www.nytimes.com/2020/09/02/opinion/coronavirus-vaccine-trump.html
5. www.nytimes.com/2020/09/12/health/astrazeneca-coronavirus-vaccine-trial-resumes.html
6. www.cnn.com/2020/09/15/health/covid-19-vaccine-trial-astrazeneca-nih-fda-kaiser/index.html
7. www.yahoo.com/news/pfizer-says-stage-coronavirus-vaccine-023343348.html
8. www.foxnews.com/politics/cdcs-redfield-contradicts-trump-admin-on-covid-vaccine-timing-says-sometime-in-2021

Maria Kootsikis, Pharm.D., is a recently retired clinical pharmacist who worked half her career for the Veteran’s Administration and the other half for the pharmaceutical industry. She and her husband, Paul Montalbano, chose to retire and live the dream in beautiful Bluff Heights. As a disclaimer, this article is based on scientific commentary and evidence with no political association intended.