Updated 2021-03-19.

Letter to people who have asked me why I'm taking the RaDVaC vaccine

Note: Nearly everyone asking me why I'm taking the RaDVaC vaccine is of course *also* (or, indeed, even *primarily*) asking me whether *they* should take the vaccine. I suspect I cannot legally speak to that question. The below is framed solely as pertaining to my own decision.

Summary of my assessment of the RaDVaC vaccine:

1. Risk cannot be eliminated from any vaccine or vaccine strategy. The risk from the RaDVaC vaccine is likely *lower* than the risk from the vaccines many are hoping will be approved in 2021.

2. Vaccines are never 100% effective. The RaDVaC vaccine strategy – aiming primarily (but by no means only) for mucosal immunity; with an optimal booster schedule not constrained by the exigencies of commercialization, long-term storage of product, and so on – could be *more* likely to be effective than the one huge-dose injection (occasionally with one booster) approach of the vast majority of vaccines for which many are waiting.

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By using the information that follows you agree to the following: 1) you are a consenting adult (in the United States, at least 18 years of age) and 2) you take full responsibility for your use of any information contained herein.

Nothing in what follows shall be construed as advice of any kind, medical or otherwise.

Dear friends, family, and colleagues,

Some of you have asked why I decided to take the RaDVaC vaccine.

The RaDVaC website contains an excellent, detailed explanation of the rationale behind the project, including a thorough assessment of the risks of the vaccine, and the risks of COVID-19 itself:

https://radvac.org/

What follows are the details of my own reasoning process, which was guided partly by the information at the RaDVaC website, and partly by my own investigations. I also met personally with members of the collaborative, and my discussions with them gave me additional insight into how the vaccine has been designed to maximize benefit while greatly reducing the risk.

Why I decided to take this vaccine

I am worried about COVID-19. It is not a hoax. The risk of death is one thing. At least as worrying is the long-term damage found in many survivors. Studies show that even in relatively mild cases, in otherwise healthy, non-elderly people – to say nothing of older or less healthy people – organ damage can occur that in many cases is permanent. I do not want to end up with permanently weakened lungs, or heart, or brain.

Vaccines generally work very well, and the RaDVaC vaccine is likely so safe, that I decided that the very small risks were well worth the significant potential benefit.

What risks might there be in taking the RaDVaC vaccine?

Toxic substances?

- Thimerosal: *not* present in the RaDVaC vaccine.

A commercial product needs a long shelf life. The preservative Thimerosal, which contains mercury, is used in some ~~many~~ commercial vaccines. (2021-03-19. But note: so far, no vaccine approved by the FDA or the EMA uses Thimerosal.) Because RaDVaC is not a commercial endeavor, the RaDVaC vaccine does not need a long shelf life, hence contains no preservatives, and hence no Thimerosal.

- Aluminum: *not* present in the RaDVaC vaccine.

Vaccines employ what's known as an "adjuvant" to increase effectiveness. An adjuvant increases the body's immune response to an antigen. Commonly used adjuvants contain aluminum. (2021-03-19. But note: so far, no vaccine approved by the FDA or the EMA uses an adjuvant containing aluminum.) The adjuvant that RaDVaC uses, however, is not an aluminum containing substance, but rather modified chitosan, which is made from the chitin shells of shrimp and other crustaceans, and has a track record of safety. (Note, however, that the amount of aluminum in vaccine adjuvants is so small that it probably poses no significant toxicity danger, but there is the separate, more serious problem of the imbalanced ["Th2-heavy"] immune response that alum can evoke.)

Immune tolerance

When I started doing my research into the safety of the RaDVaC vaccine, I encountered the notion of "immune tolerance" in connection with vaccines in general.

The body needs to be able to distinguish between self and non-self (such as a pathogen). It can fail in one direction: mistaking self for non-self. This happens in autoimmune disease. When it fails in the other direction – when something that is non-self is not targeted for elimination – we call that *immune tolerance*.

Immune tolerance to foreign substances happens all the time, in particular in the gut, where it indeed should happen: repeated exposure to antigens in food generally leads to tolerance. If that didn't happen, we'd all have multiple food allergies and there would be few foods that we could safely eat. It is this important ability we have – to know what not to label "non-self" – that can sometimes move outside its proper domain and result in tolerance of things that should not be tolerated, such as pathogens.

There are three reasons why I'm not worried about immune tolerance arising from the RaDVaC vaccine:

1. It is a rare occurrence with vaccines in general.

2. It is only likely (or rather less unlikely) with high doses of antigen – 10 to 15 times higher than the amount used in the RaDVaC vaccine.

3. An intranasal vaccine is much less likely to induce immune tolerance than an oral or parenteral vaccine.

Immune "enhancement of disease"

Sometimes exposure to an antigen creates a type of response that, paradoxically, ends up making it easier for a virus to invade a cell. This is not a problem specific to vaccines, but rather is a problem that can arise from a faulty response to any antigen – that of an actual pathogen, or that contained in a vaccine. Basically, a shoddy response to an antigen can facilitate viral entry into certain cells, thus "enhancing" the disease, instead of slowing it down or stopping it.

Immune enhancement is not a common occurrence, but is a risk that can never be entirely ruled out with any vaccine. Generally, however, most experts think the risk of immune enhancement with a SARS-CoV-2 vaccine is low. For a detailed discussion, see:

https://www.pnas.org/content/117/15/8218

(Cited at radvac.org.)

Moreover, the RaDVaC vaccine design, in particular, implements multiple mitigation strategies consistent with peer-reviewed published information. I am more concerned with immune enhancement of disease from other vaccines than from RaDVaC. (But, again, the risk of immune enhancement is very low with any vaccine.)

"Unknown unknowns"

Even with results from numerous, well-designed, well-conducted studies showing safety according to known measures, there are side effects and adverse events that might not be seen because no one knew to look for them.

The RaDVaC vaccine is of a type (intranasal, synthetic peptide–based) that, itself, has been well studied, and shown to be safe.

But some risk attends the use of any vaccine.

Why not wait until an approved commercial vaccine is available?

First, I see little reason to believe that the vaccines made available via the normal approval process will be any safer or any better than the RaDVaC vaccine. Indeed, I expect many of them will be significantly *less* safe, and less effective than the RaDVaC vaccine.

Second, despite optimistic predictions by some health officials, it will likely be at least April of 2021, if not June or July or even later, before most of us will have access to an approved vaccine. (Numerous problems attend the actual availability of the vaccine, once one is approved. For example, experts foresee a shortage of syringes.) In truth, any vaccine approved before 2022 should be regarded as experimental, regardless of what regulatory authorities say.

Why not just “shelter in place” until the pandemic is over?

Regardless of one’s presumed state of immunity, sheltering in place to the extent possible is a good idea. But attempts at risk mitigation will never be perfect. President of Harvard Larry Bacow and his wife claim they didn't leave the house or have visitors for ten days prior to becoming infected with CoV-2. Many people have similar stories, and many are now dead, or struggling – months after falling ill – to think clearly or walk up the stairs without getting winded.

I believe the RaDVaC vaccine is likely to reduce my risk of contracting COVID-19 substantially, beyond the risk reduction achieved by other measures, such as avoiding unnecessary travel, wearing masks when in public, and so on. Perhaps more importantly, I also believe the vaccine will reduce the risk that I might transmit COVID-19 to others.

Summary

The risk of taking any vaccine, including the RaDVaC vaccine, is not zero. But I decided that the risks involved in taking the RaDVaC vaccine were so small, and the potential benefits so substantial, that the risks were clearly worth it.

Next steps for me personally

I intend to take every new version, or “generation” of the RaDVaC vaccine, taking another version, or booster, every ten days to three or four weeks through November or perhaps December, at which point I will measure effectiveness, then reassess.

I also intend to manufacture the vaccine myself. It is astonishingly easy. I will write much more about that later.

Stay safe, stay strong!

Brian