

A Broader Conversation About Vaccines - Part #3
2019 Novel Coronavirus (CoVID-19): Part XIX
2019 Novel Coronavirus (2019-nCoV (first named); COVID-2019 (later named disease); SARS-CoV-2 (final name of the virus causing COVID-2019), COVID-2019 Pandemic:

January 7, 2021 update Part 19 (Vaccines - Part #3)
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Hello and good day to you and yours.

*This COVID-19 Update #19 is the companion piece to COVID-19 updates [#17](#) & [#18](#), and forthcoming updates #20 and #21 all of which focus on vaccines. I focus here on the **role organizational and educational institutions have to change the course of this pandemic as related to vaccines.***

The next update will focus on vaccine reactions. Lastly, I will write about what you, your loved ones and patients/clients can do to help prevent side effects from the vaccine if taken and to mitigate side effects that may arise.

POTENTIAL FAILURE and CONTINUED NEED FOR A PLAN B

We know that the conventional medicine community has more money than integrative or naturopathic doctor communities do, and therefore more influence. Which means, if looking at only that medical model, there will be more and more vaccines for both prevention and treatment. The vaccines for SARS-CoV-2 are only the most current ones we are hearing, reading and thinking about. And because of all the controversy, anxiety, depression, and just bad time we have all had, this vaccine has garnered more controversy than others.

I have spent the last year describing workable simple options, numerous options really, and also the direction we were going, and that, if unchanged, we would end up with this this vaccine option as Plan A and only Plan A. I will not repeat myself here. The last two updates, this one, and the next two focus on the vaccine issue itself. We are stuck in the pro/con vaccine false dichotomy which has become even more entrenched. A very complex discussion is minimized to soundbites which does a great disservice to all. In these treacherous waters, many individuals and organizations decide to sit out the debate, put their heads down and remain ambiguous. I think this, too, misses the opportunity to help science move forward to help more people. This update is aimed at organizations, trying to give more support to positions they might be able to take today, as a way to build a solid middle, a way to break through the rhetoric, to get to a closer approximation of what really happens.

Let me start with an illustration of a problem from the past, to illustrate why vaccine makers and government officials would do well to engage with naturopathic and integrative physicians soon and more closely.

In 1998, FDA approved a Lyme Disease vaccine LYMERix, with protein antigens from *Borrelia burgdorferi*. The vaccine rollout failed miserably. It was unclear if the vaccine protected you and how long protection would last. Additionally, you would have had to take multiple doses. Some

patients felt they became chronically ill post-vaccine. No one wanted to take the vaccine and it was discontinued. A complete rollout failure.

I believe the COVID-19 vaccine rollout may also fail. It has to do with *what was tested*, as I mentioned in the previous update. Most of us think of vaccines as a *one and done* effort or a series and then done. For example, when many of us received the polio vaccine, we had one series and were done. What was measured was how likely are we to become sick and/or how likely are we to pass the bug to someone else. *That is NOT what tested in the initial COVID vaccine trials.* The main endpoint tested was how many people became SEVERELY SICK with the virus in the vaccinated group versus the placebo group. But they only measured SICKNESS *if you were symptomatic*. In other words, they did not test everyone to see if they were getting sick, potentially transmitting the virus, but who may have developed only mild symptoms or those who remained asymptomatic entirely.

In other words, it may be, as I wrote the first update, that transmission may be less, or be completely unchanged, or may even be worse. We simply do not know. What they were looking at was a binary question of how many people ended up in the hospital. (Sound familiar? It is odd to me that the only folks that took my study design endpoint of paying attention in a dichotomous fashion to hospital admission need or not, were the vaccine makers and not my brethren. It is that easy. If we did the same thing, natural treatments would have been adopted by the mainstream as quickly! Let's not waste this opportunity to discuss vaccine issues in their full complexity.) So really, if the only thing that this vaccine does, is keep you out of the ICU that would be great, by itself, but it is extremely likely that other more natural means, with fewer potential side effects are able to achieve this without the vaccine. We don't know, because research for such approaches has not been properly funded.

The point I am making is, if transmission rates are not substantially diminished, this rollout may go the way of the Lyme vaccine. And remember, at this point, late December/early January we have no other easy viable choice that society or public health institutions appears ready to adopt. If this result is revealed, which may be in the next 2-4 months, the rollout runs into difficulties.

We need a reliable Plan B. Being included in discussions, distributing research funding more equitably, and sharing from our naturopathic and integrative clinical findings and recommendations related to COVID-19.

For the government agencies, for the vaccine makers, the best way to roll out a successful program here is through *open dialogue*, and in this current environment, I cannot think of a better profession to have this dialogue with, then with licensed naturopathic doctors who have been working at individualizing care and supporting the immune response from the inception of the profession. Let us help, by establishing contact and communication and by working hard to create opportunities to engage in meaningful dialogue.

If we can shift the conversation of vaccines to 'vaccines are a solution in *this* respect and not a solution in *that* respect,' or 'vaccines are a solution for *this* person and this same vaccine is not a solution for *that* person,' then we come closer to understanding in which circumstances vaccines are an important option, and in which instances they are completely the wrong path. More specifically, as long as the conversation is limited to good versus bad, one side never sees a problem and the other side never sees a solution.

BUILDING A PLAN B FROM WHERE WE ARE NOW

Sadly, at times, the actual problem that needs solved is not clearly articulated. I hope I describe where the problem and potential solutions reside. Professional associations should call for, demand and stand ready to participate in creating a new integrative perspective, a true Plan B.

Here are some of the main steps of such a path:

1. PERMANENT WORKING SEAT AT THE TABLE

- a. **FDA, FTC, and NIH (or professional associations and NHS in all countries) should come together to develop a fuller CORONAVIRUS TREATMENT ACCELERATION PROGRAM (CTAP [see this link to read further on CTAPs](#)) that properly funds integrative approaches, and that includes ND stakeholders on the relevant committees. For me this is essential, a major pivot point and a very clear ask from the integrative community. It is, actually a game changer.**
- b. Recommendations can be based on the best science available, on the prevention and/or treatment of related viruses, and on understanding of immune system function. Naturopathic and integrative physicians should be invited into protocol development, to be studied, published and promoted to include natural products and therapies, that focus on prevention of COVID-19 from gaining access into cells, reducing viral replication, supporting innate immunity, and mitigating the short term and long term impact. Naturopathic and integrative doctors have an enormous role to play at this time and should make their way to the table.
- c. In the clinical world, NDs provide patients with a variety of interventions aiming at different parts of the individual to help the overall state. This is *not* classical study design where you test only one variable. But it is here, that NDs shine. For example, we already know that modifying chronic health status of blood sugar, weight, and blood pressure impacts COVID-19 disease expression. It is time to advocate for the testing of whole person, multi-factorial protocol rather than only investigating one variable at a time.

2. FUNDING

Many billions of dollars have gone into and continue to pour into each vaccine development vs. a paltry amount to fund natural medicine testing. Funding is essential to prove how interventions with natural medicine approaches and substances diminish the severity of expression of COVID-19 or can reduce chronic effects of COVID-19 infection. We also need to study how natural and integrative approaches can increase effectiveness/longevity of the vaccines, and diminish side-effects that may arise. **As well, funding should also include** for the development of new drugs and the repurposing of older drugs, both avenues were severely curtailed when the directive was to pursue vaccines.

3. PHARMACOVIGILANCE AND PERSONALIZED MEDICINE

Within the vaccine world, away from the rhetoric, there is acknowledgement of potential harm to the recipient exemplified by vaccine makers' own disclaimers. We need this

information shared more widely so everyone understands inherent risks. Include NDs in the creation of vaccine information inserts, as a way to help further articulate potential risk/benefits. We should advocate for more detailed description of what potential harm or potential benefit exists, and for the creation of more refined tracking of actual harm. This cannot be done in the dichotomous 'vaccines are good/vaccines are bad' world. But they can be done in a world that establishes a more personalized approach to health care.

We need to allow for modifications of recommendations based on individual, personalized health concerns in order to limit harm, and at the same time increase efficacy of the vaccine. This could be done by, for example, latent class analysis, uncovering subgroups that might not be currently identified, yet nevertheless exist. If we are out front with understanding which groups of people or which kinds of people with which health concerns would be more at risk for poorer outcomes, this could be helpful information to share. NDs specialize in personalized care and could be of immense value here.

Over the years, my practice had many vaccine-injured individuals, according to the National Vaccine Injury Compensation Program. It is hard for me to believe that anyone wants this outcome! A much better outcome is a nuanced, individualized approach that seeks to prevent those more at risk and which develops specific protocols for those people. In other words, discussion how to make it safer and how to identify those more susceptible to potential harm *ahead of time*, and to prevent problems from arising is a much better discussion than we have right now. Join me in moving this discussion forward.

HOW THE INTEGRATIVE AND NATUROPATHIC PROFESSIONAL ASSOCIATIONS AND SOCIETIES CAN HELP WITH REGARD TO THE VACCINE QUESTION.

1. Highlight clearly that for the next 6 months at least, even with vaccines, we will continue wearing masks, social distancing and following public health guidelines about businesses opening, with continual but slow easing of lockdowns when and if incidence numbers go down.
2. Describe how there have been many billions of dollars spent on the creation of this vaccine and very little spent on natural treatment options.
3. Work to further access funding, create study design and carry out research related to natural medicine approaches to the prevention and mitigation of COVID-19.
4. **Work to broadcast widely results of such studies so that specific approaches become standard of care. This is the important one. There is no mechanism in the USA to allow a natural product to become standard of care, unless FDA/FTC allows this to occur.** Integrative organizations could ask for a seat at the table and together formulate minimal natural product recommendations for the prevention and treatment of disease. This would be a new, radical, and important modification in health care in the USA. This is the main focus of change that needs to occur, or else we maintain the status quo.
5. SPECIFICALLY, with relation to COVID-19 vaccine:

- a. Emphasize that it is not known how long the vaccine effect will last. Hopefully it lasts longer than the disease immunity.
- b. Share that we do not know how people will tolerate a second or third series of vaccination. (*Because of this we need a Plan B, as in the other effective natural medicine options to help prevent and mitigate COVID-19.*)
- c. Explain that we do not know if the vaccines will continue to be effective, as the virus mutates. (I mention this for completeness sake only). (*Because of this we need a Plan B, as in the other effective natural medicine options to help prevent and mitigate COVID-19.*)
- d. Explain that at this time, we do not know what the rates of transmission are for the different vaccine forms. But also ask the question, why were these not properly tracked originally.
- e. Request explanation of what the main goal of each of the vaccine forms is. Which ones lessen transmission? Which ones lessens severity?
- f. Help describe the need for and help develop special protocols towards these vaccinations, which may include stopping or creating a time gap between particular medical procedures or treatments, and the vaccine, as for example, dermal fillers, cataract lenses, etc.
- g. Continue to articulate that NDs and integrative physicians should be included in the development of protocols to lessen potential side-effects of the vaccine.
- h. NDs and integrative physicians should be included in the development of and updating post-approval side-effect surveillance, as they are uniquely trained to uncover latent subpopulations.
- i. Up front and center, should be a close following of vaccine during pregnancy.
- j. I also suggest that there should be a slowing down of the development of self-replicating mRNA vaccines until we see what the effects of the non-replicating mRNA forms is on the population.

I also believe there needs to be a rethinking of the prioritization of who receives vaccinations. No one has said this openly, but broadly speaking, you could say the choice is whether to vaccinate those that will 'restart' the economy first, or to vaccinate those most likely to die first. In the USA we chose the open the economy first plan. I think ethically it may be that medical societies might have a problem with this sequence. For example, I think vaccinating those most likely to die might be the most ethical first step as it limits mortality. If this were the case then some of the stage 2 groups might move up to stage 1. There is an ethical imperative that speaks to a better sequence. Regardless of the result of that debate, my point is that integrative physicians should be part of the discussion on the rollout.

FUTURE PATHS

To Recap:

We need scientific testing to prove efficacy. We need our medical societies, schools and leadership across all integrative and natural medicine stakeholder groups to take bold steps to investigate and generalize our work, without apology, and in partnership with funding organizations and government agencies. Our work could become standard of care across the full medical landscape. The driver of this in the short term is the need for a PLAN B now and for the longer term as a way to discuss the future of vaccinations in the clear light of day. When is it an appropriate option and

when should it be the absolute last option as better ones exist? We lost this first round of opportunities, a year wasted and lives lost. That said, I have faith that our different medical societies and leadership decide to engage in developing and promoting these other pathways now. It is not too late to alter our path forward. This is the perfect time to help lead change in a structural, institutional fashion. We have, I think 6 months or so to do so.

In the next update, I propose a conceptual model of how to talk about vaccine reactions. And in the last update on this topic some things you might want to do in preparation of the vaccine if you choose to take it.

With much hope,
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Some useful resources or links referred to in the above:

1. CORONAVIRUS TREATMENT ACCELERATION PROGRAM (CTAP): <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>

2. The 70 plus COVID-19 vaccine programs, their trial stage and side effects may be tracked in a variety of sites. Some of which are listed here:

<https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

<https://www.statnews.com/feature/coronavirus/drugs-vaccines-tracker/>

<https://covid19.trackvaccines.org/vaccines/>

3. In the last update, I suggested that people with 'altered' structures inside their body may need to be tracked separately, just in case they are at risk for side effects. Since that time the American Society for Dermatologic Surgery released guidance that looked carefully for side effects in those patients with recent dermal fillers. As an example of what these look like, to emulate, please see: <https://www.asds.net/Portals/0/PDF/secure/ASDS-SARS-CoV-2-Vaccine-Guidance.pdf>.

4. There is further information related to special populations to consider, including the pediatric population and pregnant and nursing women, which I think needs a clear understanding of as soon as possible. For those populations, where these are not possible, there should be a PLAN B that does not focus on vaccines, and for which the naturopathic physician and integrative communities can play an essential role. <https://www.fda.gov/media/144585/download>