Bioethics of Experimental COVID Vaccine Deployment under EUA: It's time we stop and look at what's going down

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I provide this brief essay for the TrialSite community because you are involved or at least interested in human subject clinical research. By way of background, please understand that I am a vaccine specialist and advocate, as well as the original inventor of the mRNA vaccine (and DNA vaccine) core platform technology. But I also have extensive training in bioethics from the University of Maryland, Walter Reed Army Institute of Research, and Harvard Medical School, and advanced clinical development and regulatory affairs are core competencies for me.

Before examining the bioethical foundations of current policy and practice which underpin experimental COVID vaccine deployment in many in many western nations, allow me to begin by sharing some "real world" first-hand evidence.

I was on a call with a Canadian primary care physician last week for a couple of hours. He related the story of the six (in his mind) highly unusual clinical cases of post-vaccination adverse events that he has personally observed in his practice involving vaccination of his patients with the Pfizer mRNA vaccine product. Keep in mind that it was Canadian physicians – acting of their own accord – who filed the FOIA to gain access to the Pfizer vaccine IND (see https://trialsitenews.com/did-pfizer-fail-to-perform-industry-standard-animal-testing-prior-to-initiation-of-mrna-clinical-trials/).

What was most alarming to me was that my clinical primary practice physician colleague told me that each of these cases were reported as per the proper channels in Canada, and each was summarily determined to not be vaccine related by the authorities without significant investigation. Furthermore, he reported to me that any practicing physician in Canada who goes public with concerns about vaccine safety is subjected to a storm of derision from academic physicians and potential termination of employment (state-controlled socialized medicine) and loss of license to practice.

This is one face of censorship in the time of COVID (see https://www.embopress.org/doi/full/10.15252/embr.202051420). But what are official public health leaders afraid of? Why is it necessary to suppress discussion and full disclosure of information concerning mRNA reactogenicity and safety risks? Let's analyze the vaccine-related adverse event data rigorously. Is there information or patterns that can be found, such as the recent finding of the cardiomyopathy signals, or the latent virus reactivation signals? We should be enlisting the best biostatistics and machine learning experts to examine these data, and the results should- no must- be made available to the public promptly. Please follow along and take a moment to examine the underlying bioethics of this situation with me.

I believe that adult citizens must be allowed free will, the freedom to choose. This is particularly true in the case of clinical research. These mRNA and recombinant adenovirus vaccine products remain experimental at this time. Furthermore, we are supposed to be doing rigorous, fact-based science and medicine. If rigorous and transparent evaluation of vaccine reactogenicity and treatment-emergent post-vaccination adverse events is not done, we (the public health, clinical research and vaccine developer communities) play right into the hands of anti-vaxxer memes and validate many of their arguments. The suppression of information, discussion, and outright censorship concerning these current COVID vaccines which are based on gene therapy technologies cast a bad light on the entire vaccine enterprise. It is my opinion that the adult public can handle information and open discussion. Furthermore, we must fully disclose any and all risks associated with these experimental research products.

In this context, the adult public are basically research subjects that are not being required to sign informed consent due to EUA waiver. But that does not mean that they do not deserve the full disclosure of risks that one would normally require in an informed consent document for a clinical trial. And now some national authorities are calling on the deployment of EUA vaccines to adolescents and the young, which by definition are not able to directly provide informed consent to participate in clinical research – written or otherwise.

The key point here is that what is being done by suppressing open disclosure and debate concerning the profile of adverse events associated with these vaccines violates fundamental bioethical principles for clinical research. This goes back to the Geneva convention and the Helsinki declaration. See https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/. There must be informed consent for experimentation on human subjects. The human subjects – you, me, and the citizens of these countries – must be informed of risks. As a community, we have already had a discussion and made our decision – we cannot compel prisoners, military recruits, or any other population of humans to participate in a clinical research study. For example, see the Belmont report, which provided the rationale for US federal law Code of Federal Regulations 45 CFR 46 (subpart A), referred to as "The Federal Policy for the Protection of Human Subjects" (also known as the "Common Rule").

Quoting from the Belmont Report:

"Informed Consent. — Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness."

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Information, comprehension, and voluntariness. To my eyes, it appears that in many regions public health leadership has stepped over the line and is now violating the bedrock principles which form the foundation upon which the ethics of clinical research are built. I believe that this must stop. We must have transparent public disclosure of risks – in a broad sense –

associated with these experimental vaccines. It is either that, or the entire modern bioethical structure which supports human subjects research will have to be re-thought.

I really think we need to

“stop, children, what’s that sound – everybody look what’s going down”

(For What it’s Worth, Buffalo Springfield)

Furthermore, as these vaccines are not yet market authorized (licensed), coercion of human subjects to participate in medical experimentation is specifically forbidden. Therefore, public health policies which meet generally accepted criteria for coercion to participate in clinical research are forbidden.

For example, if I were to propose a clinical trial involving children and entice participation by giving out ice cream to those willing to participate, any institutional human subjects safety board (IRB) in the United States would reject that protocol. If I were to propose a clinical research protocol wherein the population of a geographic region would lose personal liberties unless 70% of the population participated in my study, once again, that protocol would be rejected by any US IRB based on coercion of subject participation. No coercion to participate in the study is allowed. In human subject clinical research, in most countries of the world this is considered a bright line that cannot be crossed. So, now we are told to waive that requirement without even so much as open public discussion being allowed?

In conclusion, I hope that you will join me; stop to take a moment and consider for yourself what is going on. The logic seems clear to me. 1) An unlicensed medical product deployed under emergency use authorization (EUA) remains an experimental product under clinical research development. 2) EUA authorized by national authorities basically grants a short-term right to administer the research product to human subjects without written informed consent. 3) The Geneva Convention, the Helsinki declaration, and the entire structure which supports ethical human subjects research requires that research subjects be fully informed of risks and must consent to participation without coercion. Has that bright line been crossed? If so, what actions are to be taken? I look forward to learning from your thoughts and conclusions.

Source:

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