Experimental Drug and Vaccine Ethics Require Informed and Voluntary Consent

4-8-22 by Mary Knutson, RN, MSN

Experimental mRNA vaccines for the COVID (Coronavirus-19) pandemic

During 2020 and 2021, mRNA vaccines and some other drugs were quickly developed, promoted, and used for COVID (SARS-CoV-2 infection). They were not fully approved by the U.S. Food and Drug Administration (FDA). They were approved under an EUA (Experimental Use Authorization) because they were still under research. Clinical trials were still being conducted, which usually takes many years to complete. According to the FDA (U.S. Food and Drug Administration), an Emergency Use Authorization (EUA) facilitates the availability and use of medical countermeasures, including vaccines, during public health emergencies such as the COVID-19 pandemic. Under the EUA, FDA allowed the use of some unapproved medical products, and some unapproved uses of approved medical products to diagnose, treat, or prevent serious or life-threatening diseases or conditions such as COVID. For an EUA, certain statutory criteria must be met, including that there are no adequate, approved, and available alternatives during the emergency.

Potential off-label treatments with hydroxychloroquine or ivermectin were unapproved and strongly discouraged by the FDA. Government agencies such as the CDC recommends on their website 2-25-22 only vaccines, masking, handwashing, social distancing, testing, monitoring symptoms, and then to isolate if needed. That leaves many people who have contracted the virus asking for more options than that.

Two FDA approved brand name COVID vaccines known as Comirnaty (Pfizer) and Spikevax (Moderna), which are not being used in the U.S. By using vaccines under an EUA, drug companies do not have liability for side effects or adverse events. They cannot be sued according to Congress' PREP Act. This gives the drug companies financial protection as the mRNA vaccines and other treatments are given under an EUA. When the FDA fully approves the COVID vaccines that are being used in the U.S, the adverse effects and deaths will be the responsibility of the vaccine manufacturer. The fact sheets for recipients or caregivers combined the FDA approved vaccine wording to the experimental mRNA COVID vaccine information sheets for Pfizer and Moderna as of 1-31-22.

Because the experimental mRNA COVID vaccines used in the U. S. are not the FDA approved brand name vaccines, they are still under an EUA (as of 4-1-22). The FDA awaits ongoing research results as Phase 3 trials are still being conducted. The clinical trials research does not include pregnant women. How can we know if they are safe and effective if pregnant women are excluded from that important research? We can't know for sure. Yet, ongoing real-life "experiments" are being conducted on those groups as they are being given the vaccines.

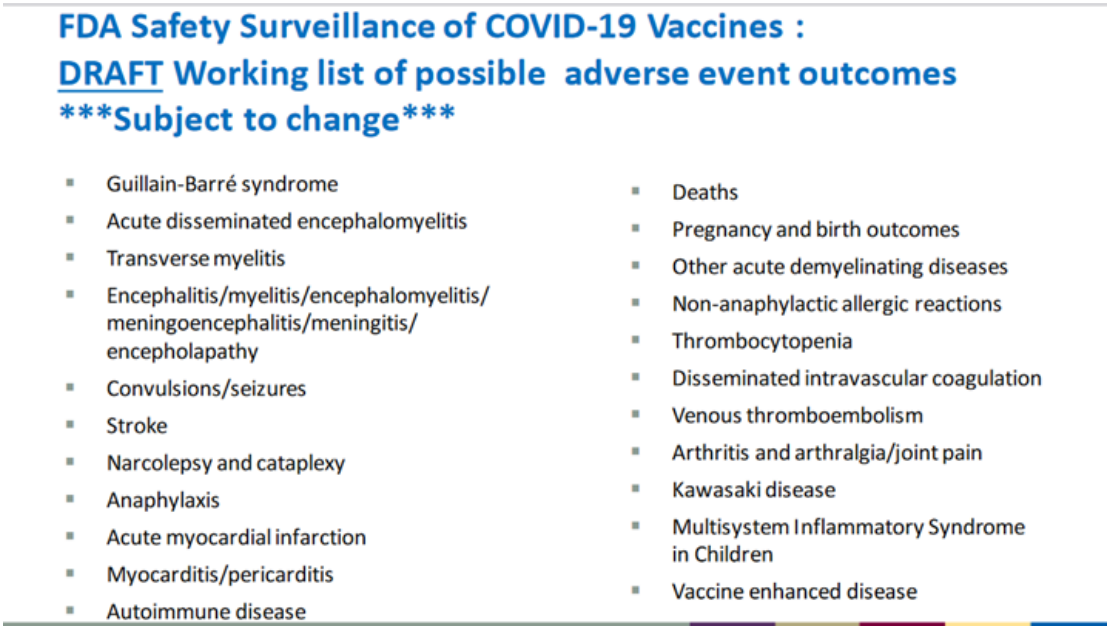
Whenever the vaccines are questioned, the quick answer is that they are “safe and effective”. Yet, the research is far from being completed, and only a fraction of the data has been reported. The experimental mRNA COVID vaccines were strongly promoted for as many people as possible, as soon as possible, while the safety risks and benefits are still unknown. Pfizer started their ongoing clinical trials April 29, 2020 and expect to complete them by May 15, 2023. Moderna’s ongoing clinical trial data is also also incomplete as of 4-1-22.

Adverse events after COVID Vaccines

It is clear that the FDA knew about many adverse events even before the mRNA experimental COVID vaccine was widely given in December 2020. The FDA presentation “Vaccines and Related Biological Products. An advisory committee on October 22, 2020 presented a working list of possible adverse events on slide 16 (below). The first link seems to be no longer working, but it can be seen at the second link.

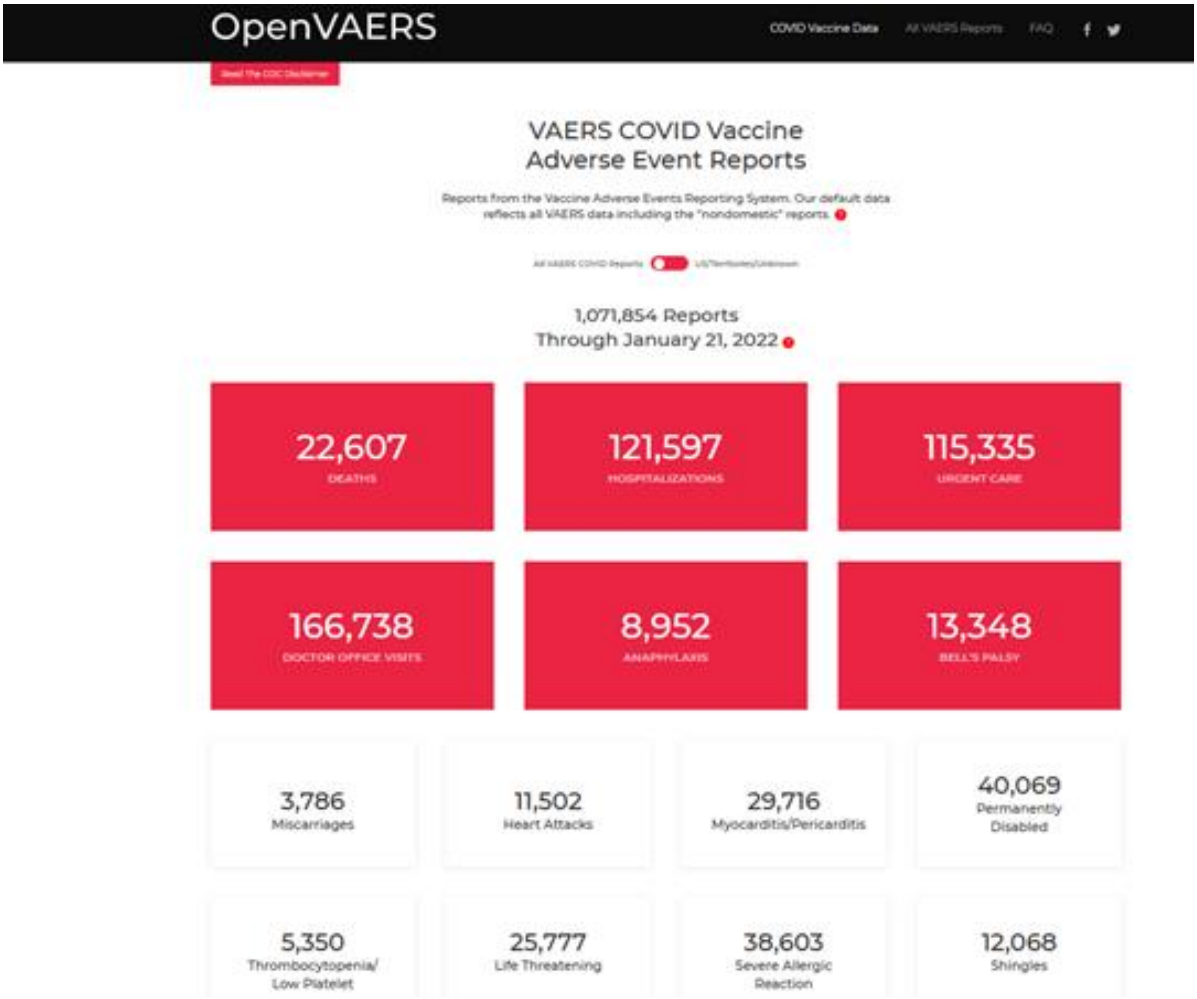
https://www.fda.gov/media/143557/download. Retrieved 1/31/2022

https://www.austintexas.gov/edims/document.cfm?id=364942



Even more known adverse events and side effects have been adding up since then. The need to report the adverse events is **required** under the EUA as is clearly stated on the experimental mRNA vaccine fact sheets. However, somehow the medical problems were not fully reported to the people who need to decide whether to take the vaccine or not. A half-hearted attempt at for informed consent seemed to be made, while negative or contradicting information was kept out of most news outlets and suppressed from social media.

The list of adverse effects from a recent VAERS report (below) at https://openvaers.com/covid-data does not match what is written on the vaccine fact sheets for Pfizer, Moderna, and Johnson & Johnson (Janssen)



Some of the side effects (above) were not reported to the public by media or government agencies. As of 1-21-22, there were 22,607 deaths following the vaccine. Shingles has been recorded as an adverse effect from COVID vaccine for 12,068 people on the VAERS, but it was not listed on the factsheets for informed consent as of 3-24-22. Miscarriages for 3,786 people were listed on the VAERS Adverse Event Report 1-21-22, but it is still being used for many pregnant women.

There is an ethical dilemma when many employers, government agencies, and businesses require vaccination. If they do not take the vaccine, many of them lose their jobs. The U.S. President, Joe Biden imposed a COVID vaccine mandate Executive Order for the experimental

mRNA vaccine. The ethics of mandating participation in this ongoing "research experiment" needs to be examined.

Ethical Principles of Research

The Belmont Report was a cornerstone document released in 1979 after the U.S Dept of Health, Education, and Welfare (now the Department of Health and Human Services). It was a summary of bioethics policy and principles needed in research, developed in response to the unethical Tuskegee research on syphilis. First it looked at the boundaries between practice and research, saying, "The distinction between research and practice is blurred partly because both often occur together… Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; **the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."**

The following links will introduce you to the Belmont Report, or allow you to read the complete document:

The Belmont Report: Respect for Persons, Beneficence, and Justice | Research Ethics | 2022 at https://www.youtube.com/watch?v=u5mRVQ3coIk (5:13 min)

Research Ethics: The Belmont Report (a summary for nurses) https://www.youtube.com/watch?v=NYjY-SRvWcQ (8:47 min)

The Belmont Report (in full) https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

There are 3 basic principles in the Belmont Report for Ethical Research with Human Subjects. This section will explore them with the COVID vaccine mandates in mind. The words below come directly from the Belmont Report, and they are indisputable to those who do research in the United States:

- Respect for Persons
- Beneficence
- Justice

Respect for Persons -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection…

“To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment…

The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.” The excerpts above were retrieved from HHS.gov on 2-6-22. The Belmont Report (1976).

The people who are under the mRNA experimental vaccine injection mandates (working in hospitals or clinics, in the Federal government, in the military, or other mandated settings and workplaces), are not being protected or given autonomy. Having the vaccine forced upon them could be similar to coercing prisoners to participate in research.

Beneficence – “Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being… an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms…

The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks… A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit… different claims covered by the principle of beneficence may come into conflict and force difficult choices.” The excerpts above were retrieved from HHS.gov on 2-6-22. The Belmont Report (1976).

Justice – “Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly… “ The excerpts above were retrieved from HHS.gov on 2-6-22. The Belmont Report (1976).

Ethical research requires participants to be fully informed of risks and benefits, including the most current data (updated for both healthcare providers and recipients). Ethical research always includes informed and voluntary consent from participants. That includes the mRNA vaccines and the other treatments that are being researched under an EUA (Experimental Use Authorization).

History of Unethical Human Experiments in the US

It is difficult to believe that the government would experiment on Americans. However, history shows that they did. It is within the realm of possibility that we are involved in another government experiment without fully informed consent. Some people are even being denied the right to refuse the experimental mRNA vaccines and losing their jobs because of it. This includes many healthcare workers, people in the military, employees in the federal government, and employees of other large companies who follow the vaccine mandate.

There is a disturbing summary (below) of some unethical experiments in U.S. history:

Fr. Nolan: Government Has Lied To Us Before (20:16 min)
https://www.youtube.com/watch?v=-zUR2HEos3A

Summary of some unethical experiments in United States, with involvement of government agencies:

- In Tuskegee, AL from 1932 to 1972 on syphilis (withholding treatment when it became available). The research was exposed because of a press leak.
- In Chicago in 1940 facility US Army and state department injected Malaria into healthy psychiatric patients to test treatments.
- Vanderbilt Nutrition experiment radioactive iodine was injected into the placenta and women told it was "vitamins".
- Atomic Energy Commission in Nevada had atmospheric explosions to determined effects of radiation exposure.
- In Maryland, Project Bluebird was conducted on 7,000 military personnel were experimented on without knowledge or consent. They used psychoactive substances, LSD, Heroin, Cocaine, PCP and ether, and/or hypnosis and forced addictions.
- In 1953-1973, the Central Intelligence Agency (CIA) mind control program called MK Ultra conducted experiments to "depattern" individuals, erase mind and memories and rebuild personalities according to the researcher.

During the COVID pandemic, information has been suppressed about the benefits of natural immunity if people already had COVID. And, any alternatives to having the vaccine were strongly discouraged. This Guide to Home-Based COVID Treatment handout has important information about potential prevention and home-based treatments.

The need to be fully informed of risks and benefits, including the most current data (updated for both healthcare providers and recipients) is not simply a request. It is a **requirement**. It is an essential part of the FDA agreement when granting the EUA. It would be good if the vaccine was safe and effective for all. However, the adverse event data shows that it is clearly **not** safe and effective for all. People must be able to freely choose whether or not to take the experimental mRNA vaccine. The OpenVARS website can be accessed online. It has been updated since this article was originally written to include 1,205,753 Reports of adverse events

through 3-25-22. And 26,396 deaths were reported with the experimental mRNA COVID vaccine. Stay tuned as more adverse event data is slowly released.

The “one size fits all” approach that the government has set seems to be an over-reach. They seem to be in denial about the harm that it has the potential to cause as they continue to strongly promote the “safe and effective” mantra. Ethical research always includes informed and voluntary consent from participants. People must have the right to decide for themselves without information being suppressed and without threats to their jobs and livelihoods. Those tactics could place the COVID mRNA vaccine mandates in the history books as the biggest unethical experimental research experiment ever.