COVID-19 Vaccines

Updated February 25, 2021

Fetal cell strains

So far no authorized vaccine or those in Phase 3 trials have avoided using fetal tissue cell strains in some way.

Vaccines listed in blue/italics do not use fetal tissue cell strains for manufacture and do not contain fetal cell strains, but did use the HEK-293 fetal cell strain for confirmatory testing. Vaccines listed in bold/red use fetal tissue cell strains in their manufacture, that is, as hosts for the antigen. The Moderna vaccine does not use a fetal cell strain for manufacture, but relied on fetal cell strains for its development.

- *BioNTech/Pfizer* (FDA emergency authorization)
- Moderna/NIH (FDA emergency authorization)
- **AstraZeneca/University of Oxford** (Phase 3/emergency authorization in UK)
- **Janssen/Johnson & Johnson** (Phase 3, emergency authorization requested from FDA)
- *Novovax* (Phase 3)

While vaccines manufactured with fetal cell strains do not formally include the cells as an ingredient, residual components of the cells may be in the vaccines. More details on the use of fetal cell strains and particular COVID-19 vaccines may be found here.

While the use of a fetal cell strain in testing is not acceptable, the Pfizer and Novovax vaccines do not use fetal cell strains in an ongoing way. For those who are at high risk for COVID-19 and desire to be vaccinated, these are the least objectionable options.

Because the AstraZeneca and Janssen vaccines continue to use fetal cell strains in their manufacture, these should be avoided and considered unacceptable.

The Moderna vaccine was dependent upon fetal cell strains not only for confirmatory testing, but also in a few stages of development (in isolating the spike protein sequence, in developing the mRNA expression, and in determining the lipid delivery system), as summarized here. This heavy dependence makes it an undesirable option, especially with other, less objectionable vaccines available.

Vaccine Effectiveness

Effectiveness claims should be received with care, as data is still very limited. Nevertheless, recent studies out of Israel suggest that the Pfizer vaccine is highly effective not only at preventing the illness, but also in reducing the seriousness of the disease, and in reducing the transmission of the disease.

Moderna's CEO expects its vaccine to provide immunity for a "couple of years," while recognizing the immunity varies across individuals. No hard evidence on the length of immunity is available yet.

The most recent research suggests that the vaccines has some efficacy against mutations. However, a booster aimed at mutations is being developed to improve this efficacy.

Safety and other Concerns

Presently, vaccines in use have been given only emergency authorization, because safety has not yet been studied in accordance with accepted practices.

Trials and initial data have positively indicated the usual adverse reactions associated with any vaccine (swelling at the injection spot, mild fever, etc.). More severe, anaphylactic reactions, are expected in very small rates. While early studies showed that anaphylactic reaction occurred at a rate roughly ten times higher than in the flu vaccine (which is about 1 reaction per 1 million doses), more recent data indicates about 4.5 anaphalactic reactions per 1 million doses. See also this CDC page on adverse events. In addition, there is some concern that polyethylene glycol, an ingredient used in both the Pfizer and Moderna vaccines, may cause anaphylactic reaction at a higher rate, even causing an allergy where one did not previously exist.

In the first month of vaccine administration, 113 deaths were reported (amidst about 14 million doses), which do not present a pattern indicating safety concerns with vaccine.

The possibility of the other safety issues have been hypothesized, but there is yet insufficient research to state if these are definitively associated with COVID-19 vaccines:

1. The use of mRNA technology (specifically in the Pfizer and Moderna vaccines) is a new way of vaccinating. While it can be called a type of gene therapy, it should be distinguished from DNA modification. The mRNA does not enter cell nuclei and is not expected to affect DNA. It stimulates creation of a SARS-CoV-2 protein, which the body's immune system then develops antibodies for. However, there is the unusual possibility of reverse transcription, in which genetic information from mRNA is transcribed into new DNA. Two other rare concerns related to mRNA technology involve autoimmune reaction and edema tied to "extracellular RNA."

2. Some have speculated that some recipients could suffer more severe cases of the disease in some recipients (Antibody-dependent enhancement [ADE]). ADE occurs when vaccine-induced antibodies fail to kill the virus, but, instead, facilitate the spread of the disease in the body. While initial research in this area has not suggested that the COVID-19 vaccines increase the chance of ADE, data is still limited.

3. There is budding research suggesting that SARS-CoV-2 itself may harm male fertility, but not enough data for a definitive statement:

   https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7252417/

   https://wjmh.org/DOIx.php?id=10.5534/wjmh.200170

   https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2765654

It's unknown from the research if some of the effects on infertility may be caused by antibodies as well as the virus; if antibodies, then the vaccine also could endanger male fertility.

4. Some have speculated that the vaccine could produce undesired antibodies against Syncitin-1, a cell fusion protein fundamental to placental development, due to an overlap in the amino acid sequence between Syncytin-1 and SARS-CoV-2. If some did develop these antibodies, they could cause infertility in women. Current hypotheses suggest that such infertility is extremely unlikely because the overlap in the amino acid sequence is too small to cause antibodies against Syncytin-1.

5. Bell's palsy. There is no definitive link to the usually temporary Bell's palsy, but FDA officials do note to watch for it in conjunction with vaccinations.

Long-term safety and data documentation

Over the long run, the public should continue to be aware of issues of safety documentation and transparency. Things to consider include plans by pharmaceutical companies and the government for documenting

- rates and types of adverse events;
- safety in different groups, such as the elderly, children, and pregnant;
- categorization of susceptible subgroups;
- long-term tracking of vaccine safety.

Conclusions

Any decision to receive the vaccine should be done with the full awareness of the extent to which fetal tissue cell strains were used, and that there is not adequate data to answer safety concerns.

Some populations at high risk for complications or death from COVID-19 may choose to receive the Pfizer vaccine, or, when available, the Novovax vaccine. Due to their use of fetal tissue cell strains in manufacture, the AstraZeneca and Janssen/Johnson & Johnson vaccines should be avoided. The Moderna vaccine, likewise, due to its heavy dependence on fetal tissue cell strains for development, should be avoided, especially with other options available.

I would warn women still capable of bearing children and without risk factors for COVID-19 against taking the vaccine. Women with risk factors for COVID, but still capable of bearing children, should consider their options conscientiously. Some men who are concerned about their fertility have ground for concern about the disease itself. However, if this is shown to be a real result of the disease, the vaccine itself could also have the same effect.

Those with allergies to ingredients should not take the vaccine, and those with a history of anaphylactic reactions should consider the benefits and risks of the vaccine in more detail.

Whatever the choice, it should be supported when made conscientiously, considering the ethical sourcing of the vaccine, possible adverse reactions, and one's specific responsibilities and circumstances.

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