The new vaccines approved by Health Canada and my evaluations and critiques of the same.

Novavax (Nuvaxovid)

This is a recombinant vaccine directed against the original Wuhan Covid-19 strain that was made by Novavax, an American company in collaboration with CEPI, one of the Gates's funded entities. It basically uses manufactured spike proteins that are replicated in a non-mammalian cell line and used as the basis of the vaccine antigenic component. It is adjuvanted with a novel saponin compound (Matrix-M) derived from a plant species.

Two doses are given, 21 days apart by injections into the deltoid muscle. The tested groups in three trials (US/Mexico; South Africa; U.K) looked at participants from 18 and up. The total participants include 48,698 people of whom 29,279 were given the active vaccine and 19,401 received the "placebo." The actual placebo was not identified, unlike with the other vaccines recently approved by Health Canada.

The Health Canada report states that Nuvaxovid is greater than 90% effective (other sources claim up to 96.4%), but recall that this is Relative Efficacy vs. Absolute Efficacy, the latter more likely to show how effective it really is against Covid-19 (original strain). It is worth noting that while the efficacy is listed as +91.5 in those 18-64 years old, the efficacy for those over 65 is given as 57.5%. This last efficacy number suggests that even at an early time point, Nuvoxavid, may offer only limited protection to older individuals.

The Health Canada site notes the usual collection of adverse reactions including redness at injection site, soreness at injection site, swelling, chills, fatigue, joint pain, fever, muscle ache, nausea and vomiting. The "rare side effects" (not quantified) include: hives, swelling of lips, face, tongue, airway, difficulty breathing, increased heart rate, loss of consciousness, sudden hypotension, abdominal pains, vomiting, and diarrhea.

Data from the product monograph (from Novavax) describes the Phase 3 trials as ongoing. The duration of follow up for adverse effects is 70 days after dose 2.

Many of the tables in the produce monograph show much higher rates of the various adverse events (up to 10x more) in the vaccinated groups. No studies were performed on pregnant women or those breast feeding, on those under 18, or those with a range of comorbid conditions.

Myocarditis was found in two young recipients of the vaccine.

Additionally, the participants were unblinded after the second vaccine with larger numbers in the placebo group then able to receive the active vaccine.

Animal studies cited were for general toxicity in rabbits and fertility studies in rats (including possible impacts on offspring). Although Novavax claimed on adverse outcomes, the duration of observation of the animals, the numbers used, any histology performed, and bio-distribution studies of the spike protein were not reported.

Concerns:

1. Lack of information about the consistency of protocols across the 3 cohorts used. This is a larger concern given that the data from the 3 separate studies were pooled.

2. Lack of long term studies for adverse effects;
3. Lack of long term efficacy studies;
4. Lack of studies on various groups, including pregnant women and those under 18 years old.
5. Lack of adequate animal studies.
6. No long term studies of the Matrix-M adjuvant.
7. The lack of defining the placebo as saline raises the possibility that the actual placebo used may contain ingredients other than saline.

Conclusions:

1. Recombinant protein vaccines of other types have been used previously and the technology itself is thus more conventional than that for mRNA or viral vector vaccines. However, the emerging notion that the spike protein may be generally toxic (including from the virus), combined with the lack of biodistribution studies, does not allow any appreciation of where the spike protein in the vaccine might wind up. If, as with the mRNA vaccines, if the spike protein were to move from the injection site, it could induce the same sorts of longer term impacts on a range of organ systems, as noted in the recently released Pfizer Phase 3 trails.
2. The lack of data on the various subgroups who are likely to receive the vaccine are concerning.
3. Health Canada relies solely on the data provided by the company to guide their decisions about approval.
4. The variability of the stated efficacy in 18 to 64 year olds vs greater than 65 year olds suggests that those in the general population most likely to become ill with Covid-19 are not well protected by the vaccine.
5. The efficacy over time for this vaccine against Covid-19 variants is unlikely to be better than for the mRNA vaccines and hence may offer protection only against the original Wuhan strain, a strain that has now largely vanished.

Medicago (Covifenz) as reported by Health Canada is a Canadian made vaccine using plant based the spike protein expressed as virus like particles of the initial Wuhan Covid-19 virus tested on 18-64 year olds with 2 doses given 21 days apart.

It uses a squalene-based adjuvant system, AS03. Squalene has been a concern in relation to the anthrax vaccine given to Coalition Forces in the 1st Gulf War that has been linked to Gulf War Syndrome.

Medicago's product monograph. Overall efficacy (and this is relative, not absolute) is given as 71% a number that may raise concerns about the efficacy in the various subgroups not tested in the phase trials. These included, those under 18 and over 64, pregnant women, those breast feeding and those with a variety of comorbid conditions. Of the participants, 11,933 received the vaccine; 11,924

received the placebo which is listed as saline. Details of adverse events are reported only for 4,094 and 3,635 participants respectively. The data are not separated by sex. Evaluations were for 7 days post the second dose.

Adverse effects are much like those reported for Novavax. Given the limited population studied, there is no way to evaluate possible adverse effects in other groups.

Phase 3 trials are listed as "ongoing". Of note, adverse effects seem only to be monitored for 1-7 days post each dose.

Animal studies for toxicity and fertility were done on rats. No data were provided on numbers, duration of observations, biodistribution of virus like particles of spike protein, or histology.

Concerns:

1. Overall, these studies seem to lack details and a generally rigorous evaluation. There is a general absence of actual data on efficacy and safety making it difficult to judge how well the vaccine works generally, particularly for specific groups. The same applies to adverse effects.
2. Evaluation of possible adverse effects from AS03 are not provided.
3. Bell's palsy was reported for 3 of the vaccinated group and 1 of the placebo group.
4. The small size of the sample used to measure efficacy against Covid-19 variants makes it impossible to judge how well the vaccine will perform against the newer variants such as Omicron and the subset of B.2.

Covaxin is manufactured in India as an inactivated whole Covid-19 virus.

The trials are small with limited numbers of participants and the data from these trials combined Phase 2 and 3.

The data from Health Canada is limited. No product monograph was found for Covaxin.

Concerns:

1. The platform is conventional and may thus be safer than that for mRNA vaccines or those discussed above that use recombinant technologies to make spike protein;
2. The overall lack of data makes it impossible to judge either efficacy or safety in the short or long term.

Spikevax

This is a Moderna mRNA product and it is not clear why it has been included in this list of novel vaccines, nor how it differs from the Moderna mRNA vaccine currently used against the original Covid-19 strain.