NEWS

How do we know the COVID-19 vaccine is safe? Who reviews it? You sent us questions, and we asked an expert at Health Canada

By Alex Boyd Calgary Bureau
Friday, November 27, 2020

It appears the day is coming when Canadians will have access to a COVID-19 vaccine.

But before Canadians are offered that choice, a team of scientists will go through thousands of pages of information on each proposed vaccine, studying how it was made and what happened when it was given to volunteers in trials around the world. Any vaccine that is rolled out must be approved by Health Canada first — work that

has already begun.

The pandemic has sparked many questions about how vaccines are made and evaluated. We took some of the questions we've received from readers, added a few of our own, and put them to one of the top experts at Health Canada.

Dr. Supriya Sharma trained as a pediatrician, but has also done research on blood diseases, worked for a year in Australia and completed a master's in public health at Harvard University in international health and health policy.

Almost 20 years ago, she signed up for a two-month stint at Health Canada — and never left. She's now the senior medical adviser for the team that oversees the approvals of pharmaceuticals, medical devices and, yes, vaccines.

Her answers to our questions have been lightly edited for clarity.

How does a COVID-19 vaccine get approved to be used in Canada?

Usually with a vaccine, the company provides all the data from all of the studies that have been done, including the laboratory studies, the animal studies, all the clinical trials, to the test in humans, and all the information around the manufacturing.

Once that's completed, that is provided to Health Canada.

For COVID-19, we realized that you needed to have a more flexible process; something that's more agile. So we put in what was called an interim order. That interim order gives us some flexibility in how we do the review.

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So the COVID-19 vaccines that we currently have under review — we have three under review — are coming through this new pathway.

Now, it's important to note that it is what we call an expedited pathway, which is intended to make the overall review process faster, but it's still maintaining the same standards for the reviews of the vaccine. So, safety; efficacy, meaning how well the vaccine works; and quality in terms of manufacturing of the vaccine.

This is happening really fast. How do we know it's still safe?

I can totally understand where those concerns are coming from, because I think what people are hearing is that we're rushing things, or they're hearing that it's happening so much faster than it was before.

I think what it's important to highlight is that the time in which these vaccines have been developed is shorter because of the advances in science, like the level of international co-operation that's happened, and how focused everyone is globally on the development of the vaccine.

An average vaccine submission is hundreds of thousands of pages, and it takes usually around 2,000 person hours to complete the review; there's a team of seven to 12 people with a whole series of different backgrounds. We're still doing that.

One of the things that the interim order process allows us to do is something called a rolling submission. So instead of the company having to wait until all of the studies are done to give us the information, they can actually give us that data as it becomes available.

So it allows our reviewers to start the review, as opposed to having to wait till everything is finished before we start.

Who reviews it? Who are these people?

There's a whole team that reviews it.

We have people like toxicologists that are looking at the laboratory data and the animal data. They focus on any safety issues and making sure that it looks promising in terms of the immunological response. Are the vaccines doing what they're supposed to do?

Then we have the clinical data, which is all the information from the Phase 1, Phase 2, and Phase 3 clinical trials. Those are the trials in humans. We have physicians, infectious disease specialists, microbiologists and immunologists looking at that type of information. They're really looking for any safety issues and figuring out what the best dose would be ... but also at the efficacy, or how well it works.

We also have biostatisticians looking at the statistics and the epidemiology.

Then there's all the information that goes into the manufacturing of the vaccine, and that's a very complicated process. We have people in microbiology that have the expertise to do the assessment of the actual manufacturing part, which is very, very

detailed.

What would make the experts say, no, we're not approving this for Canadians?

Ultimately it comes down, and this seems very simple, but the benefits have to outweigh the risks.

You say, all right, so does it meet all the standards? Can it be manufactured at a high level of quality? If there are any risks associated with it, are there systems in place to be able to decrease those risks? Do they have a really good plan for monitoring the vaccine once it gets authorized?

When we look at that, then we have to decide, OK, does it meet the standards? And if yes, it's yes. And if it's no, then we say, no.

How do you know vaccines will be safe in the long term?

That's a good question. There are requirements in terms of following up for short- and medium-term side effects. For the Phase 3 clinical studies, it's a minimum of two months (that researchers will continue to follow volunteers).

But it's also important to remember that all of the studies continue to gather information, so as time goes on, we've got more and more data. By the time the vaccine goes through the review, goes through distribution and people start to receive it, all of that time we're receiving information.

So we have months of followup, sometimes longer, at the time of authorization. All the companies will be asked to continue to monitor their vaccines for another two years after that.

But it's true, we do need to still follow these vaccines long term, to see if there are any long-term risks that might come up. The clinical trials often involve tens of thousands of people, but these vaccines are going to go out and be given to millions of people.

So if there's something that's very, very rare, it might show up as we have more people vaccinated. So that's why it's really important that the monitoring continue, even after authorization.

What happens if some rare risk does emerge and something bad happens?

If we get a report of something that's an adverse reaction that is unexpected and serious, we hold that lot of the vaccine, wherever it may be, while we investigate.

We do our laboratory testing, we work with the company to get more information. We see if whatever reaction it was, if it's actually tied to the vaccine or not.

If it is something that we need to look into, the question is, is it just that lot? Is it just that batch? Is it something in the way that it was administered? It really depends on what the issue is, but the whole system is set up to detect it quickly, and then stop, drop and roll while we figure out what the issue is and then figure out the best course of action.

Just to be clear, what are we counting as a serious adverse reaction?

Usually it's something that either creates the need to go into a hospital, or if somebody is in a hospital, it makes the hospital state worse. It has to be something quite significant. **Do you worry about people who don't feel comfortable taking the vaccine?**

Absolutely, I do. The thing is that a vaccine is only as good as it is when it's actually given to somebody. Vaccines are one of those things where it's not only yourself that you're protecting, but it's the collective.

So I can understand that there can be some hesitancy about vaccines, because I think there's a lot of misinformation out there.

But it's really important for people to understand that absolutely no vaccine will get distributed unless it's got Health Canada approval, and they should have faith and confidence in the integrity of that review.

What kind of information are you giving to the public about the decisions you're making?

We are going to be as open and transparent as possible.

At this point in time, we're just saying which vaccines we have under review. But at the time of authorization, there's a database that gets updated, and it'll say that we have authorized it. There's something called a product monograph, which is more scientific and technical information, but it summarizes how to use the vaccine and any potential adverse reactions.

But we're also developing something called a regulatory decision summary, which is just a few pages at a high level, in fairly lay language, that talks about the basis of the decision. That'll get published the day we make the decision.

Then once we get the chance to go through all the data, we've made a commitment to actually publishing all the raw data that we received as part of the submission so that other scientists can do their own assessment.

What do you wish people knew about the work you do?

I think sometimes when people think of Health Canada, they just think of this big bureaucratic organization. And they forget there's actually people in it.

The part of it that I wish people could see is just how experienced and competent and dedicated and loyal these folks are. Their only goal is to make sure that Canadians have access to medications and treatments and vaccines that are of the highest quality.

We're all living through this too. And you know, we'll be lining up to get our vaccine when it's our turn as well. We want our loved ones and our family members and our friends protected, too. We're all in it with everybody else.

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