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Chair: Mr. Ron McKinnon

# **Standing Committee on Health**

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• (1835)

[English]

The Chair (Mr. Ron McKinnon (Coquitlam—Port Coquitlam, Lib.)): I call this meeting to order.

Welcome, everyone, to meeting number 24 of the House of Commons Standing Committee on Health. The committee is meeting today to study the emergency situation facing Canadians in light of the second wave of the COVID-19 pandemic.

I would like to remind everyone that everyone has the right to participate in these proceedings in the official language of their choice. In the event that there is difficulty in hearing translations, please bring it to our attention as soon as possible so that the matter can be resolved.

I would like to welcome the witnesses at this point. From the national advisory committee on immunization, we have Dr. Caroline Quach-Thanh, chair and professor, Université de Montréal. With the Department of Health, we have Dr. Marc Berthiaume, director, health and food branch, therapeutic products directorate, bureau of medical sciences. From the Public Health Agency of Canada, we have Ms. Kimberly Elmslie, vice-president, immunization branch; Dr. Howard Njoo, deputy chief public health officer; and Dr. Guillaume Poliquin, acting scientific director general, national microbiology laboratory.

I would just advise the speakers that I will be using these cards to indicate that your time is almost up. I will typically put up the yellow one about one minute before your time is up. I will use the red one when your time is up, and if you see it, please wrap up in due course.

With that, we will carry on with our presentations. We will start with Dr. Caroline Quach-Thanh.

Doctor, please go ahead for 10 minutes.

Dr. Caroline Quach-Thanh (Chair, National Advisory Committee on Immunization and Professor, Université de Montréal): Thank you very much.

[Translation]

Mr. Chair and members of the Standing Committee on Health, thank you for inviting me to speak to you again, this time regarding the use of the AstraZeneca vaccine for adults aged 65 and older.

The recommendations of the National Advisory Committee on Immunization, or NACI, issued on March 1, 2021, were as follows.

A complete and currently authorized COVID-19 vaccine series should be offered to individuals in the authorized age group without contraindications to the vaccine. In the context of a limited vaccine supply, initial doses of the messenger RNA COVID-19 vaccine should be prioritized for the key populations listed in the NACI's "Guidance on the prioritization of initial doses of COVID-19 vaccine(s)" document.

Given the superior efficacy reported in clinical trials, the messenger RNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications, especially for those at highest risk of severe illness and death and at highest risk of exposure to COVID-19.

In the context of a limited vaccine supply, the AstraZeneca COVID-19 vaccine may be offered to individuals aged 18 to 64 without contraindications if the advantages of earlier vaccination outweigh the limitations of vaccinating with a less efficacious vaccine; the ease of transport, storage and handling of this vaccine facilitates access to vaccination that may otherwise be challenging; and informed consent includes a discussion about current vaccine options and the timing of future vaccine options.

**•** (1840)

[English]

At the time the NACI recommendations were made, the committee had assessed the data from the randomized controlled trials submitted by the manufacturer, which meant two phase one/two studies, one phase two/three study, and one phase three study, as well as a real-world effectiveness study performed in Scotland by Vasileiou and colleagues entitled "Effectiveness of first dose of COVID-19 vaccines against hospital admissions in Scotland: national prospective cohort study of 5.4 million people", which is a preprint. This means it is not yet reviewed by peers.

Data from an ongoing phase three trial in the U.S. are not yet available. Of note, the FDA is waiting on these results to make a decision on authorization. The clinical trials data submitted were challenging to interpret, as there was use of both a low dose/standard dose and a standard dose/standard dose vaccine regimen in trials, a varied interval between doses, and the recruitments of progressively older study participants after the initial focus was put on adults 18 to 55 years old.

The estimates of vaccine efficacy against confirmed COVID-19 cases occurring at least 15 days after dose two, by dosing interval, suggested an increase in vaccine efficacy with an increasing interval between doses of vaccine, but confidence intervals are wide and overlap. As a recap, a 95% confidence interval means that we are 95% confident that the true value—in this case, vaccine efficacy—will fall within these boundaries.

When confidence intervals around a point estimate overlap in a given study, it means that the two estimates could possibly be the same. In this case, the vaccine efficacy with a dosing interval of four to eight weeks was 55.7%, with a 95% confidence interval going from 39% to 68%, while the vaccine efficacy of an interval greater than 12 weeks was 81.6%, with a 95% confidence interval from 47% to 94%, so both intervals are overlapping.

A subgroup analysis of vaccine efficacy against the first occurrence of confirmed COVID-19 at least 15 days after dose two showed that, for all studied intervals between doses, the point estimate for vaccine efficacy ranged around 60% for the younger age group—that means 18 to 64—with a confidence interval that did not include zero. This means a vaccine efficacy is really there, compared with 43% for 65 years and over, with a wide confidence interval that includes zero, meaning that the actual vaccine efficacy could be null.

Based on these data, NACI felt that it was safest, given the availability of two other mRNA vaccines that were highly efficacious in people 65 years and over, to recommend the mRNA vaccines in that age group and not recommend the AstraZeneca vaccine for 65 years and over. This is awaiting further data, including the clinical trial that is ongoing in the U.S.

NACI also reviewed the Scottish paper, as these data were available. This study, which has not yet been peer-reviewed, is a real-time prospective observational cohort with national-level coverage in Scotland, using administrative data that are all linked. The cohort included 5.4 million people. The authors studied the first doses of either the Pfizer-BioNTech or AstraZeneca vaccines. The authors assessed the effectiveness—the effect of the vaccine in real life, as opposed to efficacy, which studies the effect in a randomized clinical trial—against hospital admission with COVID-19 as the main diagnosis within 28 days of a positive PCR for SARS-CoV-2.

During the study period, 35% of participants were vaccinated, mainly among the first priority groups aged 80 years and over. Younger individuals had a higher uptake of the Pfizer vaccine, while those 80 years and over had a higher uptake of the AstraZeneca vaccine. The authors reported a statistically significant adjusted vaccine effectiveness against COVID-19-related admissions in those who received a first dose of either vaccine, which increased over time until a peak at day 28 to day 34 post-vaccination.

Although these data seem promising, the committee was not able to explain why the vaccine effectiveness was so high so early on. On days 7 to 13, the reported effectiveness was already 70%, with a 95% confidence interval from 63% to 76%. This raised questions about the study's methodological validity. Moreover, given the context of the targeted vaccination and study design, NACI considered that there was a high risk of bias and that vaccinated individuals were likely not comparable to unvaccinated individuals. Given

these uncertainties, NACI decided that this study was not solid enough to change policy, and kept its recommendation not to use the AstraZeneca vaccine for those aged 65-plus at that point in time

In the short time since NACI's recommendations were published, two other real-world effectiveness studies have been preprinted. The committee met yesterday, on March 10, to discuss them and decide if these new data would change recommendations. An updated statement, which will include the real-world evidence, will be released as soon as possible.

● (1845)

[Translation]

Regarding Health Canada's authorization, it's important to understand that, while both Health Canada and the National Advisory Committee on Immunization report to the Minister of Health, they don't have a reporting relationship with each other. Health Canada's role is to authorize specific indications for use that are expected to be safe, immunogenic, efficacious, and of suitable quality for individuals. To do so, it reviews preclinical data, clinical trial data, and manufacturing information submitted by manufacturers, along with post-market surveillance data.

Once a vaccine is authorized, the NACI becomes involved. The NACI's role as a technical committee and advisory body is to recommend vaccination strategies to promote health, prevent and control infectious diseases, and prepare for or respond to public health emergencies. The NACI does this by reviewing all relevant and available evidence on the vaccines in question in the context of public health considerations, and then taking into account not only vaccine characteristics and the burden of disease, but also the concepts of ethics, equity, acceptability, and feasibility. The NACI regularly relies on the support of mathematical modellers to assess the effects of various strategies.

The NACI can make off-label recommendations when there's a clear need supported by a public health ethical analysis.

[English]

In this particular context, NACI considered the advantages of administering a COVID-19 vaccine earlier to Canadians against the limitations of administering a vaccine that, based on available data, is less efficacious. Based on mathematical modelling, various strategies were studied. In clinical trials, mRNA COVID-19 vaccines demonstrated higher efficacy than the AstraZeneca vaccine. In the context of limited supply, NACI, however, considered additional factors when assessing options for COVID-19 immunization.

Internal modelling reviewed by NACI, based on Canadian supply projections, indicated that a program including both mRNA vaccines and the AstraZeneca COVID-19 vaccine could have short-term public health benefits—preventing symptomatic disease, hospitalization and death—when the AstraZeneca COVID-19 vaccine is offered earlier to adults who are 18 to 54 instead of waiting for an mRNA vaccine, during periods of epidemic transmission. The public health benefits of offering the AstraZeneca vaccine earlier only to individuals who are 55 to 64 years old were less certain, given their shorter expected wait times to get mRNA vaccines. Modelling assumed no impact of vaccines on preventing transmission, as evidence of this is not yet available.

The population that received a lower-efficacy COVID-19 vaccine will have protection against COVID-19 disease earlier than if they had waited for mRNA vaccines to be available. However, these populations may ultimately have lower protection, depending on the duration of protection of both vaccines, as a larger proportion of the population will remain susceptible. Depending on vaccination strategies, it could potentially exacerbate health inequities if this potential harm is not considered when implementing the vaccine program in populations that experience intersecting risk factors for severe disease and exposure.

The mRNA COVID-19 vaccines have more challenging storage and transportation requirements than the AstraZeneca COVID vaccine, which may limit the venues where the vaccine may be offered. Vaccine hesitancy may be reduced by offering the COVID-19 vaccine in more convenient locations. That element was deemed important in the decision as to who should receive the AstraZeneca vaccine.

[Translation]

I hope that this explanation has helped the committee understand the thought process behind the NACI's decisions and recommendations issued on March 1.

Thank you for your attention. I would be happy to answer your questions.

[English]

The Chair: Thank you, Dr. Quach-Thanh.

We will go now to the Department of Health, with Dr. Marc Berthiaume, director, health products and food branch.

Please go ahead, for 10 minutes.

Dr. Marc Berthiaume (Director, Bureau of Medical Sciences, Therapeutic Products Directorate, Health Products and Food Branch, Department of Health): Good evening, Mr. Chair.

My name is Dr. Marc Berthiaume, and I am the director of the bureau of medical sciences at Health Canada, health products and food branch.

Thank you for inviting me to appear before the committee today. I appreciate this opportunity to discuss Health Canada's high standards for the vaccine approval process and, in particular, to address questions regarding the approval of the AstraZeneca vaccine for people over 65 years of age.

I want to begin by emphasizing that Health Canada authorizes vaccines only if they meet the department's stringent safety, efficacy and quality requirements.

As with the other vaccines, Health Canada conducted independent and thorough scientific reviews to determine that the benefits outweigh the risks for the AstraZeneca COVID-19 vaccine, which was developed in partnership with Oxford University, as well as the Serum Institute of India's version of the AstraZeneca vaccine, sponsored in Canada by Verity Pharmaceuticals.

Health Canada has rigorously evaluated the data available from clinical trials and real-world evidence, and determined that this vaccine is safe to be administered to adults 18 years of age and older.

We also collaborated with the European Medicines Agency on the review of the AstraZeneca vaccine, as part of its open process. This initiative makes it possible for trusted regulatory authorities outside of the European Union, such as Health Canada, to work together and share information throughout the review process.

All regulatory authorities that have authorized the AstraZeneca vaccine have granted unrestricted adult indications.

Even though limited information from clinical trials is available to calculate its efficacy in people 65 years of age and older, Health Canada's authorization for a broad adult population has taken the available data on immune responses into consideration. There is emerging promising evidence that is beginning to be reported from studies on the real-world use of the vaccine, along with data on the safety profile of the vaccine from millions of people who have received it.

In addition to the encouraging real-world evidence that is already showing benefits with respect to outcomes such as hospitalization, it is important to note that there were no safety issues in this age group. There were no issues in the clinical studies, where about 700 people over the age of 65 were administered the vaccine, nor in the large numbers of seniors who have been vaccinated to date in other countries that have also authorized the AstraZeneca vaccine and are administering it to people over the age of 65.

Specifically, during the first summary of the safety reporting period of January 1-31, 2021, safety data was available for over 3.7 million people who received the vaccine, with no safety issues identified. A safety signal of anaphylaxis has more recently emerged, which is currently being added to the product monograph.

Health Canada is aware of the reports in Europe of adverse events, including fatalities, following immunization with the AstraZeneca vaccine, specifically thromboembolic events such as blood clots. We are monitoring and working closely with national regulators to gather information, including the European Medicines Agency, whose safety committee has initiated an accelerated investigation. At this time, we do not believe this is a new safety issue that will impact the deployment of the vaccine in Canada. These sorts of events demonstrate that our rigorous safety system works well to identify and quickly start to investigate issues.

Health Canada is reassuring Canadians that the benefits of vaccination outweigh the risks. We expect further information from ongoing clinical trials and post-market monitoring in the coming months. If there are additional changes required with regard to safety or efficacy, Health Canada will take the necessary actions.

In the meantime, the department has been transparent regarding the data that was considered, and has reflected the limited data on efficacy for those over the age of 65 in its regulatory document, including the product monograph.

• (1850)

[Translation]

I want to point out that all COVID-19 vaccines were authorized in Canada under an interim order approved in September 2020. This enables us to speed up the review of COVID-19 treatments and vaccines, while maintaining a high level of scientific review.

With this interim order, Health Canada can approve a new vaccine based on available evidence with more agile administrative and application requirements. The interim order also allows for rolling reviews, which lets a vaccine manufacturer submit its request for authorization before it has completed all the clinical trials. This means that it can submit required data as the data becomes available. The interim order also gives Health Canada the authority to impose terms and conditions to require the manufacturer to continue providing information on the safety, efficacy and quality of the vaccine once marketed.

Additionally, we have a strong post-market safety surveillance system to monitor the safety of COVID-19 vaccines. Once a vaccine is on the market, Health Canada and the Public Health Agency of Canada monitor for any adverse events after immunization in collaboration with the provinces and territories and the manufacturer. The interim order provides the authority to impose terms and conditions on any authorization at any time, such as additional assessments of safety information. We'll take swift action if safety concerns are identified.

All Health Canada's regulatory decisions are independent and based solely on scientific data and evidence. Our COVID-19 vaccine review teams are comprised of experienced scientific and regulatory experts, including scientists and physicians with many years of experience in reviewing vaccines. Together, these measures have allowed Health Canada to authorize several clinical trials in Canada for COVID-19 vaccines, as well as for five vaccines: Pfizer-BioN-Tech, Moderna, AstraZeneca, the AstraZeneca version produced by the Serum Institute in India, and Janssen.

As part of our ongoing commitment to openness and transparency, Health Canada has published detailed information about the authorized COVID-19 vaccines on its COVID-19 vaccines and treatments portal. This information includes Canadian product monographs and regulatory decision summaries that provide a high-level summary of the evidence reviewed to support vaccine authorization.

Health Canada and the Public Health Agency of Canada provide weekly updates on reported adverse events following immunization. Our response to the pandemic is being guided by the latest science and research. We're also continuing to closely monitor the emerging viral variants and to work with manufacturers and international regulators in order to assess the impact of the new variants on vaccine efficacy and provide guidance to manufacturers.

Health Canada, together with the Access Consortium that also includes our regulatory counterparts in the United Kingdom, Australia, Switzerland and Singapore, has developed and published guidelines for the industry regarding our common regulatory approach to authorizing updates to existing vaccines in order to combat new variants.

Canadians can rest assured that the review process for each vaccine has been rigorous and that systems are in place to continue to monitor the safety and efficacy of authorized COVID-19 vaccines. The vaccines play a critical role in Canada's response to the pandemic and fight against COVID-19. The authorization of these additional vaccines, which meet Health Canada's rigorous safety, efficacy and quality standards, provides additional tools to fight this pandemic as quickly as possible.

Thank you.

• (1855)

[English]

The Chair: Thank you, Dr. Berthiaume.

We go now to the Public Health Agency of Canada, which will have collectively 15 minutes to speak. We'll start with Ms. Elmslie, vice-president of the immunization branch.

Ms. Elmslie, please go ahead.

• (1900)

Ms. Kimberly Elmslie (Vice-President, Immunization Branch, Public Health Agency of Canada): Thank you very much, Mr. Chair. Good evening, members.

This evening I will be speaking about the role of Canada's national advisory committee on immunization in the immunization system in our country. NACI, as you know, is an expert, external body that provides independent advice to the Public Health Agency of Canada on the optimal use of authorized vaccines in Canada. NACI has been operating for over 50 years as the country's national immunization technical advisory group, and it is widely respected by provinces and territories and internationally.

The committee is made up of experts from across Canada in the fields of pediatrics, infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmacoeconomics, social sciences and public health. In the context of COVID-19, Canada's federal, provincial and territorial governments utilize the advice of NACI as the authoritative body on pandemic vaccine prioritization and vaccine public health program design. Its recommendations are designed to support the pandemic public health response goals of reducing serious illness and overall death while minimizing societal disruption as a result of COVID-19.

NACI's COVID-19 advice is focused on the strategic prioritization of vaccines and specific vaccine guidance and ranking of products for clinical use. Its recommendations inform federal, provincial and territorial governments' planning for the efficient, effective and equitable allocation of COVID-19 vaccines. NACI thoroughly reviews available evidence when developing its recommendations. This includes the consideration of vaccine characteristics, such as safety, efficacy, immunogenicity and effectiveness. NACI also incorporates programmatic factors such as economics, ethics, equity, feasibility and acceptability.

NACI's guidance is advisory in nature. Immunization program planning and delivery decisions fall under provincial and territorial jurisdiction. The provinces and territories ultimately determine how to use authorized COVID-19 vaccines based on jurisdictional needs and circumstances, including local epidemiology, public health considerations, health care system capacity and vaccine management logistics.

NACI is supported by a secretariat housed within the Public Health Agency of Canada. While NACI members are not government employees and remain external to the federal government, the secretariat supports committee meetings and deliberations, the rigorous scientific review of evidence and the development of NACI statements and communication products for health care providers and the public. The secretariat support is necessary as the committee members are volunteers, holding important full-time clinical and public health roles.

NACI complements the expertise of its broad membership by conducting extensive stakeholder engagement when developing its recommendations, involving many liaison organizations. The Canadian immunization committee, which is a federal, provincial and territorial table, is actively involved at multiple points in NACI's work. When drafting guidance on COVID-19 vaccines, including the AstraZeneca vaccine, NACI sought input from the special advisory committee on COVID-19, which is made up of provincial and territorial chief medical officers of health and other senior officials.

There is an important distinction to be made between NACI's role and Health Canada's function as Canada's national regulator. It

is not uncommon for NACI to provide recommendations that are broader or narrower than the conditions of use approved by Health Canada. NACI is different from Health Canada, which does not dictate practice of medicine or make recommendations on how vaccines should be used in different age groups and subpopulations for public health impact.

In keeping with its mandate to optimize the public health benefits of immunization in Canada, NACI has historically provided preferential recommendations on the use of vaccines in key populations for diseases. Some examples include influenza and shingles vaccines. In making its recommendations, NACI also takes into consideration other vaccines available in Canada and may make preferential recommendations based on the current context. This is different from Health Canada as the regulatory authority that reviews each vaccine independently to assess if there is sufficient evidence of safety, efficacy and manufacturing quality to meet regulatory requirements for authorizations.

• (1905)

Clinicians are very used to consulting both the product monograph and NACI advice when making their clinical vaccine decisions for patients. They do not expect these to be identical, understanding that they are driven by different perspectives.

NACI's recommendations complement regulatory indications with real-world context and with information on public health strategies based on available and evolving evidence. The committee revises its recommendations when needed based on new evidence as well as the evolving context.

On the global stage, other countries rely on their respective national immunization technical advisory groups for COVID-19 expert advice. Through the NACI secretariat within PHAC, NACI is well connected to international advisory committees of this type. In fact, Canada is currently the chair of the global NITAG network, a World Health Organization-supported forum where national technical advisory committees on immunization share information and collaborate on work plans.

The NACI secretariat is in regular contact with countries bilaterally and through the global NITAG network to stay up to date on international COVID-19 developments.

PHAC expects different approaches to be adopted around the world in response to COVID-19. Every country develops immunization programs that are informed by local epidemiology, values, preferences, social infrastructure and health care systems. Naturally, these considerations vary significantly by country.

As you are all aware, real-world evidence on COVID-19 and vaccine effectiveness is evolving in real time. NACI continues to closely monitor and review this emerging evidence and will revise its recommendations as information becomes available.

I would like to thank the committee chair and members for the opportunity to address this committee.

Thank you.

The Chair: Thank you, Ms. Elmslie.

Is there anyone else from PHAC who wishes to speak?

**Ms. Kimberly Elmslie:** There is no one else speaking at this time, Mr. Chair.

The Chair: Thank you very much.

In that case, we will begin with our questioning.

We will start with Ms. Rempel Garner, please, for six minutes.

Hon. Michelle Rempel Garner (Calgary Nose Hill, CPC): Thank you, Chair.

To Dr. Berthiaume from Health Canada, does Health Canada have any concerns that any age group or demographic is at an increased risk of pulmonary embolism or DVT after receiving a dose of the AstraZeneca vaccine?

**Dr. Marc Berthiaume:** There is an ongoing investigation in Europe about thromboembolic events. They are thought to be potentially related to some lots, but more needs to be found.

At this point, there is no concern in Canada about the potential risk for thromboembolic adverse events with the AstraZeneca vaccine. I could add, as a complementary piece of information, that in the U.K., where 11 million doses of the AstraZeneca vaccine were administered, there were no safety signals of thromboembolic events that were identified.

### Hon. Michelle Rempel Garner: Thank you.

Dr. Quach-Thanh, Dr. Berthiaume spent most of his presentation talking about the safety of the AstraZeneca vaccine, but it's my understanding that your recommendation against using the AstraZeneca vaccine in seniors was related to efficacy. Is that correct?

Dr. Caroline Quach-Thanh: You are correct.

Hon. Michelle Rempel Garner: Okay.

Do the other vaccines that have been approved in Canada—the two mRNA vaccines as well as Johnson & Johnson—have higher levels of efficacy for age 65 and older?

**Dr. Caroline Quach-Thanh:** If you look at the two mRNA vaccines, the efficacy is actually close to 95% for those aged 65 and over. For Johnson & Johnson, NACI hasn't reviewed all the data, so our recommendation is not out yet, but we do have data on those aged 65 and over that is statistically significant, meaning that the 95% confidence interval does not include zero.

• (1910)

#### Hon. Michelle Rempel Garner: Okay.

In your comments, you talked about making decisions within the context of limited supply. Do you think that the lack of vaccine

supply in Canada to date, coupled with the threat of variants, played into the government's decision to approve the AstraZeneca vaccine for those aged 65 and older in spite of your recommendation?

**Dr. Caroline Quach-Thanh:** I think you would have to ask Health Canada for the exact reasons.

#### Hon. Michelle Rempel Garner: Certainly.

Dr. Berthiaume, I'll ask you the same question. Did the lack of supply or limited supply of mRNA vaccines play into your decision to ignore NACI's advice?

**Dr. Marc Berthiaume:** No, it did not. Health Canada based its decision on a number of elements. There was evidence of immunogenicity—that people over 65 in immunogenicity studies were building antibodies when administered this vaccine. The paucity of the data is related to the small number of people who were in clinical trials who were 65 and over, and that's reflected in the product monograph—

Hon. Michelle Rempel Garner: But all else considered equal, what we've just heard is that the mRNA vaccines are significantly more effective for ages 65 and over than AstraZeneca is, so why did Health Canada not recommend prioritizing the Pfizer vaccines for that age group and AstraZeneca for other age groups, in which it would have a higher level of efficacy?

**Dr. Marc Berthiaume:** If you make a comparison, for example, with antibiotics for pneumonia, Health Canada would approve a set of antibiotics for pneumonia but would not necessarily say "this one is better than this one." Then it would come down to the practice guidelines of different experts to guide the clinical decision-making.

**Hon. Michelle Rempel Garner:** But in this case, with limited supply and the economy in lockdown and the variants obviously being a threat, wouldn't Health Canada be well advised to consider the most vulnerable population when recommending prioritization of vaccines?

**Dr. Marc Berthiaume:** Health Canada's strategy is to have a portfolio of vaccines that offer different characteristics. For example, the AstraZeneca vaccine has one characteristic that's very interesting, which the others don't have, and that is that the vial, once you take the first dose, can be refrigerated and used for other patients for up to 48 hours, while all three others are only for six hours—

Hon. Michelle Rempel Garner: But-

Dr. Marc Berthiaume: Let me finish, please.

**Hon. Michelle Rempel Garner:** Sure. I have very limited time. I have only a minute and a half left.

Dr. Marc Berthiaume: Okay. Sorry.

**Hon. Michelle Rempel Garner:** You can table that with committee if you'd like, although none of your colleagues tend to do that on a regular basis.

With the minute that I have left, you and other officials from the federal government have said that it's a province's decision what advice it takes, essentially. Are you not concerned that a balkanization of vaccine recommendations across Canada would potentially lead to vaccine hesitancy or to people age 65 and older holding off getting vaccinated given the lack of clarity and advice from the government?

**Dr. Marc Berthiaume:** I think that's a question for my PHAC colleagues.

Hon. Michelle Rempel Garner: Go ahead.

**Ms. Kimberly Elmslie:** Thank you very much. Maybe I'll start on that one.

In the context of the vaccine strategy and the need to ensure there is a diverse strategy and availability of vaccines across the country, what's important is that we're getting vaccines to the provinces and territories and they're getting effective vaccines into the arms of Canadians.

**Hon. Michelle Rempel Garner:** Are you concerned at all about vaccine hesitancy due to the confusion in advice?

**Ms. Kimberly Elmslie:** We have been providing clear advice to Canadians through the work with the provinces and the territories. We'll continue to do that.

**Hon. Michelle Rempel Garner:** I would say you are not. By what stretch does conflicting advice mean clarity?

**Ms. Kimberly Elmslie:** There will be advice that changes over time. That is exactly what is happening as science becomes clearer and as more studies are reading out their results. We can expect to see changes in advice.

It's really important to continue to provide as much information as clearly as we can, recognize that it will change, and inform the public that things will change as evidence changes.

The Chair: Thank you, Ms. Rempel Garner.

We'll go now to Ms. Sidhu for six minutes.

Ms. Sonia Sidhu (Brampton South, Lib.): Thank you to all the witnesses for joining us today. I know that all of you have been working very hard for all Canadians. Thank you very much for that.

Mr. Chair, by the end of the month we'll have 8.5 million doses of COVID vaccines. By July we will have 36.5 million vaccine doses. This does not even include the one from Johnson & Johnson.

My first question is for Dr. Quach. A lot of Canadians are listening, and some data presented by the experts may be complex to understand. In simple terms, based on all the data you have considered, how effective is AstraZeneca?

• (1915)

**Dr. Caroline Quach-Thanh:** In terms of efficacy, it is 60% efficacious for 18 to 64 and approximately 40% efficacious for the older population. However, when you look at effectiveness, it seems to have a 70% to 80% effectiveness in preventing hospitalizations and death, which is comparable to the other vaccines.

These are real-world data, which are not of the same high-standard quality as what we usually see in randomized control trials, but they are the data that we will have moving forward with the rollout of the vaccines. That's what we are also looking at.

In terms of preventing complications, it's good.

Ms. Sonia Sidhu: Thank you.

Dr. Quach, for the sake of clarity, do you think that Canadians should choose to wait for a specific vaccine, or should they take the first one that is offered to them?

**Dr. Caroline Quach-Thanh:** At this point in time, I think that you take whatever is offered to you, because the risk of catching the infection is now, while the transmission in the community is high. If you wait until June or July, when your turn comes for the mRNA vaccine for instance, you're still at risk of infection until then.

Our hope is that the Canadians who are most vulnerable to infections and complications will be able to get vaccinated as quickly as possible.

**Ms. Sonia Sidhu:** Dr. Berthiaume, can you tell us about the data that Health Canada considers when it makes recommendations for who is eligible for a vaccine? Obviously, you examined the clinical data that came in on a rolling basis. Do you take information from any other sources?

**Dr. Marc Berthiaume:** When we examine a submission, like for the AstraZeneca vaccine, we evaluate based on the data provided by the sponsor. For this specific submission, the sponsor provided the data from four clinical trials, two of which were more important in terms of the analysis. They also provided the real-world data from Scotland as part of the evidence to consider for the approval of their vaccine.

Ms. Sonia Sidhu: Thank you.

As we know, NACI recently advised that the second dose could be effectively administered with longer gaps. For any of the witnesses, does extending the COVID-19 vaccination have particular concerns for any particular population or group?

**Dr. Caroline Quach-Thanh:** In terms of the extended interval, the most vulnerable in long-term care facilities, for example, are probably the group we wouldn't be extending. The reason NACI didn't put that out explicitly was that when we spoke to our counterparts, the provinces and territories all said that most of their population was already vaccinated.

However, when we look at data provided by Quebec, B.C. and the U.K., we see that even in those very fragile populations we still have a vaccine effectiveness above 80% up to eight weeks, which does not seem to be declining over time. That was one of the bases on which that recommendation was made.

Ms. Sonia Sidhu: Thank you.

With all that being said, do you think the recommendations that we have discussed will put any Canadians at risk?

**Dr. Caroline Quach-Thanh:** I think what you really have to look at is the risk-benefit, as we were saying. What we are aiming for is to get as many Canadians vaccinated with the first dose, with an overall effectiveness of approximately 80%, which then can help control the pandemic and decrease the impact of variants on that transmission.

Of course, if we had plenty of vaccines and we were able to give the vaccine quickly, we would not be trying to extend that interval. I think this interval is also of limited duration. It doesn't mean that all Canadians are going to have their two doses at a four-month interval. It means that now, to be able to use up the vaccines we're getting, which are still in limited supply, we are hoping that the first dose is given to as many people as possible, and when the bulk of the rest of the vaccines come in, at that point we can shorten the interval closer to six weeks or so.

• (1920)

Ms. Sonia Sidhu: Thank you.

Mr. Chair, do I have more time? **The Chair:** You have 40 seconds.

Mr. Marcus Powlowski (Thunder Bay—Rainy River, Lib.): Can I make a point of clarification? Isn't that a procedural thing you can do? There's something the witness said...or am I totally wrong? Dr. Quach-Thanh, I think it's really important—

An hon. member: Mr. Chair, point of order. He can't come in here-

The Chair: Steady down, everybody.

Doctor, you'll have a time slot in the third round.

**Mr. Marcus Powlowski:** Is there no such thing as a point of clarification on the witness testimony?

The Chair: It interrupts the-

**Mr. Marcus Powlowski:** I think it's totally central to what we're talking about.

Mr. John Barlow (Foothills, CPC): Mr. Chair, he has a speaking slot. That's it.

The Chair: Doctor, we can't allow it at this time. If one of your colleagues would like to share their time with you, that would be okay, but at this point, the speaking time for all the parties is well defined.

**Ms. Sonia Sidhu:** Mr. Chair, I will share my time with Dr. Powlowski.

The Chair: All right, Ms. Sidhu, you have 40 seconds left.

Dr. Powlowski, you have 40 seconds.

Mr. Marcus Powlowski: Thank you, Ms. Sidhu, for that.

I think this is really important and probably most of the members in the committee didn't pick this up. A large part of the public might not appreciate the difference.

Dr. Quach-Thanh, you talked about the efficacy versus the efficiency, and the numbers are very different. Can you once again

clarify that so we understand the difference between those two terms? What is the efficacy versus the efficiency?

**Dr. Caroline Quach-Thanh:** Absolutely. Thank you for that question.

Efficacy means the vaccine impact in a randomized control trial where you actually choose the population—choosing in the sense that you have very strict inclusion and exclusion criteria. Usually your population is healthier than when you use it in the real world.

Effectiveness is the impact of a vaccine when it's rolled out at the population level, which means that everybody is vaccinated. You have immunosuppressed patients, people with underlying medical conditions and malnourished people who might not respond as well to a vaccine. You always expect the rate of effectiveness to be a little bit lower than the efficacy because you have a much more varied population in whom the vaccine might not work as well as when you select—not cherry-pick, but very strictly select—the participants in a study.

The Chair: Thank you, Doctor.

[Translation]

We'll now turn to Mr. Thériault.

Mr. Thériault, you have six minutes.

Mr. Luc Thériault (Montcalm, BQ): Thank you, Mr. Chair.

Dr. Berthiaume, why wasn't the AstraZeneca vaccine approved with a warning for people aged 65 and over?

**Dr. Marc Berthiaume:** The AstraZeneca vaccine was approved because Health Canada considered that it had enough information to recommend its use for people aged 65 and over. I can say that—

**Mr. Luc Thériault:** Sorry to interrupt you, Dr. Berthiaume. You said that there was enough information. What does that mean?

**Dr. Marc Berthiaume:** It means that there's enough evidence. Health Canada makes a decision based on the evidence submitted.

**Mr. Luc Thériault:** Okay. Obviously, the National Advisory Committee on Immunization, or NACI, is telling us that the vaccine is 43% effective. Isn't that right?

Who should take the advisory committee into account? The Public Health Agency of Canada must deal with a pandemic. It has two bodies. The goal is to get vaccines, but when it comes to the AstraZeneca vaccine, there's some passing the buck.

Some people in Quebec say that the vaccine was approved. However, it was approved without any warning about its effectiveness for people aged 65 and over. When we're told about the relevance of the vaccine, we hear that this falls under a vaccination strategy based on the scarcity of the resource.

If the resource isn't in short supply, is the approval granted anyway? Is this done without any warning? In other words, why was this vaccine approved?

**Dr. Marc Berthiaume:** As I tried to explain earlier, there are several pieces of data to consider when looking at the effectiveness of the AstraZeneca vaccine. For example, in groups of 600 to 700 patients aged 65 and over that included a placebo group and a vaccine group, there were no hospitalizations among the vaccinated individuals and eight hospitalizations among the non-vaccinated individuals.

When we look at the efficacy of a vaccine, we take into account different factors, such as the prevention of asymptomatic infection and the prevention of symptomatic infection. Most of the efficacy data discussed so far today concerned efficacy against symptomatic infection.

Then there's the efficacy against hospitalization and death. This is a significant aspect of vaccine efficacy. In the case of the AstraZeneca vaccine, not only the clinical trial data, but also the real-world efficacy data have shown that the vaccine prevents and significantly decreases severe and serious cases, such as the cases that clog hospitals and cause deaths.

(1925)

**Mr. Luc Thériault:** You're saying that, even though the vaccine is 43% effective in people aged 65 and over, it prevents serious forms of the illness.

Is the decision to offer this vaccine optimal for all people? In a way, doesn't the decision to offer it without a warning create uncertainty for people who are feeling uncertain right now?

We learned today that there was an issue. Who will make a decision? Certainly not the National Advisory Committee on Immunization, or NACI, because the committee is advisory.

Will it be the Public Health Agency of Canada, Health Canada?

Who will make the decision to suspend the use of this vaccine, as was done in Norway, Denmark and Iceland?

Why didn't you apply the precautionary principle?

**Dr. Marc Berthiaume:** The 43% effectiveness that I referred to wasn't statistically significant, because there were too few cases.

I could add that the agency—

**Mr. Luc Thériault:** Wait. Are you telling me that the NACI is currently saying that the use of a vaccine that's 43% effective isn't recommended and that you're ignoring this because the data isn't significant?

**Dr. Marc Berthiaume:** As Dr. Quach-Thanh explained, I'm saying that the 43% has a very wide confidence interval that even extends into the negative.

Even though the rate obtained is 43%, this isn't a statistically reliable value given the small number of cases in the study.

**Mr. Luc Thériault:** The new studies likely to undergo a review in the next few days will give us a little more insight. However, you didn't answer my question.

Who, according to the precautionary principle, will suspend vaccination until the adverse effects of the vaccine are clarified?

Dr. Marc Berthiaume: You're referring to a-

Mr. Luc Thériault: Do you make the decision?

**Dr. Marc Berthiaume:** Mr. Thériault, I would like to answer your question.

You were referring to thromboembolic events in Europe. The vaccination of certain groups has been suspended in some countries. However, the administration of the AstraZeneca vaccine hasn't been completely suspended in Europe. The vaccine is currently under investigation.

The point is that, when you give a vaccine to millions of people, sometimes there will be—

Mr. Luc Thériault: I understand that-

Dr. Marc Berthiaume: —thromboembolic events that will be—

Mr. Luc Thériault: I understand that, Mr. Berthiaume. I don't have much time.

However, in terms of the precautionary principle, just because we can administer the vaccine safely here doesn't mean that we can't wait for developments related to an issue elsewhere. What's the rush?

Put yourself in the shoes of a 70-year-old person who sees all this in the news and who is told no, there's no consent to sign for the vaccine, you just take what you're given.

Don't you think that the public health message could create uncertainty among people who feel safe?

Are you taking this into account?

What does this take away from the vaccination process, when we wait for clarification on the adverse effects of the vaccine, which are quite significant?

**Dr. Marc Berthiaume:** The thromboembolic events in Europe that you're referring to are being reviewed.

Health Canada is in direct contact with the European agencies. If a safety issue were to come up in relation to this matter, Health Canada would take the necessary steps with respect to the vaccination—

Mr. Luc Thériault: What do you know about it right now?

You can't say anything definitive about this matter.

[English]

The Chair: Thank you, Mr. Thériault.

[Translation]

**Mr.** Luc Thériault: Since you can't say anything definitive about this matter, you should temporarily withdraw the vaccine as a precaution.

The Chair: Thank you, Mr. Thériault.

[English]

We'll now go to Mr. Davies.

Mr. Davies, please go ahead for six minutes.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you, Mr. Chair.

Dr. Quach-Thanh, on March 1, about 10 days ago, NACI said this about the Oxford-AstraZeneca vaccine: "NACI does not recommend the use of this vaccine in individuals 65 years of age and older due to limited information on the efficacy of this vaccine in this age group at this time."

Do you stand by this statement?

• (1930)

**Dr. Caroline Quach-Thanh:** You are asking if I still stand by the statement we issued on March 1. As we said, we are reviewing the data. We met yesterday—

**Mr. Don Davies:** I'm not asking if you're reviewing the data. I'm asking if you stand by that statement.

**Dr. Caroline Quach-Thanh:** As of now, yes, because we're reviewing it at this point in time.

Mr. Don Davies: Thank you.

Ms. Elmslie, you talked about changing over time. The reason we're having this meeting tonight is that there is a simultaneous contradiction in advice, because at about the same time there was Health Canada's summary of the rationale for its February 26 authorization. Just days before NACI said what it said, Health Canada said this: "Efficacy in individuals 65 years of age and older is supported by immunogenicity data, emerging real world evidence and post-market experience in regions where the vaccine has been deployed, which suggest at this point in time a potential benefit and no safety concerns."

How do you square that? We have NACI telling us there's insufficient evidence of efficacy, and Health Canada, at the very same time, is telling Canadians that efficacy is supported by data. Help me understand that contradiction and whom Canadians should believe

**Ms. Kimberly Elmslie:** What I would say to that is that data are being looked at by NACI and its experts and by Health Canada and their experts. From the point of view of the regulatory approach, Dr. Berthiaume can speak very well to that in the context of making decisions on the safety, efficacy and quality of vaccines to be authorized for use in Canada. NACI is going to look at this from the perspective of the use of the vaccine, the optimal use of the vaccine in Canada.

**Mr. Don Davies:** No, that's not the case. I read a direct quote where both groups were speaking about efficacy. One was not talking about use and the other about efficacy; both were talking about efficacy. NACI said there's no sufficient evidence; Health Canada said there is.

I'm going to move toward what Dr. Nathalie Grandvaux, professor in biochemistry and molecular medicine, told this committee this week. She said:

PHAC authorizes vaccines based on the clinical trial data, and the NACI subsequently adjusts the recommendations for their use based on real-life data as it becomes available

It goes without saying that the different messages emitted by these two organizations lately induce a major confusion that is incomprehensible for the majority of the population. This is without taking into account the additional confusion induced by the different opinions of the provincial advisory committees.

...It is important to understand that inconsistent messages will likely lead to a loss of confidence in the population in the vaccination campaign and one cannot risk losing the adhesion of the population to immunization with the safe and effective vaccines that we have.

Is she wrong, Ms. Elmslie?

**Ms. Kimberly Elmslie:** I would say she's not wrong. I think it is important that we always strive for clarity and consistency in messaging. That is our objective, for sure.

In this situation, as science is evolving, it is just sometimes not possible to be there at exactly the same time, and we need to accept that. Canadians need to understand, and I think they do understand, that science is evolving very rapidly, at a very fast pace, and experts at NACI and experts at Health Canada are very seized with looking at this on an ongoing basis and making their best recommendations for the benefit of all Canadians.

Mr. Don Davies: Let's turn to real-time evidence, then.

Dr. Berthiaume, today Denmark, Norway and Iceland announced that they will temporarily suspend the use of the Oxford-AstraZeneca vaccine as a precaution after "reports of severe cases of blood clots" in people who have been vaccinated with the COVID-19 vaccine from AstraZeneca. This follows a similar move by Austria at the start of this week, where authorities are investigating the death of one person and the illness of another after they received doses.

Is Health Canada currently investigating these reports of potential adverse effects? In your view, should Health Canada temporarily suspend use of the Oxford-AstraZeneca vaccine as a precaution while these reports are investigated? If not, why not?

Dr. Marc Berthiaume: Thank you for your question.

As very well explained by Dr. Quach, the clinical trial data is very robust. When you look at the data that was generated for the AstraZeneca vaccine, you see that 24,000 people were in the clinical trials, and the level of severe adverse events that were identified was no different between the vaccine and the people who got the control, so we have strong data to support the fact that there is no safety concern with the vaccine itself.

There have been reports in Europe of thromboembolic events, and they're investigating them. What will have to be determined by the regulatory authorities is whether or not there's a causal relationship between those situations and the vaccine.

• (1935

Mr. Don Davies: I know what happened. It's not that they're investigating; they've suspended it. I just named you four countries that have suspended the use of that vaccine. It's not just investigation.

I want to move to something else. Last week—

The Chair: Mr. Davies, thank you.

**Mr. Don Davies:** I have to say, Mr. Chair, you gave the Liberals an extra two full minutes, and you also gave the Bloc an extra full minute. I was timing and I know that's the case. I would like to get one more question in, in fairness.

The Chair: I don't think it's correct that I gave the Liberals two minutes. Certainly, sometimes it happens that answers go over the time and I try not to cut people off, but you'll have another opportunity in the next round.

That ends round one. We'll go to round two, starting with Mr. Barlow for five minutes, please.

Mr. John Barlow: Thank you very much, Mr. Chair.

I will continue on with Mr. Davies' questions. Do we know, either Dr. Berthiaume or Dr. Quach, if we have any of the same batch of the AstraZeneca vaccine that has caused the problems in Europe and Scandinavia with the blood clots? Do we know if we have any of that same batch in Canada?

Dr. Marc Berthiaume: Thank you for your question.

Yes, we know the answer to that, and the answer is no, we don't have the same batches here in Canada.

Mr. John Barlow: The WHO and the FDA have set minimum standards of efficacy of the AstraZeneca vaccine of 50%. Do we have a similar standard that has been set by Health Canada or PHAC?

**Dr. Marc Berthiaume:** That standard has been adopted internationally.

**Mr. John Barlow:** If we have the same standard of 50% in Canada, why are we approving the use of the AstraZeneca vaccine, which has not met that minimum standard here?

**Dr. Marc Berthiaume:** The AstraZeneca vaccine has demonstrated 100% efficacy in clinical trials to prevent cases of hospitalization, so there has been evidence of efficacy. On the symptomatic cases, the data was not sufficient, because the number of cases was too small because the number of patients in clinical studies was too low.

**Mr. John Barlow:** To that question, Dr. Berthiaume, it sounds like you're being creative with the numbers. The stats that we have are that AstraZeneca is 43% effective, so the answer is either that we're approving the use of AstraZeneca, which has 43% efficacy, or that we don't have enough data. To me, it sounds like you're approving the use of a vaccine that is below the standard that is set internationally. It's either 43% or non-existent.

**Dr. Marc Berthiaume:** If I can comment on that, please, the standard of 50% is for the overall efficacy of the vaccine. It's not subject to subpopulation analysis. The overall efficacy of the AstraZeneca vaccine is 62%, and when the doses are spaced, there's some evidence to suggest it could go up to almost 78%.

**Mr. John Barlow:** You're touching on the problem, I think, that all of us on this committee are having—and I would argue the vast majority of Canadians—where every single time, on this health committee, when we're asking questions of those we would expect to be experts, we are getting different answers, different numbers, different statistics.

I don't want to say you're manipulating numbers, but you're finding a way to ensure that AstraZeneca fits a very narrow window where the vast majority of Canadians.... There is confusion here. When we're hearing what's happening in Europe and Scandinavia,

on this panel you're giving very different answers to each one of us on this committee, whether it's me or Mr. Davies or Mr. Thériault—

Dr. Marc Berthiaume: Health Canada's information—

Mr. John Barlow: I haven't asked you a question.

**Dr. Marc Berthiaume:** I'm sorry.

Mr. John Barlow: It's okay.

To either Dr. Berthiaume or Dr. Quach, has the Minister of Health raised the concern of the confusion and the impact that will have on vaccine hesitancy or concerns amongst Canadians? Has the minister raised with Health Canada or PHAC the concern that this confusion is causing?

• (1940)

**Dr. Caroline Quach-Thanh:** I can tell you that the Minister of Health hasn't raised anything with us. We realize, not being stupid, that having conflicting recommendations is going to be a problem. That's why we're aiming to have technical briefings or whatever to explain why there is divergence.

The problem is that we are an independent committee. As much as we would all like to say the same thing, aiming for uniformity would mean that if we were not in agreement, we would have to comply. I'm not sure that aiming for harmony is necessarily what we should be doing.

**Mr. John Barlow:** I would argue, Dr. Quach-Thanh, the opposite. Canadians are looking for direction. When we have two organizations we should trust giving us two different answers, you can understand the concern and the worry this is causing among Canadians.

I have time for one last question.

The AstraZeneca vaccine that we've been given has an expiration date of early April. Is there any data that shows that the closer this vaccine gets to its expiration date, the efficacy or effectiveness of that vaccine deteriorates? Is there any data that shows that it is just as effective on the day of its expiration date as it is the week before that expiration date?

**Dr. Marc Berthiaume:** The answer is that pharmaceutical products or vaccines are as good on the first date as they are on the last date before the expiry. So, yes, from a quality perspective, it's as good as if it was further from the expiry date.

The Chair: Thank you, Mr. Barlow.

We go now to Mr. Van Bynen.

Please go ahead for five minutes.

Mr. Tony Van Bynen (Newmarket—Aurora, Lib.): Thank you, Mr. Chair.

I'd like to take a moment to acknowledge the one-year anniversary since COVID-19 was declared a pandemic, and the lives across Canada that have changed, some of them forever. Today, my respect goes out to all who have lost loved ones and friends, and to our health care heroes who have been on the front line of this fight since the very beginning, as well as to our scientific community, including the ones who are here with us today. I want to thank you all for joining us.

I'll begin with a question for Dr. Njoo. I believe some Canadians may not be aware of the reason why COVID-19 vaccines use a two-dose schedule to reach the very high levels of immunity. Can you walk us through how each of us will gain immunity to COVID-19 through vaccination? Let's start with getting the first dose and going through to the second.

Dr. Howard Njoo (Deputy Chief Public Health Officer, Public Health Agency of Canada): Thank you very much for the question. I would also defer to Dr. Quach-Thanh for further comments, because NACI, Dr. Quach-Thanh and the other members went through the evidence to look at exactly what the real-world data shows, in comparison to the clinical trial data that was obviously used by Health Canada in terms of the approval of the vaccine.

Based on the very good evidence that was presented...for example even Canadian evidence of what happened in British Columbia and Quebec in terms of the high level of protection even after one dose to the residents in long-term care facilities. Based on the principles of vaccinology and immunology, we know that immunity normally doesn't just drop right off after a few months. Certainly, there's been no evidence from other experiences in other countries that this has been the case.

That's why.... And I certainly would defer to Dr. Quach-Thanh. They came out with the recommendation that the interval could be extended up to four months. As Dr. Quach-Thanh said, that doesn't mean that every Canadian who gets the first dose will have to wait exactly four months. It all depends on the shifting of supply, because obviously we're anticipating getting many more millions of doses into the second quarter and beyond.

Overall, from a population health perspective, the thinking is.... Certainly the chief medical officers of health in the provinces and territories, having heard the presentation by NACI a week or so ago, are of a general consensus that it makes sense to immunize more Canadians rapidly with that first dose, given the high level of protection, to have that overall level of population protection. Certainly, as the doses come in, in greater quantity, they would be able to give that second dose.

That is the overall end result in terms of how the provinces and territories are taking the NACI advice. Obviously, within their own context, they are operationalizing it to the maximum benefit of their populations.

Mr. Tony Van Bynen: Thank you.

I'd like to share my time with Dr. Powlowski, but I want to clarify one point. Dr. Njoo, the doses are administered after the advice of professional medical doctors, and not administered by rote. Is that correct?

• (1945)

**Dr. Howard Njoo:** At the end of the day, yes, giving a vaccination is a clinical medical decision. It is a medical act between a health professional and the patient. I think in the normal, ideal setting there's always informed consent. The patient is obviously informed about the risks and benefits. That's an individual interaction between a physician or a health care provider and a patient.

I think what you're also referring to is that, at a population level, from a programmatic perspective, certainly as the vaccine programs

are rolled out in each of the provinces and territories, the overall stance in operationalization has taken that population perspective into account.

Thank you.

Mr. Tony Van Bynen: Thank you.

I'll turn it over to Dr. Powlowski.

The Chair: Dr. Powlowski, you have 45 seconds.

**Mr. Marcus Powlowski:** I'd like to ask a question about the association between the AstraZeneca vaccine and DVTs or PEs. Just because some of the very many people who got the vaccine developed PE or DVT, that obviously doesn't mean a lot. In a place like Thunder Bay, with a population of 100,000, the regional hospital may see five to 10 DVTs or PEs any given day.

How many people actually got DVT or PE, and how does that compare with the overall incidence of those things in the general population? From what I hear, it doesn't sound all that impressive an association.

**Dr. Marc Berthiaume:** I'm sorry; is that a question?

The Chair: Give a quick answer, please.

**Dr. Marc Berthiaume:** The point I was trying to make before is that those events occur naturally in the population. To make a link between the vaccine and the event, you have to determine if the rate of events is higher than the natural occurrence in the population, which has not been made at this point in time.

The Chair: Thank you.

Thank you, Dr. Powlowski.

We'll now go to Mr. Maguire.

Please go ahead for five minutes.

Mr. Larry Maguire (Brandon—Souris, CPC): Thank you, Mr. Chair.

I may share some of my time with some of my colleagues who have questions as well.

Dr. Quach, you indicated that you were looking at.... You are an independent committee, there is no doubt about that, but your decisions are public. You are experts in these fields, and the public knows that. Do you not feel there's an expectation among the public to wait with bated breath for every word you say? The contradictions here have certainly left skepticism among the Canadian public as to what they should do in regard to vaccines. We've talked about vaccine hesitancy. Can you elaborate on that?

Dr. Caroline Quach-Thanh: Yes, absolutely.

We have to realize that Health Canada will authorize a vaccine or a medication, and it's not the first time the clinical guidelines will differ from what has been authorized. In this particular case, Health Canada deemed the vaccine was safe and efficacious enough to be used in all age groups, which is its decision. What we had in terms of data did not make us comfortable enough at that point to allow for the use of AstraZeneca in those aged 65-plus. I realize that since then real-world evidence has emerged. As I said, we met yesterday to review that data.

It's possible that at points in time we will differ in opinion, but I would ask the members of this committee if they think it would be preferable that we would have erred with Health Canada, even though in our opinion we weren't ready to make that recommendation.

We make recommendations based on multiple issues, including looking at other vaccines that are available. As I said, we had two mRNA vaccines that were highly efficacious in those aged 65-plus, and our mathematical modelling showed us that what we had proposed was a recommendation that was completely sane, and that's what the committee was comfortable with.

Mr. Larry Maguire: The other side here too is that we were talking earlier about the time frame, and that a few days can make a difference and change the advice. This was two days, and such conflicting views within that two-day period. I know that science has been extrapolating right through this whole process for a year now, but for the public to absorb the fact that the change took place before the AstraZeneca vaccines even got here.... Can you tell us why?

• (1950)

**Dr. Caroline Quach-Thanh:** Had we known that Public Health England was going to publish its real-world evidence the next day, showing such a high effectiveness in preventing hospitalization, we would have waited an extra day. It's easy when you look back in the—

Mr. Larry Maguire: Would that have changed your mind?

**Dr. Caroline Quach-Thanh:** As I said, we have looked at that, and the recommendations will be updated, but you don't know what's coming in front of you. It's impossible, moving forward, so at one point in time you have to say, "These are the data we had." We had said to the Public Health Agency of Canada that we would aim to get a recommendation out for AstraZeneca within days of Health Canada's approval, because of the fact that vaccines were going to be used in Canada, and therefore provinces and territories needed to know how to use them.

**Mr. Larry Maguire:** You would have had information before you that indicated that some of these products hadn't been used in certain sectors of society, in certain age groups, certain races, people with health concerns, and other areas. Why would the recommendation come out for the vaccine not being used on anyone over 65 if you knew there were other areas that hadn't had trials?

**Dr. Caroline Quach-Thanh:** I'm not sure I'm following your question.

**Mr. Larry Maguire:** Well, there wasn't efficacy done in some of the younger age groups. Certainly they were saying you shouldn't use it on anybody over 65, but—

**Dr. Caroline Quach-Thanh:** We had data on the 18 to 64, with a confidence interval that did not include zero, so I am not sure what you're referring to.

**Mr. Larry Maguire:** You didn't have it, but then you know there were conflicting views within a few days of the decisions that you were making.

**Dr. Caroline Quach-Thanh:** The fact that Health Canada and our recommendations do not align is not conflicting views, to my sense. Health Canada is looking at data with a different paradigm. We are looking at the data knowing what else we have in our portfolio. Health Canada is not ranking one product versus the other; we are.

The Chair: Thank you, Mr. Maguire.

We go now to Mr. Fisher.

Mr. Fisher, please go ahead for five minutes.

Mr. Darren Fisher (Dartmouth—Cole Harbour, Lib.): Thank you very much, Mr. Chair.

At the start of every time I get a chance to speak at committee, I always thank the witnesses, but I have to tell you, I am so appreciative that we have experts and scientists like the people on this panel, the people at Health Canada and the people at NACI, who are making these decisions and these recommendations for provinces and territories, and not politicians. My gosh, what a state we'd be in. Thank you so very much for all that you are doing.

We talk about NACI, and we heard that they have been independent expert advice providers for over 50 years and have been appreciated by provinces and territories for 50 years. This is absolutely....

I want to go to Dr. Quach-Thanh.

When it comes to the health and safety of Canadians, we know that we need to rely, as I said, on experts in science. It's imperative that medical decisions be made by health professional experts, as I said, and not by politicians. Canadians need to know that the vaccines they are taking are safe and that the recommendations made for their use are based on what is best for them and what is best for Canadians across the country.

Dr. Quach-Thanh, can you talk just a little bit more about the role of the national advisory committee on immunization? Whom does NACI create their recommendations for, and what factors are you considering when making those recommendations?

Dr. Caroline Quach-Thanh: Thank you for your question.

Basically, NACI creates the recommendations for provinces and territories so that each province and territory can then take up the recommendations and apply them to its own epidemiology, jurisdiction, logistics concerns, etc. Once our recommendations are out, they are then taken up, mashed up and put into the Canadian immunization guide, which is used by health care providers.

The problem with the pandemic is that everything changes so quickly that the CIG does not have a piece about COVID vaccine. Health care professionals are looking into the statements to try to understand the background to our recommendation. That piece is happening, but it's a little bit delayed, so we've decided that the statements would be used, at the same time, by health care professionals and provinces and territories.

NACI does not speak directly to Canadians, usually. We are there to support the public health measures. Having people go through it and try to understand it might be more complicated. We realize that the language we use is not layman's language. It is what public health understands and what health care providers understand. Even at that level, some health care providers called us to say they were not sure they understood the differences between strong NACI recommendations and discretionary, because this was based for provinces and territories.

The elements we look at to make a recommendation are burden of illness and vaccine characteristics, including safety, immunogenicity, efficacy and effectiveness, but also, as Kim said, ethics, equity, acceptability, feasibility, mathematical modelling and economics, when it comes to that. At this point in time, economics hasn't been incorporated in NACI vaccine decisions, because regardless of how much it costs, we are going to use those vaccines.

When we look at all of those elements, it is possible that a little bit less efficacy will be trumped by the ability to deliver more vaccines to more Canadians, because in our mathematical model, when you compare various possibilities and various scenarios, that seems to be the most optimal.

Are we always right? I can't say that we're 100% right. I mean, things are evolving. You make recommendations based on the best of your knowledge, and we really work at this from a generous and *de bonne foi....* There's nothing here that we're trying to conceal; it just happens that this time around, we and Health Canada did not say the same thing.

As I said, it's not the first time it has happened. It's just the first time that people noticed.

• (1955)

Mr. Darren Fisher: Thank you.

Do I have any time, Mr. Chair?

The Chair: You have 30 seconds.

**Mr. Darren Fisher:** To some extent, Kim, the opposition is helping to sow some of this confusion. They continuously talk about how Health Canada ignored the advice of NACI.

Maybe you could tell us how NACI and Health Canada have totally different mandates.

**Ms. Kimberly Elmslie:** Of course, I will turn to Dr. Berthiaume in terms of the regulatory mandate, but as we know, Health Canada carries the mandate to regulate vaccines, and therefore looks at clinical trial data, data from the manufacturer, to understand and assess the quality, efficacy and safety of vaccines.

NACI, of course, is using similar data and looking also at realworld data as it becomes available. The mandate of NACI is very much to use the expertise on that committee, which is very multidisciplinary, to provide advice to provinces and territories on the "how" of using authorized vaccines in Canada.

**Mr. Darren Fisher:** The provinces choose to take that advice or not. They decide whether they're going to take advice from NACI.

Ms. Kimberly Elmslie: That's absolutely correct.

**The Chair:** Mr. Fisher, you're done. **Mr. Darren Fisher:** Thank you.

The Chair: Thank you.

[Translation]

We'll continue with Mr. Thériault.

You have the floor for two and a half minutes.

Mr. Luc Thériault: Mr. Chair, we had an interpretation issue.

Personally, I take comfort in the fact that NACI is not complacent, that it renders opinions based on the science available to it, and that it may not be what we would like to hear. I am perfectly fine with that.

The Public Health Agency of Canada, on the other hand, must ensure that there is buy-in for the message. For the public to buy in, you need their confidence. So we are in a vaccination situation where we have no choice. We are told to take whatever they say we should take.

Ms. Elmslie, don't you feel a little uneasy that 300,000 doses of AstraZeneca's vaccine to come are expired?

Moreover, because of its adverse effects, some countries have decided to stop administering it until more light is shed on the matter. Do you not feel uneasy about that?

Isn't it unusual to receive 300,000 doses of a vaccine that will expire in under a month?

• (2000)

[English]

**Ms. Kimberly Elmslie:** From the point of view of vaccine safety, that is of course the highest priority for the Public Health Agency of Canada and our work with our colleagues at Health Canada.

[Translation]

**Mr. Luc Thériault:** I'm sorry, but interpretation is not working. [*English*]

**Ms. Kimberly Elmslie:** From that perspective, the safety system in Canada is very strong. We have a system that works with manufacturers, provinces and territories—

**The Chair:** Pardon me, Ms. Elmslie. Could you make sure your microphone is in the right place?

Yes, absolutely, Mr. Thériault. If you have a problem, raise a point of order immediately so we can deal with it.

Say a few words, Ms. Elmslie, and we'll see if the translation is happening.

Ms. Kimberly Elmslie: Is the translation happening now?

The Chair: Mr. Thériault, could I have a thumbs-up?

[Translation]

Mr. Luc Thériault: Yes, it's working now.

[English]

The Chair: Thank you.

Mr. Thériault, I will resume your time at this point.

Go ahead, Ms. Elmslie.

Ms. Kimberly Elmslie: Thank you.

If you don't mind, I'll just conclude quickly by saying that the safety system in Canada is very strong. It is watching very carefully for any safety signals and investigating any side effects that occur after administration of COVID-19 vaccines.

Dr. Berthiaume-

[Translation]

**Mr. Luc Thériault:** That doesn't answer my question. I'm sorry, perhaps I didn't make myself clear.

The media are reporting that 300,000 doses will expire on April 2. Health Canada is not following the National Advisory Committee on Immunization's recommendations on the use of AstraZeneca's vaccine.

The Chair: Mr. Thériault—

**Mr. Luc Thériault:** Aren't you concerned about message buy-in or confidence in vaccination?

Was that the extra time allotted to me, Mr. Chair?

The Chair: Yes.

**Mr. Luc Thériault:** All right. Can we get a response anyway? [*English*]

The Chair: Mr. Thériault, I did give you extra time, but we'll get an answer to the question and then move on to Mr. Davies.

Please answer the question. Thank you.

Ms. Kimberly Elmslie: Thank you for the question.

If I understand correctly, you are talking about the doses of vaccine that are coming into Canada and their use within the time frame. As Dr. Berthiaume pointed out, those doses are usable from the point of their arrival until their expiry date. We're not concerned about a tailing off of effectiveness.

Perhaps I misinterpreted your question.

[Translation]

The Chair: Thank you, Mr. Thériault.

[English]

We'll go now to Mr. Davies.

Mr. Davies, please go ahead for two and a half minutes.

Mr. Don Davies: Thank you.

Ms. Elmslie, last week it was confirmed that 300,000 of the 500,000 doses of AstraZeneca doses that Canada received from the

Serum Institute of India will expire in just one month's time. Did another jurisdiction or purchaser reject those doses?

**Ms. Kimberly Elmslie:** I do not have any information on that question. I will certainly be happy to get back to you with an answer, but I'm not aware of that.

Mr. Don Davies: Thank you.

Dr. Quach-Thanh, in light of NACI's recommendation against use in adults 65 and older, are you confident that those doses will be administered before they expire?

**Dr. Caroline Quach-Thanh:** I hope so, but the rollouts are provincial jurisdiction, so I don't have any say on that matter.

**Mr. Don Davies:** I want to turn to the issue of extending second doses to four months.

Cole Pinnow, the president of Pfizer, said the following this week to this committee:

All the research to date on our vaccine has been done with two doses that have a schedule of 21 days. The recommendation that's been put in place by NACI, as highlighted earlier, in Canada is the only one in the world that is recommending an extended dose delivery.

He then continued:

The data that we've seen from a real-world evidence perspective that has been used to make arguments to extend the dose schedule has been with regard to much younger populations. The fact is that we don't have any data after two months to know what the impact of one dose will be.

Is extending the dose interval to four months a responsible choice for older populations in light of what Mr. Pinnow told this committee?

**Dr. Caroline Quach-Thanh:** As I said, you're right. We have data up to two months on, including data for long-term care facility residents, in whom the vaccine effectiveness is above 80%. In that data, we don't see a decline of vaccine effectiveness over time, up to two months.

What the modelling has shown us is that even if we were to include a 5% decline of vaccine effectiveness over time, the benefit in terms of a decrease in hospitalizations and mortality at the Canadian level would still be beneficial.

**●** (2005)

**Mr. Don Davies:** Well, that's your speculation based on models. It's not based on data.

**Dr. Caroline Quach-Thanh:** But you know what? Because we're in a pandemic, at times we have to make decisions that are difficult

**Mr. Don Davies:** Fair enough. I'm just trying to figure out what it is we're basing it on.

This is my last question. Dr. Mona Nemer said the following with respect to that, which was that this "amounts right now to a basically population level experiment". She said, "I think it's really important that we stick with the data and with the great science that gives us these fantastic vaccines, and not tinker with it."

Is this a "population level experiment"?

**Dr. Caroline Quach-Thanh:** Know that during the pandemic everything is more or less a "population level experiment". When we decide to do a lockdown and when we decide to do other things, we don't necessarily have the data. We have to make decisions based on incomplete data, and that's why you have experts who will generalize from what they know from other situations to try to make the best decision.

I agree that if we had that data it would be perfect, but waiting to have that data just makes it impossible to reopen the economy, try to vaccinate the population and get children back to school. At one point in time, not deciding or deciding to stick with the on-label recommendation is often much easier, but it doesn't mean that in the end it will end up giving us the best outcome for our population.

Trust me. If I were able to just stick to label, I would. My life would be so much easier today. But I don't think, and the committee didn't think, that was the best thing to do for the Canadian population, so we recommended to try to use the first doses for as many people as possible, and give the second doses when they come.

As we said, four months is the maximum interval. It doesn't mean that you stick to four months; it just means you can go up to four months to try to curtail the pandemic as quickly as possible and try to combat variants that are showing up a little bit across Canada.

The Chair: Thank you, Mr. Davies.

Mr. Don Davies: Thank you.

The Chair: That was actually just about an extra two minutes.

We'll start round three now, with Ms. Rempel Garner.

Ms. Rempel Garner, please go ahead for five minutes.

Hon. Michelle Rempel Garner: Thank you, Chair.

Continuing on with Mr. Davies' comments, Ms. Quach-Thanh, do you have data that you're able to table with the committee showing that the benefits you just stated outweigh any potential risks associated with the four-month interval?

**Dr. Caroline Quach-Thanh:** There is a bulletin that was published last week from NACI with the pros and cons of that recommendation. We will be having more data in that statement when the provinces have published their data. At this point in time, they were provided to us, but under a confidentiality agreement, and we're waiting for those to be public to update that statement.

**Hon. Michelle Rempel Garner:** Would you have made that recommendation if there had been more supply of the Pfizer vaccine?

Dr. Caroline Quach-Thanh: Of course not.

Hon. Michelle Rempel Garner: On January 7, the Montreal Gazette said:

The Pfizer and Moderna vaccines use a new technology, and it can't be taken for granted that what has worked in the past will also work now.

"My gut feeling is that up to six weeks, I won't have any problems," said Quach-Thanh. "After that, can I say that up to 12 weeks there are still no problems? I'm not sure"

Is the four-month recommendation a "gut feeling"?

**Dr. Caroline Quach-Thanh:** It's based on the data we have from the U.K., from B.C. and from Quebec, where up to eight weeks we see that actually the effectiveness is quite good. As I said, we don't have data for up to four months in terms of effectiveness, but we have modelling data and we have expertise in immunology. It's really a decision that was very hard to make, but—

**Hon. Michelle Rempel Garner:** But you wouldn't be making that decision had there been supply of the mRNA vaccine.

**Dr. Caroline Quach-Thanh:** If we had had enough vaccines to vaccinate all Canadians quickly, or at least those most at risk, with two doses of vaccines, we would not have needed to extend the interval. That's for sure.

#### Hon. Michelle Rempel Garner: That's interesting.

You started talking about the Pfizer vaccine being used. You characterized the four-month interval as an off-label usage. Would that be a correct characterization?

Dr. Caroline Quach-Thanh: Absolutely.

Hon. Michelle Rempel Garner: I'll go to Health Canada.

Are there any contract implications for recommending the Pfizer vaccine for off-label usage in this manner?

• (2010)

**Dr. Marc Berthiaume:** I'm not aware of any contract details. Those were dealt with by Public Services and Procurement Canada.

**Hon. Michelle Rempel Garner:** On that, I'd like to pause my time for a minute, Chair.

On a point of order, we did ask that Dr. Roman Szumski, the senior vice-president of the vaccine acquisition branch, appear before the committee as part of this motion. Could you tell me why he's not here tonight?

**The Chair:** All of the witnesses requested were invited, but they weren't all able to attend.

I will also note that bells are going, so we need unanimous consent to proceed. I suggest that we might be able to squeeze in the rest of this round. I'll ask the committee if they wish to do that.

Is there any will to try to squeeze in the rest of this round before we suspend for the vote?

#### Hon. Michelle Rempel Garner: Sure.

The Chair: I'm seeing general consent, so we'll carry on. If it looks like we're running too close to the wire, we'll pull the plug then.

Thank you, all. We'll carry on.

Ms. Rempel Garner.

Hon. Michelle Rempel Garner: Thank you, Mr. Chair.

Dr. Quach-Thanh, do you know how many doses of the Pfizer vaccines we would have needed in Q1 in order to avoid the recommendations you made?

**Dr. Caroline Quach-Thanh:** You would have to ask the Public Health Agency of Canada how many people fell into the high-risk categories. They have that data. It's just that I don't know them by heart.

**Hon. Michelle Rempel Garner:** Ms. Elmslie, would you table that with the committee, preferably at a quicker pace, without me having to submit a motion to compel it here—let's say, in the next week?

**Ms. Kimberly Elmslie:** Yes, we will take that back to the department. Thank you.

#### Hon. Michelle Rempel Garner: Okay.

Ms. Elmslie, I will note that I might have to put forward motions to compel information from your committee that you said you would provide but have not been provided yet. I find that unacceptable.

Dr. Berthiaume, have you had any interaction with Pfizer or Health Canada with regard to the decision on the dosing interval going from three weeks to four months? Have they advised you in any way on that?

**Dr. Marc Berthiaume:** I'm sorry. I'm not sure I understand the question. The discussions between Health Canada and Pfizer were for the approval, and they continue about ongoing data and safety issues, but the way the doses are administered in the provinces is not a matter that is written—

**Hon. Michelle Rempel Garner:** Thank you. I'm on my last question with the time I have left.

Dr. Quach-Thanh, did NACI consider the possibility of the development of vaccine-resistant variants, as a paper in The Lancet recently discussed, in your decision to recommend increasing the dosing interval of the Pfizer vaccine to four months?

**Dr.** Caroline Quach-Thanh: We did, and the immunologists we consulted said that this was a theoretical risk and that they didn't see why extending the interval would increase the risk of having variants show up. The most important thing—

**Hon. Michelle Rempel Garner:** Can you table that data with this committee in the next week?

**Dr. Caroline Quach-Thanh:** It was a discussion, but I can try to get you something in writing.

Hon. Michelle Rempel Garner: Thank you.

Thank you, Mr. Chair.

The Chair: Thank you, Ms. Rempel Garner.

We'll go now to Mr. Kelloway.

Please go ahead for five minutes.

Mr. Mike Kelloway (Cape Breton—Canso, Lib.): Thank you, Mr. Chair.

Before I get into my questions, I just want to thank all the witnesses as well for the work they're doing on behalf of Canadians, and I want to thank them for answering all the questions tonight. In my opinion, it's easy to criticize distribution plans, recommendations and decisions, and in some cases to incite fear in people when it comes to the vaccines. However, I have full confidence in you

folks, and I know that you have the best interest of all Canadians in mind. I'm really filled with gratitude for the work you're doing. In my opinion, you're not just Canadian leaders; I truly believe you're world leaders.

I'm going to start off with Dr. Quach-Thanh. I guess it's a practical scenario, and it's kind of how we roll here in Cape Breton—Canso. Here in Nova Scotia we've begun vaccinating seniors over the age of 80. My mom actually received her letter last week. We are all very pleased by that.

I noticed when booking a vaccine appointment that there is now up to a 105-day waiting period between the administration of the first dose and the second dose, rather than two to three weeks between the doses.

I think you've highlighted this, but this is a chance for you to do a deeper dive. I'm wondering if you can explain to the committee—and, just as important, to those following at home—why NACI is recommending that COVID-19 vaccine intervals between the first and second dose could be extended up to 105 days. Also, can you give us a deeper synopsis of what has changed since the original recommendations?

#### • (2015)

**Dr. Caroline Quach-Thanh:** I'll start with the last part of your question.

What changed since the original recommendation was that data came out of the U.K., Quebec and B.C. showing that at eight weeks we still had higher than 80% effectiveness, even in the long-term care residences, which to us was a sign that these vaccines are actually quite good.

As I said, given the mathematical modelling, what we did was decrease the vaccine effectiveness over time which...a more or less steeper curve to that decline. Regardless of the decline, giving one dose of vaccine to as many Canadians as possible was the scenario that most decreased the number of hospitalizations and deaths, mainly when you give it now because what's important is now. Maybe Nova Scotia is great, as you don't have that much transmission, but in other provinces it's rampant.

What we want is to decrease transmission as quickly as possible, because then you decrease the risk of having variants come up. A variant happens when the virus replicates and makes a mistake, and that mistake is actually good for it. If it replicates less, because it's transmitting less, then you decrease the risk of those variants occurring. Based on the data, we decided to extend the interval to allow for that first dose to be given to as many people as possible.

I think what is very important in all this is that we have surveillance systems for effectiveness so that we have real-time data of what's happening. In Quebec, B.C. and Alberta, and probably in Nova Scotia as well, people are able to say, "We're now at nine weeks and the vaccine effectiveness is X. We're still good to go. We're now at 10 weeks and the vaccine effectiveness is Y. We're still good to go." When we see that it decreases anywhere, it's then easy to say, "We're rolling back the vaccines and starting to give that second dose now." All it means is that the vaccines are there, instead of decreasing in the people under 60, people with underlying medical conditions between 18 and 59. You bring back those vaccines and you say, "Those who were first vaccinated aged 70 and over, we're now giving it to them."

We have the ability to follow a vaccine's effectiveness in time, and it is because of this that we're able to say.... We don't have all the data. I would be lying to you if I said we did, but we have the ability to change our recommendations quickly, and the provinces are doing that very well.

Mr. Mike Kelloway: Thank you, Doctor.

How much time do I have left, Chair?

The Chair: You have 40 seconds.

Mr. Mike Kelloway: I'll try to get this in.

I'm sure many of you here today are familiar with the famous French scientist and vaccine pioneer Louis Pasteur. He once said, "Do not let yourself be tainted with a barren skepticism." I think that quote is relevant today.

Dr. Njoo, are you concerned that questioning the safety of the delay of the second dose, despite clear science and the evidence that's available, feeds into the vaccine hesitancy? Basically, how can we reassure Canadians that all vaccines approved for use in Canada are safe and effective?

**Dr. Howard Njoo:** Thank you very much for the question about vaccine hesitancy. Obviously, it's a complex issue and there are many facets to it in terms of improving vaccine confidence in Canadians overall. There are multiple facets.

First of all, we have one of the most respected and most rigorous regulatory systems in the world with our colleagues at Health Canada. I think Canadians have assurance that any vaccine approved in Canada is both safe and effective. I think that's the first step.

Certainly, mass campaigns and the press conferences that many people, including me and Dr. Tam, are involved with are also important, in terms of reinforcing key messages to Canadians about the importance of vaccination and how it benefits them in terms of protection.

We also recognize—and I think this is a key point that maybe hasn't been raised—that Canadians, in terms of getting information to improve their comfort level with vaccines.... It's not because of me personally; I think it's because they have trust in their personal health care provider. One of the important things that we're also doing, through webinars and so on, is giving the tools so that frontline health care professionals and providers feel empowered and are able to give credible information so their patients can make an informed decision regarding getting vaccinated. I think that's a key step.

Another part is that we recognize there might be different levels of reticence or vaccine hesitancy in certain racialized communities. Therefore, it's also very important to engage with community leaders in those communities. We've seen them do that, for example, in various indigenous communities. The leaders have come forward, gotten vaccinated, put it on social media and said, "Look at this. I

got my vaccine. I'm protected. My family is protected. It's good for me. It's good for everyone." Those are the kinds of things we're doing.

I would also say that, at the end of the day, there is a bit of a responsibility on every Canadian. The fact is that the Internet is a powerful tool and there's a lot of misinformation, disinformation and so on. The responsible use of the Internet, in terms of not using clickbait and making misinformation go viral, is also very important

Finally, I want to say that-

• (2020)

The Chair: Doctor, I'm going to have to cut you off there.

Dr. Howard Njoo: That's fine. Thank you very much.

The Chair: We'll go back now to Ms. Rempel Garner for five

Hon. Michelle Rempel Garner: Thank you, Chair.

Dr. Quach-Thanh, why was four months selected as the dosing interval for Pfizer? Why not three or five? Why four?

Dr. Caroline Quach-Thanh: That's an excellent question.

The modelling has shown us that the ideal interval would be six months if we wanted to have the most gain in terms of decrease in hospitalizations for Canadians. However, when we looked at six months and the supplies that we were going to have, we were told that we would never need to go beyond four months because we would have enough doses to do that.

**Hon. Michelle Rempel Garner:** So four months was chosen simply based on a vaccine delivery schedule?

**Dr. Caroline Quach-Thanh:** It was based on vaccine delivery and mathematical modelling.

**Hon. Michelle Rempel Garner:** Okay, so there was no actual scientific.... This was based purely on a procurement schedule, like desperation in a procurement schedule.

**Dr. Caroline Quach-Thanh:** There is a basis of science, but you're right that four months—and not four and a half or five—was based on procurements.

Hon. Michelle Rempel Garner: Wow. I'm kind of shocked.

Do you think Canadians might be concerned that you're making decisions based on procurement schedules rather than on solid clinical data?

**Dr. Caroline Quach-Thanh:** The thing is that we looked at a six-month interval but didn't think we would need to go up to six months. You can look at the literature. Very renowned vaccinologists, such as Stanley Plotkin in the U.S., are also recommending delaying the second dose for as long as needed to give that first dose to as many people as possible.

**Hon. Michelle Rempel Garner:** But the Americans are all going to be vaccinated by May 1, so it's kind of—

Dr. Caroline Quach-Thanh: That's because they have—

Hon. Michelle Rempel Garner: They have supply, right?

**Dr. Caroline Quach-Thanh:** They have supply.

Hon. Michelle Rempel Garner: We don't.

We're at the heart of this here. We are, to use the chief science officer's words, conducting a population-based experiment on a non-data-driven dosing interval because we failed on procurement.

Is that a correct characterization?

**Dr. Caroline Quach-Thanh:** I can't tell you how procurement works. It's not my—

**Hon. Michelle Rempel Garner:** We don't have the supply, so we've been forced into this corner because we don't have the supply.

**Dr. Caroline Quach-Thanh:** I think that given the scarcity of vaccines, you have to make the best decision given what you have.

**Hon. Michelle Rempel Garner:** It just blows my mind. I know it's not your fault. I get the situation you're in, and it must be hard.

Dr. Caroline Quach-Thanh: I can't say it's easy, no.

Hon. Michelle Rempel Garner: On that, I think you and I share something, because I get calls in my office from people who say, "What should I do? Should I take the AstraZeneca vaccine? Should my mom take the AstraZeneca vaccine?" Obviously I can't say one way or the other; I have to rely on advice. I have you guys saying one thing and Ms. Elmslie saying that everything's changing every day, and I feel as though this lack of a protocol and lack of supply are leading to confusion in the Canadian public. It's really hard.

Perhaps I'll go to Dr. Njoo.

Has the minister given you any direction to develop a better communication protocol, given the debacle on the conflicting advice and balkanization of provincial guidelines on dosing and availability?

Dr. Howard Njoo: Thank you very much for the question.

If I understand your question, no, the minister has not given me any personal direction in terms of communication. I think it's fairly clear—

• (2025)

**Hon. Michelle Rempel Garner:** Do you think it's necessary, though? This seems like a bit of a cluster in the public. Do you think that perhaps a better communications protocol is needed at this point?

**Dr. Howard Njoo:** I think in the general area of risk communications, we could always do better. I think even I personally—

**Hon. Michelle Rempel Garner:** What would you do better? What would you say to the person who is really confused right now and is listening to this testimony saying we're going way off label on dosing interval because we don't have adequate supply?

**Dr. Howard Njoo:** I would say, go to your trusted health care professional because—

Hon. Michelle Rempel Garner: Who is that here? Is it you? Is it NACI?

**Dr. Howard Nioo:** No, it's the family doctor of the person—

Hon. Michelle Rempel Garner: Where does the family doctor—

Dr. Howard Njoo: —who would actually administer the vaccine.

Hon. Michelle Rempel Garner: So now it's doctors.

**Dr. Howard Njoo:** The decision would obviously rest with the programs in the provinces and territories that made the decision in terms of the population level—

Hon. Michelle Rempel Garner: It feels like everybody is pointing at each other.

**Dr. Howard Njoo:** It comes down to the individual health care professionals and the patients.

**Hon. Michelle Rempel Garner:** So it's not the doctors. It's not PHAC.

**Mr. Tony Van Bynen:** On a point of order, Mr. Chair, if the member doesn't want to hear the answer, maybe she shouldn't ask the question.

**Hon. Michelle Rempel Garner:** No, I'm just very frustrated, Mr. Chair. I think a lot of Canadians are as well. I get that everybody has a heavy job, but there's a lot of finger-pointing here. I think a lot of responsibility needs to be taken, perhaps by the minister.

The Chair: Thank you, Ms. Rempel Garner.

It's becoming clear to me that we're not going to be able to finish this round before the votes. On that basis, I suggest that we suspend and resume as soon as we can all get back here after the vote. We will resume with Dr. Powlowski, followed by Mr. Thériault and Mr. Davies

With that, members, we are suspended for—

**Mr. Don Davies:** Mr. Chair, I have a quick point of order. I can vote virtually. I don't know if my colleagues can. If we can all vote virtually, why can't we carry on the meeting? It will take me 30 seconds to vote on my phone virtually.

Does anybody on the committee have to be present in the chamber to vote, or can we all vote virtually?

The Chair: If we want to do that, it's going to require unanimous consent. We can all vote virtually. I think all of us are in our respective non-chamber locations.

I'm still not 100% confident that all of the technology has been worked out, so I'm much more comfortable being logged into the Zoom session. However, I'll ask the committee if there's unanimous consent to carry on and vote virtually. The suspension will probably be only 20 or 25 minutes.

**Mr. Don Davies:** It's out of respect for the witnesses' time as well. It seems like we only have about 10 minutes of time left anyway, don't we?

The Chair: I have to look at my virtual thing here.

Mr. Chris d'Entremont (West Nova, CPC): We have 10 minutes and 48 seconds.

The Chair: Yes, so we don't have time for Dr. Powlowski's question, as well as yours and Luc's. We do need to—

**Mr. Don Davies:** Mr. Chair, I'm sorry, but what I meant was that we only have about 10 minutes left of questioning.

**The Chair:** That's what I mean. I don't think we have.... We could try to shoehorn that in, I suppose.

Is it the will of the committee to carry on a bit further?

**Mr. Tony Van Bynen:** I don't support that, Mr. Chair. Unfortunately, this is a very critical vote for the House. If there are any glitches in the system, I want my voice to be heard. I therefore want to sign in and be present.

The Chair: Thank you, Mr. Van Bynen.

We will suspend and then resume as soon as we can all get back here after the vote. It shouldn't be too long. My apologies to the witnesses.

We are suspended.

• (2025) (Pause)

• (2120)

The Chair: We now resume the meeting.

I thank the witnesses for hanging in there with us all during the vote. It's one of the costs of doing business in this place.

The Clerk of the Committee (Mr. Jean-François Pagé): Mr. Chair, just a second. The interpretation is not ready.

The Chair: Okay.

I was saying nice things, too.

**The Clerk:** It's a technical problem with the interpreters.

**Mr. Tony Van Bynen:** Mr. Chair, as well, my video doesn't seem to be working. Maybe I should do a restart.

**The Chair:** I would just as soon not wait for you to restart. We can hear you and we have a nice picture of you on the screen. For me, that's good enough.

Let's get this under way. Are we all good with translation?

The Clerk: Not yet, Mr. Chair. We need 30 seconds.

The Chair: Okay. Thank you.

The Clerk: Mr. Chair, it's all good. Go ahead.

The Chair: Thank you, Mr. Clerk.

As I said, we are resuming meeting number 24 of the Standing Committee on Health as we continue our study into the consequences of the COVID-19 pandemic.

I certainly want to thank the witnesses for hanging in there while we had to suspend for that vote. It is certainly one of the costs of doing business. We are certainly very much aware of the kind of time and effort you guys put in on a daily basis, so it's really appreciated that you were able to hang in here with us. With that, we will resume our third round of questions, with Dr. Powlowski.

Dr. Powlowski, please go ahead. You have five minutes.

**Mr. Marcus Powlowski:** I think Ms. Rempel Garner asked a key question. Canadians want to know, is this a good vaccine? Should I recommend it for my parents, if they have the opportunity to get this vaccine, or for my brother, who has a lot of underlying medical problems? I think the answer is yes. Unfortunately, in this meeting it's about as clear as mud, as far as I'm concerned, because there are so many different numbers out there. I think part of the confusion is the difference between "efficiency" and "effectiveness".

I'll direct this to you, Dr. Quach-Thanh, because I think you know the numbers pretty well. My understanding of the efficiency comes from the phase three randomized control trial, where you had either the AstraZeneca vaccine or the placebo. Overall, the efficacy was 62%, but it was something like 40% in people over 65. However, to my understanding, I think in North America it showed 72% efficiency, and with half the first dose 90% efficiency.

That's from a randomized control trial, where you pre-select the people. In the actual real-world experience, the effectiveness has actually shown AstraZeneca looking better. There was the study by Hung and Poland in The Lancet, with 17,000 people. This was the one where they looked at giving the booster four months afterwards. They found an 81% effectiveness, including in the elderly. The other numbers I saw showed, with a four-month interval in spacing, 76% to 82%. They were certainly a lot better numbers than the 62% and the 40%. If you look at the efficiency or efficacy from the actual trial with AstraZeneca in preventing deaths, it was 100% efficient or effective in preventing death. In hospitalizations, the Scottish study showed 94%, but you're not going by those numbers.

Is that about right? In the actual study by AstraZeneca, nobody who got the vaccine died, and giving it four months apart was about 80% effective in preventing clinical illness. Is that right? As well, what is the hospitalization rate?

**●** (2125)

**Dr. Caroline Quach-Thanh:** You right that it's very complicated because there are so many numbers. Basically, 60% is the overall efficacy estimate, but if you look at people who got it with a longer interval, so 12 weeks and over, you're right that it then goes up to over 80%. In real-world effectiveness in terms of preventing hospitalization and death, it's above 80% even for elderly populations.

What I was saying was that those data came out after the NACI recommendation was released on March 1, and therefore these data are being included in the updated statement that will be published within the next few days.

**Mr. Marcus Powlowski:** Is the updated data from the Lancet study, or is there some other data supporting the use in people over 65?

**Dr. Caroline Quach-Thanh:** There are two Public Health England publications. I can't remember exactly what journals they were in. Those two studies are being added to the corpus of the evidence. They are all real-world effectiveness. We do not have new efficacy data. These will come out when the U.S. trial is looked at, which should come sometime in April.

**Mr. Marcus Powlowski:** To reiterate, the effectiveness is actually the more impressive number. It's the better number.

Dr. Caroline Quach-Thanh: Yes.

**Mr. Marcus Powlowski:** We would have thought it would have been the other way around, that the efficiency would be higher.

Dr. Caroline Quach-Thanh: Correct.

**Mr. Marcus Powlowski:** I think when you actually look at the numbers for AstraZeneca, it's really not too bad.

I also I want to ask you about the Scottish study. I think that's based on the NIH, which automatically has data collection. To my understanding, in that, over 400,000 people, many of them in their eighties, got AstraZeneca, and they were reporting a 94% reduction in hospitalization. Now, I realize that you said that if you look at the data, they were reporting a pretty significant reduction in hospitalization in the first few weeks, which doesn't make much sense immunologically. However, when you look at the total number, 400,000, that's a pretty well-powered study—

**Dr. Caroline Quach-Thanh:** I wasn't talking about power. The problem is that there is a bias in the study because the people who were vaccinated were very different from those who weren't. Not being able to explain this 70%-something effectiveness in the first two weeks following vaccination in terms of decrease in hospitalization just makes one wonder what the problem with that study is.

We have better studies. Based on just that study, we didn't feel comfortable changing our recommendation at that point in time.

The Chair: Thank you, Dr. Powlowski.

• (2130)

[Translation]

Mr. Thériault, you have the floor for two and a half minutes.

**Mr. Luc Thériault:** My first question will be brief, and the second will be about methodology.

Dr. Berthiaume, to retain people's confidence in the vaccination process, would it not be better to be proactive, given that there is no connection between not being proactive and the fact that 300,000 doses of AstraZeneca will expire on April 2?

Would it not be better to just suspend vaccination with the AstraZeneca vaccine until we have the full story on what's happening in Denmark and Norway? That would take a few days or a week at the most, in my opinion.

Dr. Marc Berthiaume: Thank you for your question.

This evening, Health Canada issued an advisory to say that it currently has no safety concerns with Canadian doses.

In Europe, they are investigating, but several advisories they have issued say that the side effects were probably not related to the vaccination. Currently, it's likely that the events are related to the effects seen in the general population and not to the vaccination. However, that remains to be confirmed.

At this time, it would be premature to go ahead and stop vaccination based on the current data.

**Mr. Luc Thériault:** All right, but how many days will it be before we find out?

**Dr. Marc Berthiaume:** Based on the data we have, I believe there are 30 cases out of 20 million doses. I would have to look at the numbers again. However, we already know that this number of cases is well below the normal incidence of these pathologies.

Those cases are linked in time, but not in causality.

**Mr. Luc Thériault:** So you're saying that those countries suspended the use of the vaccine for nothing, and that, if we had the same data, we would have no reason to suspend vaccination here in Canada.

**Dr. Marc Berthiaume:** Europe has not reached a consensus on suspension. In the United Kingdom, where the vaccine is most widely used, they have decided not to suspend the use of the vaccine.

Mr. Luc Thériault: Thank you very much.

Dr. Quach-Thanh, in response 3 that you sent us today, you state the following:

At present, there is uncertainty as to the degree to which the vaccines prevent people from acquiring the infection...

Later, you add:

Until such data is available, modellers are not in a position to estimate the proportion of the population needed to vaccinate to reduce R below 1...or to compare between vaccines in their capacities to do so.

Can you explain to me how you plan to compile data on the vaccines administered so that, for example, you can compare their capacity to deal with variants?

**Dr. Caroline Quach-Thanh:** I will try to answer your question. I'm not convinced that I fully understood it.

In terms of asymptomatic infections, that data is being collected in various studies. We know that, for AstraZeneca, which looked at this factor when the other companies did not—we will at least give them that—the efficacy from the standpoint of decreasing asymptomatic infections was not good. The other companies did not study this factor, so that may be the case for them as well.

In terms of variants, no link has been established between an asymptomatic infection and a variant. Currently, several ways are being used to find out if a vaccine works against a variant or not. We have in vitro methods. After vaccinating a person, we take their antibodies to see if they are able to neutralize the variant virus. In addition, we look to see if the person's cellular immunity has any effect on the variant.

The other way is to do vaccine effectiveness studies. They involve determining how many infections the vaccine is able to prevent from a variant, compared to when there is no variant.

In their phase 3 studies, AstraZeneca and Johnson & Johnson struggled with the South African and United Kingdom variants. So they sometimes have somewhat lower vaccine efficacy rates than Pfizer and Moderna, who did their studies much earlier, before the variants emerged. You have to take that into account in the data analysis as well.

As to how the current data can be used to determine whether or not we're able to control the variants, it's really possible by monitoring vaccine effectiveness in the population.

Mr. Luc Thériault: How will you compile the data?

**Dr. Caroline Quach-Thanh:** They have already been compiled—

The Chair: Thank you, Mr. Thériault.

[English]

We go now to Mr. Davies.

Mr. Thériault got a bit of extra time, so we'll extend yours as well. Go ahead, please.

(2135)

Mr. Don Davies: Thank you.

Dr. Quach-Thanh, NACI has previously recommended that adults over 70 years of age should be prioritized in the first phase of vaccine rollout across Canada, but we know that many seniors over 70 have not been vaccinated yet. NACI also said that efforts should be made to complete that stage before proceeding to any subsequent stage as vaccine supply increases.

In your view, how should the provinces and territories prioritize administration of the AstraZeneca vaccine in light of NACI's recent recommendation against use in adults 65 and older?

**Dr. Caroline Quach-Thanh:** At this point, based on our recommendation from March 1—because nothing else has been issued since; it's still in the works—provinces and territories still have the ability to decide what they want, but what we had said was to try to use that vaccine in people up to 64 years of age. If some provinces decide to use the vaccine in the elderly, it's absolutely up to them. I know that Quebec has decided to use it because they have looked at the newer data, the real-world effectiveness data, and therefore have decided that it was acceptable to use that vaccine.

As I said, things are moving; you will have an updated recommendation within the next few days.

**Mr. Don Davies:** We already heard that Canada is the only country in the world that is permitting the duration for the second shot to be up to four months. Does the fact that we're alone among all the countries in the world give you any discomfort?

**Dr. Caroline Quach-Thanh:** As I said before, I would have preferred to be within the label. However, what we decided to do here—given the doses we had and the at-risk population we had—was to try to give that first dose to as many people as possible.

**Mr. Don Davies:** With respect, I heard that, but the issue is that many other countries are in the exact same position and they have not taken that step. We stand alone in this one area.

**Dr. Caroline Quach-Thanh:** Other people are currently looking at that too, and they're wondering if that's not something they should also do. Because we have good effectiveness surveillance data, I think that saying we can go up to four months, and being able to shorten that interval as needed, is absolutely possible.

If we didn't have surveillance data, we wouldn't have gone that way, but because we're able to do that real-time surveillance, that's reassuring to me.

Mr. Don Davies: I guess this will be my last question.

On Monday, Dr. Grandvaux said, "The most important problem, in my opinion, is undoubtedly that NACI's recommendations are not always based on scientific evidence, but in some cases on assumptions and expert opinions." Is it correct that NACI is making recommendations based on assumptions and opinions, rather than scientific evidence?

**Dr. Caroline Quach-Thanh:** When we do expert opinion recommendations, we state it. It happens that we have to do such a thing; that's why we're an expert committee. It's the same thing when I treat a patient; I don't always have all the data, and I don't always have all the facts in the science to be able to treat that patient, because it's something unique. You have to take the data and generalize it to your patient's clinical scenario.

It's the same thing here. It's something that hasn't been seen before. So yes, it is an expert opinion, and we say so.

The Chair: Thank you, Mr. Davies.

Committee, that brings round three to a close.

I would like to ask if there's consensus to adjourn the meeting at this time. We've had a lot of great testimony from our witnesses. Recognizing the lateness of the hour, do we have consensus to adjourn? I'm seeing that.

I'd like to thank the witnesses, absolutely, for their extraordinary effort and the time they put in just on general principles, all the time, but mostly for the time they've given us today and the great and very helpful testimony. Thank you, all.

Thank you to the members.

With that, we are now adjourned.

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