

# Canada Approves New and Obsolete COVID-19 mRNA Vaccine Boosters (XBB.1.5)

Pushes them on children 6+ months and pregnant women - Major Safety Concerns! NO SAFETY studies done on children or pregnancy!

By <u>Dr. William Makis</u> Global Research, September 13, 2023 <u>COVID Intel</u> Region: <u>Canada</u> Theme: <u>Science and Medicine</u>

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Canada is RE-BRANDING obsolete and failed COVID-19 mRNA vaccines to remove the word "BOOSTER". This is an intentional move to forcefully make COVID-19 vaccines an "annual shot" like the flu shot, which they consider wildly successful (Sep.12, 2023).

"There is an Internationally agreed upon simplified dosing schedule NOW" – "It may be much like the flu vaccines where people may be on a REGULAR SCHEDULE getting an Updated vaccine" (Canada's chief medical advisor, Dr. Supriya Sharma – Sep.12)



### Click here to view the video.

Masking is being pushed again: "now is the time to get your mask ready." (Sep. 12, 2023)



## Click here to view the video.

They are going after children again (Canada's chief medical advisor, Dr. Supriya Sharma):

- "5 years or older should receive 1 dose regardless of COVID vaccination history"
- "6 months to 4 years should receive 2 doses if not previously vaccinated, 1 dose if previously vaccinated"



Click here to view the video.

SAFETY: Florida Surgeon General **Joseph Ladapo** warns against getting the Covid booster shot:

"There's been no clinical trial done in human beings showing that it benefits people. There's been no clinical trial showing that it is a safe product for people." "There are a lot of red flags."



<u>Click here to view the video</u>.

<u>SAFETY</u>: Newly Approved Moderna XBB.1.5 Covid-19 vaccine was tested on only 50 adult participants and only monitored over a 20-day period with no control group. Also, Health Canada states that it authorized the vaccine based on older data from the original primary series and booster vaccines.



#### MENU 🗸

# **Regulatory Decision Summary for Spikevax XBB.1.5**

Medicinal Ingredient(s):	Andusomeran
Control Number:	275936
Therapeutic Area:	Vaccines, for human use
Type of Submission:	New Drug Submission (New Active Substance) (COVID-19)
Decision issued:	Authorized; issued a Notice of Compliance in accordance with the Food and
	Drug Regulations

The safety, reactogenicity, and immunogenicity of Spikevax XBB.1.5 are evaluated in an ongoing Phase 2/3 openlabel study in participants 18 years of age and older (study mRNA-1273-P205, Part J). In addition, the safety and effectiveness of Spikevax XBB.1.5 for individuals 6 months of age and older is inferred from studies of a primary series and booster dose of Spikevax Bivalent (Original/Omicron BA.1) in individuals 6 months to 5 years of age, a booster dose of Spikevax Bivalent (Original/Omicron BA.1) in individuals >18 years of age, as well as data from studies which evaluated the primary series and booster vaccination with Spikevax (original).

In study mRNA-1273-P205 Part J, 50 participants received a 50 mcg dose of Spikevax XBB.1.5, and 51 participants received a dose of an investigational bivalent vaccine (XBB.1.5/Omicron BA.4/5). Overall, of the Spikevax XBB.1.5 group 60.0% were female and 40.0% were male. The mean age was 51.6 years (range: 21 to 84 years) and 22.0% of participants were ≥65 years of age. The interval between the fourth dose (Spikevax Bivalent Original/Omicron BA.4/5) and the fifth dose of Spikevax XBB.1.5 was a median of 8.2 months. Spikevax XBB.1.5 elicited neutralizing responses at Day 15 against the SARS-CoV-2 variants assessed, including XBB.1.5, XBB.1.16, BA.4/5, BQ.1.1 and D614G. When assessed against XBB.1.5 the neutralising antibody geometric mean titre (GMT) and corresponding 95% CI was 2,579.0 (1,809.1, 3,676.7) 15 days after the Spikevax XBB.1.5 dose, and the GMR (95% confidence interval [CI]) was 16.7 (12.8, 21.7). When Spikevax XBB.1.5 was assessed against BA.4/5, the GMT (95% CI) was 9,673.4 (6,965.6, 13,433.8) and the GMR was 6.3 (4.8, 8.2). Data on Day 29 will be submitted at a later time as a Term and Condition for authorization. The immunogenicity results suggest that a dose of Spikevax XBB.1.5 could provide superior protection against antigen-matched and related Omicron variants.

Regarding safety, the median follow-up time in the interim analysis was 20 days (data cutoff date of 16 May 2023). Reactogenicity was similar to prior doses of the original Spikevax vaccine and Spikevax Bivalent Original/Omicron BA.4/5. The percentage of participants reporting any solicited local (68% Spikevax XBB.1.5, 84.3% Spikevax XBB.1.5 + BA.4/5) and systemic adverse reactions (58% Spikevax XBB.1.5, 64.7% Spikevax XBB.1.5 + BA.4/5) within seven days after vaccination. The XBB.1.5-containing vaccines (monovalent Spikevax XBB.1.5, bivalent Spikevax XBB.1.5 + BA.4/5) given as a fifth dose were well tolerated. There were no Grade 4 local or systemic reactions and no fatal events or serious adverse events in this interim analysis. No adverse events of special interest (AESI) were reported during the study period. Specifically, there were no reports of myocarditis, pericarditis, myopericarditis, or thrombosis.

Given the aforementioned immunogenicity data from the Spikevax XBB.1.5 vaccine administered as booster dose in individuals 18 years of age and older, combined with accumulated experience with the primary series of the Spikevax monovalent formulation, and a booster dose of Spikevax Original/Omicron BA.1 or Spikevax Original/Omicron BA.4/BA.5, along with the understanding that the Spikevax XBB.1.5 vaccine is manufactured by the same process as the currently approved Spikevax formulations, it is reasonable to generalize the inferred effectiveness of Spikevax XBB.1.5 administered under the new simplified schedule in individuals 6 months and older.

Variant-containing vaccine studies to date suggest that a variant-containing primary series should also induce superior nAb responses against circulating variants, translating to enhanced vaccine effectiveness. More effective COVID-19 vaccine primary series will be particularly relevant to children in each new birth cohort who may lack prior natural infection or vaccine-induced immunity. The two dose regimen is considered because this young population is more likely immune naïve against COVID-19, and in order to ensure that the efficacy will be the similar clinically to that of the 2 dose primary series achieved with original trials.

The current context encompasses, the state of the pandemic transitioning towards an ongoing health issue, the need for vaccines that are more targeted to currently circulating strains, and the overall impact on public health systems and incorporation into future immunization programs within Canada. This context has been taken into account when deciding the level of clinical evidence required to support approval of the Spikevax XBB.1.5 vaccine in individuals 6 months and older. Based on the totality of data reviewed, the safety profile of Spikevax XBB.1.5, administered as a 5<sup>th</sup> booster dose in individuals 18 years of age and older is expected to be comparable with the safety profile of other formulation of Spikevax formulations.

"Safety and effectiveness of Spikevax XBB.1.5 for individuals 6 months of age and older is INFERRED from studies of a primary series and booster dose." They did NO safety studies for children!

NO studies done to ensure safety in pregnancy!

"Reactogenicity was similar to prior doses of the original Spikevax and Bivalent."

USA situation is even worse: They are pushing 3 Pfizer doses on children 6 months to 4 years!



USA: "Annual COVID-19 vaccine shots" are being pushed.



Click here to view the video.

FDA Approved 13:1, the member who voted "NO":"

Pablo J. Sanchez, M.D., who voted no, explained, "We have extremely limited data on children and infants and other individuals, and I think that needs to be made available to the parents.

I also think that in certain circumstances, **we do have to be concerned about potential side effects, especially in young adults and in young adult males**. And so, I think all of that needs to be weighed. And so, that's why I hesitate to make it just a universal recommendation."



Click here to view the video.

# Why Are New COVID-19 Boosters Obsolete?

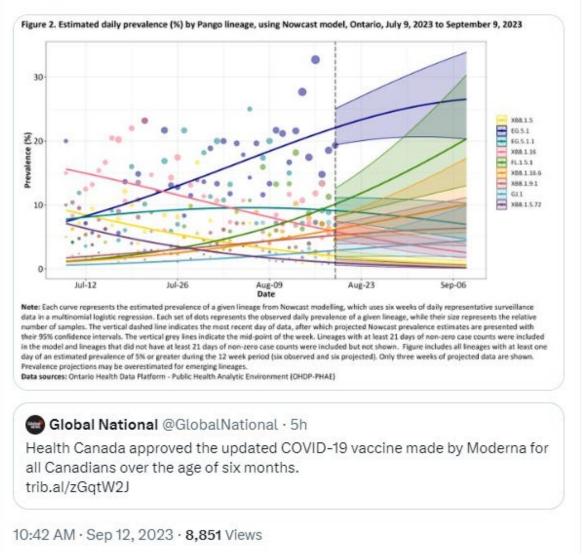
- XBB.1.5 will be extinct by the time the new boosters are rolled out
- Health Canada just approved a product that is all risk and no benefit



This new vaccine targets the XBB.1.5 subvariant.

In Public Health Ontario's most recent report (Jul 23-Aug 19), XBB.1.5 accounted for just 77 out of 2048 detections (3%).

PHO's modelling suggests that this variant (yellow) will be statistically eliminated within a month.



COVID-19 mRNA Vaccine induced myocarditis is 1 in 35 per dose, this includes young adults and children:

• The Switzerland study is here



Click here to view the video.

# My Take...

FDA and Health Canada just approved a new & obsolete COVID-19 mRNA vaccine monovalent booster shot for XBB.1.5 variant which is almost extinct.

- Only "safety study" done on this product was 50 adults monitored for 20 days, with no control group! This is medical fraud.
- No safety studies done on children 6 months or older (recommended by Health Canada anyways this is medical malfeasance and malpractice).
- FDA Member who voted NO cited "extremely limited data on children and infants" and concerns about side effects in young adults (& young adult males).
- No safety studies done on pregnant women (recommended by Health Canada anyways this is medical malfeasance and malpractice).
- "Reactogenicity was similar to prior doses of the original Spikevax vaccine and Spikevax Bivalent" - this is an admission that we will see 1000s of COVID-19 mRNA vaccine induced injuries & deaths of children, young adults and pregnant women (I've documented thousands of these injuries & deaths on my substack and Twitter).
- "Spikevax XBB.1.5 vaccine is manufactured by the same process as the currently approved Spikevax formulations" - this is an admission that we will see potentially lethal "hot lots", "bad vaccine batches", metallic contamination, DNA plasmid contamination, SV40 promoter contamination and all the quality control problems of the original products! They've done nothing to improve quality control.

#### Where this is going:

Health Canada intends to continue injuring & killing thousands of children, young adults, pregnant women, the immuno-compromised and other vulnerable groups with these new and obsolete COVID-19 mRNA Vaccine XBB.1.5 Booster shots.

There is an "internationally agreed upon" push to re-brand these toxic, failed experimental mRNA gene therapy products as "updated vaccines" or "annual vaccines" and stop using the word "booster". This is in both Canada and the US.

The goal is to make these "annual COVID-19 vaccines" MANDATORY as a condition of being able to visit your family doctor (you don't get to see a doctor unless you have your updated annual COVID-19 vaccine).

They think they can implement this new kind of "vaccine mandate".

All doctors and nurses will be forced (mandated) to have this new COVID-19 XBB.1.5 booster and will be forced to push it on all their patients or they will be stripped of their licenses, fined and possibly jailed (already law in Bill 36 in British Columbia).

I've done an extensive substack on this which you can find <u>HERE</u>.

Finally, they want 2 or 3 of these new updated COVID-19 XBB.1.5 boosters in children under the age 5 (the only group they're pushing multiple shots on) – EVERY PARENT should ask themselves WHY.

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