From:	Julian Northey, Ph.D.
To:	Board of Health
Subject:	Re: my thoughts on children and the vaccine
Date:	November 24, 2021 9:12:47 PM
Attachments:	21Nov16_CritiquePfizer.pdf Untitled attachment 00005.htm signature.asc

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Dear James,

Thank you for the call the other day and the helpful information to help guide me.

Please find below the message that I would like to bring to the meeting and agenda for discussion on December 2, 2021, with 1 attachment.
Please also feel free to make it publicly available on your website.
I hope this format is acceptable?
Thank you, Julian

Dear Board of Health of CITY OF, TORONTO,

Several months of study and ongoing discussion with international colleagues has confirmed, yes, in the near term (2-3 months), the mRNA encoding pathogenic a variant spike protein does confer a measure of immune support with clinical relevance i.e. marginally decreased hospitalizations and ICU numbers as seen in several countries (UK, Israel and Canada evidence analyzed most throughly, among others). It begins to wane around then and that has its own questions and concerns for another conversation.

The purpose of this submission is to alert you to NEW data of serious concern.

1) A more sophisticated analysis using the overlooked supplemental data within the Pfizer 6mo trial data has uncovered **a misrepresentation and grossly disproportionate calculation of efficacy relative to adverse effects using their absolute and relative risk measures.**

Summary from our work, "Results of the BNT162b2 mRNA COVID-19 phase III clinical trial, clearly demonstrate that the risks associated with the BNT162b2 mRNA COVID-19 vaccine outweigh the benefits in healthy adults and do not provide clear evidence to support its use."

(see attached "Critique of Phase III trial of the BNT162b2 mRNA COVID-19 Vaccine Through 6 Months" for the full analysis, also posted below in Appendix 1 of the email)

2) NACI incessantly uses a statement of "very rare risk of myocarditis and/or pericarditis following immunization" - let's unpack this statement with some BASIC math in the context of our youth.

We have 13,168,344 individuals <29 in CANADA
- Of those:
  - 75 deceased
  - 532 ICU
  - 4433 hospitalized.

between between January 8 (near start of vaccine rollout) and November 19, 2021

That gives **0.57**/100,000 deceased, **4.04**/100,000 ICU, **33.66**/100,000 hospitalized.

Take our "Public Health Ontario AEFI October 2021 document), a '*very conservative'* conditional probability calculation puts the risk of myocarditis around **59/100,000. Males only accounts for a whooping 48/100,000!**
Based on CDC reported data, (slide 13, https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-08-30/03-COVID-Su-508.pdf) a similar standard calculation yields **27/100,000.**

Key point, this is just one adverse effect being analyzed!!

And so, by "**very rare**", must mean that the incidence of ICU and death by COVID-19 is **…even more rare, would that be fair to say?** Maybe you could please share the basis of your calculations within (e.g. NACI, ON Gov etc etc.) to alleviate my misunderstanding of

this consistent propagandized use of the word "*rare*."

—>>> 0.57 versus 59 per 100,000 …**a minimum 100fold increase, relative to death, minimum!**
—>>> 4.04 versus 59 per 100,000 …**a minimum 14fold increase, relative to ICU, minimum!**

How can anyone reasonably deduce that vaccinating children is logical??
***We suspended the AstraZeneca vaccine for 2/100,000 for blood clots.**

And again, that is just adverse reactions from myocarditis… think about the molecular mechanism of this!!! It is so obvious it creates an autoimmune response from most basic immunological principles!
Have you noticed other countries banning it or restricting based on age-groups? They have likely come to a similar conclusion based on their calculations.

THE PERSON READING THIS - DO YOUR OWN CALCULATIONS and ANALYSIS and STOP FOLLOWING ORDERS, POLITICAL POLICIES AND DIRECTIVES NOW!

I apologize in advance if this comes across harshly but the intellectually misguided perspective, policy driven group think, thirst for centralized guidelines of the medical community (as summarized by the Canadian Medical Forum "Getting vaccinated is the best hope we have to move forward" - utterly simplistic and ridiculous statement of ignorance) **has dissuaded proper scientific rigour and debate that can lead us into a better era of hope, not fear-based medicine.**
Please consider canceling your endorsement of vaccination in the appropriate age-groups and the discriminatory function of "passports" within your jurisdiction.

Critique of Phase III trial of the BNT162b2 mRNA COVID-19 Vaccine Through 6 Months

Phase III trials are the highest level of evidence and our best tool for ascertaining the risks and benefits of a treatment. Results from the phase III trial of the BNT162b2 mRNA COVID-19 vaccine through 6 months recently reported by Thomas *et al.* in the *New England Journal of Medicine* (2021) show that the risks associated with the vaccine outweigh the benefits in the studied trial population.[1]

The study which compared the mRNA COVID-19 vaccine to placebo in healthy adults, showed an absolute risk reduction (ARR) in symptomatic COVID-19 cases among fully vaccinated adults and adolescents of 3.7% (77 vs 850, vaccine vs placebo, respectively) but even with a limited safety monitoring schedule the absolute risk increase (ARI) in unsolicited, treatment-related adverse effects among vaccine recipients of 17.9% (5,241 vs 1,311, vaccine vs placebo, respectively). An increased risk of severe adverse events was also reported. Although, the study reported an ARR in severe COVID-19 cases among fully vaccinated adults of 0.1% (1 vs 23, vaccine vs placebo, respectively), it reported an ARI in severe adverse events of 0.5% (262 vs 150, vaccine vs placebo, respectively) and serious adverse events of 0.05% (127 vs 116, vaccine vs placebo, respectively) among vaccine recipients. When results of all severe and serious events were pooled, it resulted in an ARI in severe events of 0.5% (390 vs 289, vaccine vs placebo, respectively) among vaccinated adults, differences which were found to be statistically significant when a simple chi-square calculator was applied to assess differences ($p=0.0001$). Moreover, although deaths were relatively comparable across arms in the blinded portion of the trial (15 vs 14 deaths, vaccine vs placebo, respectively), 5 additional deaths were reported in vaccine recipients in the open label portion bringing the total death count after vaccination to 20. Of note, there were almost twice as many cardiovascular deaths on the vaccine arm compared to the placebo arm (9 vs 5 deaths). Furthermore, their data clearly shows that the increase in adverse events observed in vaccine recipients (RRI 298.3% and ARI of 17.9% as previously mentioned; $p<0.00001$) was greater than the reduction in COVID-19 cases observed in fully-vaccinated individuals (RRR 90.9% and ARR 3.7%; $p<0.00001$). **Results of the BNT162b2 mRNA COVID-19 phase III clinical trial, clearly demonstrate that the risks associated with the BNT162b2 mRNA COVID-19 vaccine outweigh the benefits in healthy adults and do not provide clear evidence to support its use.**

Table 1. Differences in efficacy and safety events in eligible populations reported in the 6-month update of the BNT162b2 mRNA COVID-19 Vaccine

Event	BNT162b2 (n)	Placebo (n)	Absolute Difference (p-value)	Absolute Risk Change* (%)	Relative Risk Change* (%)
Total Randomized Adults and Adolescents (n)	23,219	23,210			
Cases in Adults and Adolescents 7 days after 2nd dose$	77	850	-773 (p<0.00001)	-3.7	-90.9
Any Treatment-Related Adverse Event Adults#	5,241	1,311	+3,930 (p<0.00001)	+17.9	+298.3

Any Severe Event Adults[/]	390	289	+101 (p=0.0001)	+0.5	+34.9
Severe Cases in Fully Vaccinated Adults[&]	1	23	-22 (p<0.00001)	-0.1	-95.6
Unsolicited Severe Adverse Events[~] in Adults Prevents daily routine activity or requires intervention or worse	262	150	+112 (p<0.00001)	+0.5	+74.6
Unsolicited Serious Adverse Event Adults[§]	127	116	+11 (p=0.5)	+0.05	+9.5
Deaths during placebo-controlled period [additional deaths during open-label period in vaccine recipients or placebo-only][%]	15 [+5]	14 [NR]	+1 [+5] (p=0.9)	+0.005	+7.1
Deaths due to cardiovascular events^	9	5	+4		

[?] Significance figures (p-values) estimated using chi-square calculator available at https://www.socscistatistics.com/tests/chisquare. P-values are without the Yates correction. This procedure was applied following the framework used by Classen (2021) in their analysis of "All Cause Severe Morbidity" based on data from the initial reports of the vaccine Phase III trials[2]

* Absolute and relative risk change calculations were performed using the common statistical definition, ie. number of events relative to total number of eligible patients for each event analysis reported,[3] similar to previous analyses of this nature;[2,4] vaccine efficacy estimates reported at source used total surveillance time as denominator, however, this value is not available for all the events analyzed

[$] ≥7 Days after dose 2 among participants without evidence of previous infection

[#] Adverse events reported outside of the reactogenicity subgroup and assessed by the investigator as related to investigational product

[/] In calculations combining efficacy and safety events, the number of patients randomized that received any dose of vaccine or placebo was used as the study population in the statistical calculations, following the framework used by Classen (2021) in their analysis of "All Cause Severe Morbidity".[2] Differences in the total (event-incident) population (randomized vs efficacy vs safety) used as denominator are relatively small and are expected to have minimal impact on the relative differences between groups

[&] ≥7 Days after dose 2; severe COVID-19 defined as "presence of at least 1 of the following: • Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg); • Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO); • Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors); • Significant acute renal, hepatic, or neurologic dysfunction*;• Admission to an ICU; • Death

~ Severe (grade ≥3) adverse events were generally defined as those that interfere significantly with participant's usual function, those that affect daily living or require medical care; grade 4 events were generally defined as those that required emergency room visit or hospitalization

[§] Serious adverse events were defined as any untoward medical occurrence that, at any dose: a. Results in death; b. Is life-threatening; c. Requires inpatient hospitalization or prolongation of existing hospitalization; d. Results in persistent disability/incapacity.

[%] Deaths during the open-label period were reported only in vaccine recipients, 3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding

^Those with reported cause of death due to: aortic rupture, arteriosclerosis, cardiac arrest, cardiac failure congestive, cardiorespiratory arrest, hypertensive heart disease, or myocardial infarction

1. Thomas SJ, Moreira ED, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months. N Engl J Med 2021;385:1761-73.
2. Classen B. US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint,"All Cause Severe Morbidity". Trends Int Med 2021;1:1-6.
3. » Evidence based medicine (EBM) toolkit » Learn EBM » How to calculate risk. 2021. (Accessed October 1, 2021, at https://bestpractice.bmj.com/info/toolkit/learn-ebm/how-to-calculate-risk/.)
4. Larkin A, Waitzkin H. COVID-19 vaccines and evidence-based medicine. medRxiv 2021. doi: 10.1101/2021.06.28.21259039.