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What is the Number Needed to Vaccinate (NNTV) to prevent a single COVID-19 fatality in kids 5 to 11 based on the Pfizer EUA application?

And what are the risks that go along with injecting that many kids?



 Toby Rogers

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NNTV, the standard policy tool that Pharma, the FDA, & CDC no longer want to talk about

A funny thing happened this afternoon. Not funny as in "haha". More like funny as in, "ohhhhh that's how the FDA rigs the process."

I was reading the CDC's "<u>Guidance for Health Economics Studies Presented to the</u> <u>Advisory Committee on Immunization Practices (ACIP), 2019 Update</u>" and I realized that the FDA's <u>woeful risk-benefit</u> analysis in connection with Pfizer's EUA application to jab children ages 5 to 11 violates many of the principles of the CDC's Guidance document. The CDC "Guidance" document describes 21 things that every health economics study in connection with vaccines must do and the FDA risk-benefit analysis violated at least half of them.

Today I want to focus on a single factor: the Number Needed to Vaccinate (NNTV). In four separate places the CDC Guidance document mentions the importance of coming up with a Number Needed to Vaccinate (NNTV). I did not recall seeing an NNTV in the FDA risk-benefit document. So I checked the FDA's risk-benefit analysis again and sure enough, there was **no** mention of an NNTV.

Because the FDA failed to provide an NNTV, I will attempt to provide it here.

First a little background. The Number Needed to Treat (NNT) in order to prevent a single case, hospitalization, ICU admission, or death, is a standard way to measure the effectiveness of any drug. It's an important tool because it enables policymakers to evaluate tradeoffs between a new drug, a different existing drug, or doing nothing. In vaccine

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research the equivalent term is Number Needed to Vaccinate (NNTV, sometimes also written as NNV) in order to prevent a single case, hospitalization, ICU admission, or death (those are 4 different NNTVs that one could calculate).

Pharma HATES talking about NNTV and they hate talking about NNTV even more when it comes to COVID-19 vaccines because the NNTV is so ridiculously high that this vaccine could not pass any honest risk-benefit analysis.

Indeed about a year ago I innocently asked on Twitter what the NNTV is for coronavirus vaccines.



Toby Rogers PhD, MPP @uTobian · Sep 24, 2020

Has anyone calculated a **Number Needed to** Treat (NNT) in order **to** prevent 1 coronavirus death via any of the proposed coronavirus vaccines? It's a very important **number** for rational policymaking but I have yet **to** see anyone attempt an estimate. Please share if you find a link.

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Pharma sent a swarm of trolls in to attack me and Pharma goons published hits pieces on me outside of Twitter to punish me for even asking the question. Of course none of the Pharma trolls provided an estimate of the NNTV for COVID-19 shots. That tells us that we are exactly over the target.



- Ronald Brown, a health economist in Canada, estimated that the NNTV to prevent a single *case* of coronavirus is from 88 to 142.
- Others have <u>calculated</u> the NNTV to prevent a single *case* at 256.
- German and Dutch researchers, using a large (500k) data set from a field study in Israel <u>calculated</u> an NNTV between 200 and 700 to prevent one case of COVID-19 for the mRNA shot marketed by Pfizer. They went further and figured out that the "NNTV to prevent one death is between 9,000 and 100,000 (95% confidence interval), with 16,000 as a point estimate."

You can see why Pharma hates this number so much (I can picture Pharma's various PR firms sending out an "All hands on deck!" message right now to tell their trolls to attack this article). One would have to inject a lot of people to see any benefit and the more people who are injected the more the potential benefits are offset by the considerable side-effects from the shots.

Furthermore, the NNTV to prevent a single case is not a very meaningful measure because most people, particularly children, recover on their own (or even more quickly with ivermectin if treated <u>early</u>). The numbers that health policy makers should really want to know are the NNTV to prevent a single hospitalization, ICU admission, or death. But with the NNTV to prevent a single case already so high, and with significant adverse events from coronavirus vaccines averaging about 15% nationwide, Pharma and the FDA dare not calculate an NNTV for hospitalizations, ICU, and deaths, because then no one would ever take this product (bye bye \$93 billion in annual revenue).

Increased all cause mortality in the Pfizer clinical trial of adults

As Bobby Kennedy explains, Pfizer's clinical trial in adults showed alarming increases in all cause mortality in the vaccinated:

In Pfizer's 6 month clinical trial in adults — there was 1 covid death out of 22,000 in the vaccine ("treatment") group and 2 Covid deaths out of 22,000 in the placebo group (see Table s4). So NNTV = 22,000. The catch is there were 5 heart attack deaths in the vaccine group and only 1 in placebo group. So for every 1 life saved from Covid, the Pfizer vaccine kills 4 from heart attacks. All cause mortality in the 6 month study was 20 in vaccine group and 14 in placebo group. So a 42% all cause mortality increase among the vaccinated. The vaccine loses practically all efficacy after 6 months so they had to curtail the study. They unblinded and offered the vaccine to the placebo group. At that point the rising harm line had long ago intersected the sinking efficacy line.

Former NY Times investigative reporter Alex Berenson also wrote about the bad outcomes for the vaccinated in the Pfizer clinical trial in adults (<u>here</u>). Berenson received a lifetime ban from Twitter for posting Pfizer's own clinical trial data.

Pfizer learned their lesson with the adult trial and so when they conducted a trial of their mRNA vaccine in children ages 5 to 11 they intentionally made it too small (only 2,300 participants) and too short (only followed up for 2 months) in order to <u>hide harms</u>.

Estimating an NNTV in children ages 5 to 11 using Pfizer's own clinical trial data

All of the NNTV estimates above are based on data from adults. In kids the NNTV will be even higher (the lower the risk, the higher the NNTV to prevent a single bad outcome). Children ages 5 to 11 are at extremely low risk of death from coronavirus. In a <u>meta-</u> <u>analysis</u> combining data from 5 studies, Stanford researchers Cathrine Axfors and John Ioannidis found a median infection fatality rate (IFR) of 0.0027% in children ages 0-19. In children ages 5 to 11 the IFR is even lower. Depending on the study one looks at, COVID-19 is slightly less dangerous or roughly equivalent to the flu in children.

So how many children would need to be injected with Pharma's mRNA shot in order to prevent a single hospitalization, ICU admission, or death?

Let's examine Pfizer's <u>EUA application</u> and the FDA's <u>risk-benefit analysis</u>. By Pfizer's own admission, there were zero hospitalization, ICU admissions, or deaths, in the treatment or control group in their study of 2,300 children ages 5 to 11.

So the Number Needed to Vaccinate in order to prevent a single hospitalization, ICU admission, or death, according to Pfizer's own data, is infinity. ∞. Not the good kind of

infinity as in God or love or time or the universe. This is the bad kind of infinity as in you could vaccinate every child age 5 to 11 in the U.S. and not prevent a single hospitalization, ICU admission, or death from coronavirus **according to Pfizer's own clinical trial data as submitted to the FDA**. Of course Pfizer likes this kind of infinity because it means infinite profits. [Technically speaking the result is "undefined" because mathematically one cannot divide by zero, but you get my point.]

Estimating an NNTV and risk-benefit model in children ages 5 to 11 using the limited data that are available

Everyone knows that Pfizer was not even trying to conduct a responsible clinical trial of their mRNA shot in kids ages 5 to 11. Pfizer could have submitted to the FDA a paper napkin with the words "Iz Gud!" written in crayon and the VRBPAC would have approved the shot. They are all in the cartel together and they are all looking forward to their massive payoff/payday.

But let's not be like Pharma. Instead, let's attempt to come up with a best guess estimate based on real world data. Over time, others will develop a much more sophisticated estimate (for example, <u>Walach, Klement, & Aukema</u>, 2021 estimated an NNTV for 3 different populations based on "days post dose"). But for our purposes here I think there is a much easier way to come up with a ballpark NNTV estimate for children ages 5 to 11.

Here's the benefits model:

- As of October 30, 2021, the CDC <u>stated</u> that 170 children ages 5 to 11 have died of COVID-19-related illness since the start of the pandemic. (That represents less than 0.1% of all coronavirus-related deaths nationwide even though children that age make up 8.7% of the U.S. population).
- The Pfizer mRNA shot only "works" for about 6 months (it increases risk in the first month, provides moderate protection in months 2 through 4 and then effectiveness begins to wane, which is why all of the FDA modeling only used a 6 month time-frame). So any modeling would have to be based on vaccine effectiveness in connection with the 57 (170/3) children who might otherwise have died of COVID-related illness during a 6-month period.

- At best, the Pfizer mRNA shot might be 80% effective against hospitalizations and death. That number comes directly from the FDA modeling (p. <u>32</u>). I am bending over backwards to give Pfizer the benefit of considerable doubt because again, the Pfizer clinical trial showed NO reduction in hospitalizations or death in this age group. So injecting all <u>28,384,878</u> children ages 5 to 11 with two doses of Pfizer (which is what the Biden administration wants to do) would save, at most, 45 lives (0.8 effectiveness x 57 fatalities that otherwise would have occurred during that time period = 45).
- So then the NNTV to prevent a single fatality in this age group is 630,775 (28,384,878 / 45). But it's a two dose regimen so if one wants to calculate the NNTV per injection the number doubles to 1,261,550. It's literally the worst NNTV in the history of vaccination.

If you inject that many children, you certainly will have lots and lots of serious side effects including disability and death. So let's look at the risk side of the equation.

Here's the risk model:

- Because the Pfizer clinical trial has no useable data, I have to immuno-bridge from the nearest age group.
- 31,761,099 people (so just about 10% more people than in the 5 to 11 age bracket) ages <u>12 to 24</u> have gotten at least one coronavirus shot.
- The COVID-19 vaccine program has only existed for 10 months and younger people have only had access more recently (children 12 to 15 have had access for five months; since May 10) — so we're looking at roughly the same observational time period as modeled above.
- During that time, there are <u>128 reports</u> of fatal side effects following coronavirus mRNA injections in people 12 to 24. (That's through October 22, 2021. There is a reporting lag though so the actual number of reports that have been filed is surely higher).
- Kirsch, Rose, and Crawford (2021) <u>estimate</u> that VAERS undercounts fatal reactions by a factor of 41 which would put the total fatal side effects in this age-range at 5,248. (Kirsch et al. represents a conservative estimate because others have put the underreporting factor at <u>100</u>.)

• With potentially deadly side effects including myo- and pericarditis <u>disproportionately impacting youth</u> it is reasonable to think that over time the rate of fatal side effects from mRNA shots in children ages 5 to 11 might be similar to those in ages 12 to 24.

So, to put it simply, the Biden administration plan would kill 5,248 children via Pfizer mRNA shots in order to save 45 children from dying of coronavirus.

For every one child saved by the shot, another 117 would be killed by the shot.

The Pfizer mRNA shot fails any honest risk-benefit analysis in children ages 5 to 11.

Even under the best circumstances, estimating NNTV and modeling risk vs. benefits is fraught. In the current situation, with a new and novel bioengineered virus, where Pfizer's data are intentionally underpowered to hide harms, and the FDA, CDC, & Biden Administration are doing everything in their power to push dangerous drugs on kids, making good policy decisions is even more difficult.

If the FDA or CDC want to calculate a different NNTV (and explain how they arrived at that number) I'm all ears. But we all know that the FDA refused to calculate an NNTV *not* because they forgot, but because they knew the number was so high that it would destroy the case for mRNA vaccines in children this age. Your move CDC — your own Guidance document states that you must provide this number.

Update: CDC finally mentions NNTV, but . . .

Toward the end of the six-hour CDC's Advisory Committee on Immunization Practices (ACIP) <u>Nov. 2 meeting</u> where the committee voted to recommend Pfizer's EUA vaccine for children 5 - 11, there was finally a mention of NNTV. It was on slide 36 of a <u>presentation</u> by CDC official D.r Sara Oliver. Unfortunately the CDC estimate was untethered from reality. I'll explain:

Oliver claimed the NNTV to prevent a single case is 10, even though the best lower bound estimate is <u>88</u> and other estimates are 200 or higher (see calculations <u>here</u> and <u>here</u>).

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Then she claimed the NNTV to prevent a single hospitalization is between 2,213 and 8,187. This is dishonest and a violation of scientific norms.

NNTV is calculated by dividing 1 by the Absolute Risk Reduction. There was no Absolute Risk Reduction in hospitalizations in the Pfizer clinical trial in kids 5 to 11, because no one was hospitalized in either the treatment or control group. 1/0 is "undefined" not 8,187.

Oliver made no estimate of NNTV to prevent a single COVID-19-related death because that is also undefined (again, there were no COVID-related deaths in the treatment or placebo group in the trial so the absolute risk reduction was zero).

Oliver also did not model injuries or deaths from the vaccine (she immuno-bridged from an older age group to show benefits but ignored the reported harms from the vaccine in the older age group).

I should also note that my estimates of NNTV were based on CDC data showing 170 deaths from COVID-19-related illness in kids ages 5 to 11 over the last 18 months (I got the number directly from the CDC <u>COVID tracking website</u>).

However at the ACIP meeting, the CDC said the number of children in this age group who have died of COVID-19-related illness is 94.

If 94 is the correct number to use, then the NNTV to prevent a single death from COVID-19 related illness in this age group would be 28,384,878 / 31 = 915,641. But it's a two-dose regimen, so if one wants to calculate the NNTV-per-injection the number doubles to 1,831,282.

I imagine that at most, half of American parents will be foolish enough to inject this toxic product into their kids. At a 50% uptake rate, the ACIP decision to approve the Pfizer shot will likely kill 2,624 children via adverse reactions in order to potentially save 12 from COVID-19-related illness.

Now you know why the CDC did not release the meeting materials prior to the ACIP meeting — they could not stand up to any public scrutiny.

Update 11/05/21:

I see that El Gato Malo engaged in a similar set of calculations back in September when Pfizer first released its "results." He faced the same challenges as I did — namely, there is no usable data from Pfizer and so one has to pull from others sources. He builds a steel man case (the most generous possible defense of the Pfizer product) and yet his results are still in line with mine (my numbers are higher though because I use a lower estimate of vaccine effectiveness and correct for VAERS underreporting). So again, even under the most generous assumptions, the Pfizer mRNA shot fails any honest risk benefit assessment in connection with children 5 to 11.



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This is utterly gut wrenching. It is so disgusting to keep propping up this novel vax that is so bad the CDC had to change their definition of vaccine. I am a healthcare provider. There has always been "fudged" statistics to justify big pharma's newest creations. But this outright deceit takes big pharma to a whole new level of corruption for me. And on a personal level, I cannot convince my daughters, who are also healthcare providers, to not vax their kids. It is breaking my heart......literally.

Thank you for your excellent article. I will pass it on.

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