

PD speeches Nov 2, 2021

Hello. I'm Peter Doshi. I am on the faculty at the University of Maryland and an editor at The BMJ. I have no relevant conflicts of interest and my comments today are my own.

In pharmacy school, I teach a required course on how to critically appraise the medical literature. We train students how to go beyond a study abstract, and start to pick apart and critically assess biomedical studies--not just take them at face value.

I want to use my 5 minutes here to harness that spirit of critical thinking. I am saddened that we are supersaturated, as a society right now, in the attitude of "everybody knows" that has shut down intellectual curiosity and led to self-censorship.

So let me start with a few "everybody knows" examples that I'm not sure we should be so certain about.

EVERYBODY KNOWS that this is a pandemic of the unvaccinated. But if hospitalizations and deaths were almost exclusively occurring in the unvaccinated, why would booster shots be necessary? Or why would the statistics be so different in the UK, where most covid hospitalizations and deaths are among the fully vaccinated? There's a disconnect there - there's something to be curious about - there's something not adding up and we should all be asking "is it true that this is a pandemic of the unvaccinated? What does that even mean?"

[next slide] Then there's this - EVERYBODY KNOWS that covid vaccines save lives. In fact, we've known this from early 2021 -- the clinical trials **proved** that to be the case, as you can see in the quote here of a February article in JAMA ... but is it true? When that statement by prominent public health officials was penned, there had been just 1 death - one death - across some 70,000 Pfizer and Moderna trial participants. Today we have more data - and you can see that there were similar numbers of deaths in the vaccine and placebo groups. The trials didn't show a reduction in death. Even for covid deaths, as opposed to other causes, the evidence is flimsy - with just 2 deaths in the placebo group versus 1 in the vaccine group.

My point is not that I know the truth about what the vaccine can and cannot do. My point is that those who claimed the trials showed the vaccines were highly effective in saving lives were wrong. The trials did not demonstrate this.

[next slide] Now let's talk about anti-vaxxers. EVERYBODY KNOWS you should discount what anti-vaxxers have to say. But what does the term mean? The Merriam-Webster dictionary defines it as "a person who opposes the use of vaccines or regulations mandating vaccination."

The first part of the definition I expected. The second part stunned me. There are entire countries - from the United Kingdom to Japan - which do not mandate childhood vaccines. Both achieve high levels of vaccination -- just not through regulations mandating vaccination. There are no mandates there and I would wager that a large minority, perhaps a majority, of the world's population meets the definition here of an anti-vaxxer.

Another definition worth checking is “vaccine.” I am one of the academics that argues that these mRNA products which everybody calls vaccines are qualitatively different than standard vaccines. And so I found it fascinating to learn that Merriam-Webster changed its definition of vaccine early this year. mRNA products did not meet the definition of vaccine that has been in place for 15 years at Merriam-Webster. But the definition was expanded such that the mRNA products are now vaccines.

I highlight this to ask a question: how would you feel about mandating covid vaccines if we didn't call them “vaccines”? What if these injections were called “drugs” instead?

So here's the scenario: we have this DRUG - and we have evidence that it doesn't prevent infection, nor does it stop viral transmission. But the drug is understood to reduce your risk of becoming very sick and dying of covid. Would you take a dose of this drug every six months or so for possibly the rest of your life, if that's what it took for the drug to stay effective? Would you not just take this drug yourself, but support regulations mandating that everybody else around you take this drug? Or would you say “hold on a sec.” Maybe you'd say that if that's all the drug does, why not use a normal medicine instead - the kind we take when we're sick and want to get better? And why would you mandate it?

The point is just because we call it a “vaccine” doesn't mean we should assume these new products are just like other childhood vaccines which get mandated. Each product is a different product, and if people are OK with mandating something simply because “it's a vaccine and we mandate other vaccines, so why shouldn't we mandate this,” I think it's time to inject some critical thinking into that conversation - and that is what we are going to be doing today. Thank you.

TALK TWO

In the video just now, Dr. David Healy mentioned that what is under the hood of Pfizer clinical trials is not science, it's business. I've been reviewing industry-sponsored clinical trials for over a decade and I tend to agree with Dr. Healy that business and marketing often seem to be in the driver's seat. In my case, it took place a decade ago in the midst of another pandemic - swine flu - and for four years we fought to gain access to the clinical trial data for the drug Tamiflu. Instead of an 8 page journal article telling us about a clinical trial, we wanted the 1000 pages of internal company study documents that we knew were under the waterline. The fact that the Tamiflu data were inaccessible came as a shock to even the editors of medical journals - who had reasonably assumed that since data is fundamental to the scientific process, surely it must be available.

But it wasn't then for Tamiflu, and it isn't today for covid vaccines.

In fact, if you are interested in analyzing the data for, say, Pfizer's trial, you will have to wait until May 2025 before you can even request it from the company. For Moderna, they recently said that data - quote - "may be available ... with publication of the final study results in 2022." And since the trial is not officially to end until October 2022, we are probably talking late 2022. So yes, the trial has still not ended. And yes, doctors and researchers who want to see the clinical trial data will have to wait another year from now before getting access.

For J&J, try next July.

If you weren't aware that the data were inaccessible, I suspect this is because so few healthcare practitioners and researchers are accustomed to conducting an independent review of the raw data--so there is little outcry when those data are inaccessible.

[Next slide] So while we are told to keep "following the science," what we are following is not a scientific process based on open data. We are following a process in which the data are treated as secret, and in my view, there is something very unscientific about that.

I feared we would end up in this situation because data secrecy, I am sorry to say, is the status quo. In 2015, the Institute of Medicine published a consensus study calling for a culture change in which data sharing became the norm, not the exception. But not enough has changed. Last August, before we had results from any of the pivotal covid vaccine trials, I co-authored a commentary with Dr. Healy saying clinicians and professional societies need to declare that they will not endorse treatments or vaccines unless there is complete data transparency.

The point I'm trying to make is fairly simple.

- The data for covid vaccine trials isn't available, and it won't be available for years
- Yet we are not just asking, but mandating millions of people take these products
- Whatever word you want to use to describe this situation, without data, it isn't science