

## What's Crazy in Health Care Times Two

A friend in her sixties called to ask if she should take the new RSV vaccine, which is being heavily promoted to people over sixty. That it is being so heavily promoted is driving *me* a little crazy.

Here's the skinny: RSV -- respiratory syncytial virus -- is a virus that has been around a long time. We've all been exposed to it. Most of us had had it, as a cold. Most of us have had it a bunch of times, because our immunity to it isn't that robust, and fades with time. It isn't dangerous, unless you are an infant or unless you are very elderly and frail, most of the time. RSV causes a very severe pneumonia and respiratory failure in infants, and too many deaths, and it can also cause a similar picture in frail adults -- it was one of the gemish of viruses that caused what we used to call Adult Respiratory Distress Syndrome and many ICU admissions, back before we had good laboratory tools to identify the actual virus. Now we know their names. These viruses can still wreak havoc with the lungs of the frail elderly and the immunosuppressed, but thankfully do that relatively rarely.

The good news is there is a new vaccine for RSV called Abryso. (I don't make up these names. I only report on them.) The bad news is that it costs about \$320 a dose. The good news, sort of, for people over 65 is that it is covered by Medicare. The bad news is that it is approved for people over 60, some of whom will have to pay for it out of pocket. If every American over sixty-five with Medicare (almost 66 million people, it happens) got the vaccine, the government would be out \$20 billion, which is more than the total annual budget of each of 18 states, and enough money to send 258,461 students to Harvard or another Ivy League college for a year (although there only about 68,000 at all the Ivy League colleges at any one time), or enough money or enough money to build 57,000 two bed room apartments and house 14,000 to 228,000 homeless Americans, of the about 500,000 homeless Americans each year. We won't spend nearly that amount of money, though, because we don't have a health care system in the US, which mean we don't have a way to get the vaccine to all sixty-five million Americans with Medicare, so this very expensive vaccine isn't going to bankrupt us, at least not yet, which is a good thing because we don't know yet whether it actually works in any meaningful way.

None of which answers my friend's question: should she get the vaccine? Here's the data, straight from the manufacturer, which reported it to FDA in order to get the vaccine approved: Abryso was tested in just over 17,500 people over 60. That's about three times as many people as the Covid vaccines were tested on initially, and that is relatively reassuring -- there aren't lots of common bad side effects -- but understand we often don't learn the true side effect profile of a drug or vaccine until over a million people get it. (Guillain- Barre syndrome, a kind of paralysis that is rare but occurs in reaction to vaccines, drugs and infections, occurs about one of a million exposed people, so you have to test a million to understand what the relative risk of that condition.) But simply put, Abryso seems safe so far but hasn't been that widely tested yet.

But does Abryso work? Well, sort of. It works to keep the people on whom it was tested from getting cough, congestion, and sore throat. Most of the people it was tested on were 60-69, many were 70-79 and only a few -- a little over 5 percent, or 970 people, were over 80. Which means the vaccine wasn't tested on very many of the people we worry about most, people who are oldest, and most likely to be infirm, the people for whom RSV infection is likely to be most treacherous.

But here's the rub. The vaccine company studied how the vaccine worked on preventing cough, sore throat, congestion and other symptoms of a lower respiratory tract infection. However there weren't enough people in the study to tell if the vaccine prevents hospitalization and death. It's nice to know that the vaccine prevents cough, nasal congestion and sore throat. But I think most of us don't get vaccinated to prevent those things, particularly because the protection rendered by many of these vaccines last only a few months, particularly in the elderly. Most of us get vaccinated to prevent hospitalization and death. And we just don't know yet if Abryso prevents what most of us want to avoid. It might. We just don't know yet.

SO. Should *you* get the RSV vaccine? The CDC itself isn't so sure. On its website, CDC says "Adults aged 60 years and older may receive a single dose of RSV vaccine using shared decision-making." Translated into English from CDCspeak, that means CDC thinks you should probably wait until we learn more about the vaccine, but if your doctor thinks you should take it, it's okay for you to take it. Notice CDC *isn't* saying, "we recommend all older adults take this vaccine." That's huge. They read the same data I did, and for once, actually drew the same conclusion. But CDC can't be clearer than that because they don't want to piss off the vaccine manufacturer and the vaccine manufacturer's lobbyists. Talk about crazy.

Who should take the RSV Vaccine? It's hard to know. A few older or immunosuppressed adults might want to think about it if they are at very high risk for respiratory failure, for ending up on a ventilator if they get a viral pneumonia. But if they take it, they need to understand that we don't know if the vaccine will likely prevent that. All we know is that the RSV vaccine prevents cough, sore throat and congestion and perhaps some shortness of breath -- and we don't really know how well it works in people at high risk for respiratory failure. (On the other hand, women 32-36 weeks pregnant SHOULD take Abryso if their doctor agrees. The data for that group is VERY good. The evidence is clear that the vaccine is very effective in preventing hospitalization for RSV in their infants.)

But for the rest of us, I'd say talk to your doctor if the TV advertisements have you wondering, but most of us can wait a year or two until we have data good enough to allow us to draw reasonable conclusion. If the data isn't that good yet, you might ask, then why is the manufacturer allowed to advertise this stuff all over the place? Welcome to the US, I answer, where we have a market that exists to generate profit for investors, and not a health care system. For a great democracy to have such a mess is more than a shame. It's crazy.

One more thing. It's mask time again. For about the next six weeks. Sorry to be the bearer of bad news. As most of us expected, there's lots of covid, flu, RSV and other viruses in circulation, which occurs every year after the holidays, when people congregate, travel and stay inside. Covid alone is back to killing about 1500 people a week. That said, most of us will get something, but because we've seen Covid before and most people have been vaccinated, most of us won't need the hospital and relatively fewer, but too many, will die.

Masks work to prevent the spread of infection. I'm masking again when I go out, not because I'm worried about dying, but because I'd rather not get sick, and if I can, I'd like to slow the transmission of

all these viruses. Just doing my small part, like dipping my high beams when I'm driving into oncoming traffic.

But note that the RI Department of Health isn't saying to mask. They are saying, generically, "take prevention measures." I suspect but don't know that they'd like to say mask, but the politicians, who are afraid of their own shadows, are getting in the way because those politicians don't want anyone to yell at them. Instead, they'll let some people die unnecessarily and let other people get sick.

Rhode Island has been without a permanent DOH Director for almost two years now, and the current excellent and courageous interim director is about to retire. That the politicians can get away with this, that they can exert political control over public health professionals, that we don't have anyone permanent whose job it is to protect the health and safety of all Rhode Islanders because we as a people don't care enough about the public's health, well, that's even crazier yet.

Thanks again to my colleague Nick Landekic, who helped me with this analysis. His suggestions are fantastic. Any errors are all mine. Thanks as well to all my colleagues at RIDOH and all those who practice primary care in Rhode Island, for their tireless work to keep us all safe.

Originally posted on WhatsupNewp on January 8, 2024

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