

Analysis: A new era of vaccines leaves old questions about prices unanswered

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The world is entering a new era of vaccines. Following the success of COVID-19 mRNA shots, scientists have a far greater capacity to tailor shots to a virus's structure, putting a host of new vaccines on the horizon.

The most recent arrivals—as anyone on the airwaves or social media

knows—are several new immunizations against respiratory syncytial virus, or RSV.

These shots are welcome since RSV can be dangerous, even deadly, in the very old and very young. But the shots are also expensive—about \$300 for those directed at adults, and up to \$1,000 for one of the shots, a monoclonal antibody rather than a traditional vaccine, intended for babies. Many older vaccines cost pennies.

So their advent is forcing the United States to face anew questions it has long sidestepped: How much should an immunization that will possibly be given—maybe yearly—to millions of Americans cost to be truly valuable? Also, given the U.S. is one of two countries that permit direct advertising to consumers: How can we ensure the shots get into the arms of people who will truly benefit and not be given, at great expense, to those who will not?

Already, ads on televisions and [social media](#) show active retirees playing pickleball or going to art galleries whose lives are "cut short by RSV." This explains the lines for the shot at my local pharmacy.

But indiscriminate use of expensive shots could strain both public and [private insurers'](#) already tight budgets.

Other developed countries have deliberate strategies for deciding which [vulnerable groups](#) need a particular vaccine and how much to pay for it. The U.S. does not, and as specialized vaccines proliferate, public programs and private insurers will need to grapple with how to use and finance shots that can be hugely beneficial for some but will waste precious health dollars if taken by all.

A seasonal viral illness, RSV can cause hospitalization or, in rare cases, death in babies and in people age 75 or older, as well as those with

serious underlying medical conditions such as heart disease or cancer. For most people who get RSV, it plays out as a cold; you've likely had RSV without knowing it.

But RSV puts about 2% of babies under age one in the hospital and kills between 100 and 300 of those under six months, because their immune systems are immature and their airways too narrow to tolerate the inflammation. Merely having a bad case of RSV in young childhood increases the risk of long-term asthma.

That's why Barney Graham, the scientist who spent decades at the government's National Institutes for Health perfecting the [basic science](#) that led to the current shots, said, "The most obvious use is in infants," not adults.

That's also why European countries trying to figure out how best to use these vaccines without breaking the bank focused first on babies and determining a sensible price. Though more of the very old may die of RSV, the years of life lost are much greater for the very young. (Babies can get the monoclonal antibody shot or gain protection through a traditional vaccine given to the mother near the end of pregnancy, conferring immunity through the womb.)

A consortium of European experts led by Philippe Beutels, a professor in [health economics](#) at the University of Antwerp in Belgium, calculated that the shots would only be "worth it" in terms of the lives saved and hospitalizations averted in infants if the price were under about \$80, he said in a phone interview. That's because almost all babies make it through RSV with supportive care.

The calculation will be used by countries such as Belgium, England, Denmark, Finland, and the Netherlands to negotiate a set price for the two infant shots, followed by decisions on which version should be

offered, depending partly on which is more affordable.

They have not yet considered how to distribute the vaccines to adults—considered less pressing—because studies show that RSV rarely causes severe disease in adults who live outside of care settings, such as a nursing home.

Why did the United States and Europe approach the problem from opposite directions?

In the U.S., there was a financial incentive: Roughly 3.7 million babies are born each year, while there are about 75 million Americans age 60 and older—the group for whom the two adult vaccines were approved. And about half of children get their vaccines through the Vaccines for Children program, which negotiates discounted prices.

Also, babies can get vaccinated only by their clinicians. Adults can walk into pharmacies for vaccinations, and pharmacies are only too happy to have the business.

But which [older adults](#) truly benefit from the shot? The two manufacturers of the adult vaccines, GSK and Pfizer, conducted their studies presented to the FDA for approval in a population of generally healthy people 60 and older, so that's the group to whom they may be marketed. And marketed they are, even though the studies didn't show the shots staved off hospitalization or death in people ages 60 to 75.

That led to what some have called a "narrow" endorsement from the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices for people 60 to 75: Patients in that age range could get the shot after "shared clinical decision-making" with a health provider.

It is likely that because of this fuzzy recommendation, some Americans 60 and over with commercial insurance are finding that their insurers won't cover it. Under Obamacare, insurers are generally required to cover at no cost vaccines that are recommended by the ACIP; however, if a provider recommends vaccination, then it must be covered by insurance.

(In late September, the ACIP recommended immunization of all babies with either the antibody or the maternal [vaccine](#). Insurers have a year to commence coverage and many have been dragging their feet because of the high price.)

There are better and more equitable ways to steer the shots into the arms of those who need it, rather than simply administering it to those who have the "right" insurance or, swayed by advertising, can pay. For example, insurers, including Medicare, could be required to cover only those ages 60 to 75 who have a prescription from a doctor, indicating shared decision-making has occurred.

Finally, during the pandemic emergency, the federal government purchased all COVID-19 vaccines in bulk at a negotiated price, initially below \$20 a shot, and distributed them nationally. If, to protect public health, we want vaccines to get into the arms of all who benefit, that's a more cohesive strategy than the patchwork one used now.

Vaccines are miraculous, and it's great news that they now exist to prevent serious illness and death from RSV. But using such novel vaccines wisely—directing them to the people who need them at a price they can afford—will be key. Otherwise, the cost to the [health](#) system, and to patients, could undermine this big medical win.

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