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## New COVID Vaccines Will Be Ready This Fall. America Won't Be.

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Not so long ago, America's next COVID fall looked almost tidy. Sure, cases might rise as the weather chills and dries, and people flock indoors. But Pfizer and Moderna were already cooking up America's very first retooled COVID vaccines, better matched to Omicron and its offshoots, and a new inoculation campaign was brewing. Instead of needing to dose up three, four, even five times within short order, perhaps Americans

could get just *one* COVID shot each year, matched roughly to the season's circulating strains. Fall 2022 seemed "the first opportunity to routinize COVID vaccines," says Nirav Shah, the director of the Maine Center for Disease Control and Prevention, and simultaneously recharge the country's waning enthusiasm for shots.

## Read: This fall will be a vaccination reboot

Now that fall is [checks notes] officially 10 weeks away, that once-sunny forecast is looking cloudier. The Biden administration could soon offer second booster shots to all adults—an amuse-bouche, apparently, for fall's Omicron-focused vaccines, which may not debut until October at the earliest, by which time BA.5 may be long gone, and potentially too late to forestall a cold-weather surge. In April, the FDA's leaders seemed ready to rally around a fall reboot; in a

statement last month, Peter Marks, the director of the agency's Center for Biologics Evaluation and Research, struck a more dispirited tone. The coming autumn would be just a "transitional period," he said. Which checks out, given the nation's current timetable. "I see this fall shaping up to be more incremental," says Jason Schwartz, a vaccine-policy expert at Yale, "rather than that fresh start of *let's begin again*."

This, perhaps, is not where experts thought we'd be a year and a half ago, when the vaccines were fresh and in absurdly high demand. Since then, the tale of the U.S.'s COVID immunity has taken on a tragicomic twist: First we needed a vaccine; then we needed more people to take it. Now the problem is both.

Yes, fall's vaccine *recipe* seems set. But much more needs to happen before the

nation can be served a full immunization entrée. "It's July, and we *just* heard that the FDA would like to see a bivalent vaccine," with the spike of BA.4 and BA.5 mixed with that of the OG SARS-CoV-2, Schwartz told me. When, exactly, will the updated shots be ready? How effective will they be? How many doses will be available? We just started prepping for this new inoculation course, and are somehow already behind.

Then, once shots are nigh, what will be the plan? Who will be allowed to get one, and how many people actually will? Right now, America's appetite for more shots is low, which could herald yet another round of lackluster uptake.

There's little time to address these issues.
Fall "is, like, tomorrow," says Jacinda AbdulMutakabbir, an infectious-disease
pharmacist at Loma Linda University, in

California. Autumn, the season of viral illnesses and packed hospitals, already puts infectious-disease experts on edge. "We dread fall and winter season here," says Yvonne Maldonado, a pediatric-infectiousdisease specialist at Stanford University. The system has little slack for more logistical mayhem. The world's third COVID autumn, far from a stable picture of viral control, is starting to resemble a barely better sequel to the uncoordinated messes of 2020 and 2021. The coming rollout may be one of America's most difficult yet—because instead of dealing with this country's vaccination problems, we're playing our failures on loop.

In an ideal version of this fall, revamped COVID vaccines might have been doled out alongside flu shots, starting <u>as early as</u>

<u>August or September</u>, to prelude a probable

end-of-year surge. But that notion may have always been doomed. At an FDA advisory meeting in early April, Marks told experts that the fall vaccine's composition should be decided no later than June. The agency didn't announce the new ingredients until the final day of last month. And it chose to include BA.4 and BA.5, the reigning Omicron subvariant—rather than the long-gone BA.1, which Pfizer and Moderna had been working with. That decision may further delay the shots' premiere, punting the delivery of some doses into November, December, or even later, depending on how the coming months go. If the goal is preventing a spate of seasonal sickness, that's "cutting it quite close," says Wilbur Chen, an infectiousdisease physician and vaccine expert at the University of Maryland.

Whenever the shots do appear, they could

once again be hard to keep in stock.

Coronavirus funds are still (still!) stalled in congressional purgatory, and may never make it out. Although the Biden administration has agreed to purchase more than 100 million doses of Pfizer's revamped Omicron vaccine for the months ahead, federal officials remain worried that, as Ashish Jha, the nation's top COVID-response coordinator, has said, "we're not going to have enough vaccines for every adult who wants one" this fall.

Meanwhile, state and local leaders are awaiting marching orders on how much vaccine they'll be getting, and who will be eligible for boosters—intel they may not receive until after the updated shots are authorized. With a year and a half of experience under their belts, health workers know how to roll out COVID shots, says

Chrissie Juliano, the executive director of the Big Cities Health Coalition. But distribution could still get tangled if "we're back to a situation of scarcity," she told me. The government may allocate shots based on states' populations. Or it could opt to dole out more doses to the regions with the highest vaccination rates, wasting fewer shots, perhaps, but widening gaps in protection.

More than two years into the pandemic, with the health-care system under constant strain and staff exhausted or frequently out sick, local communities across the nation may not have enough *capacity* to deploy fall shots en masse. In particular, pharmacies, a vaccination mainstay, will need to handle a simultaneous surge in demand for flu and COVID shots amid "a serious nationwide staffing shortage," Michael Hogue, the dean

of Loma Linda University's pharmacy school, told me. A lack of funding only compounds these problems, by making it harder, for instance, to get doses to people who aren't insured. For that reason alone, "some of the contractors we've used in the past have not been able to keep up the same services," including vaccination drive-throughs, Phil Huang, the director of Dallas County Health and Human Services, told me. In Douglas County, Nebraska, pop-up vaccination sites are closing because not enough nurses can staff them. How do you get people vaccinated, Lindsay Huse, the county's health director, asked me, "when nobody wants to work for what you're paying, or they're just burned out?"

Even if more resources free up, greater shot availability may not translate to greater protection: Less than half of eligible

vaccinated Americans, and less than a third of all Americans, have received a first booster dose, a pattern of attrition that experts don't expect to massively improve. And just how much of an immunity boost the updated shot will offer is still unclear. When the FDA recommended including BA.4/5's spike, it had limited data on the proposed recipe, collected in mice by Pfizer's scientists. And Pfizer and Moderna won't have time to generate rock-solid efficacy data in humans before the shots are authorized, then roll out in the fall. "So when we get these vaccines cranking off the assembly line, the case public-health officials may be able to make will be tempered," Schwartz told me. That these doses will offer big improvements on their predecessors is a decent bet. But believing that will, for the public, require a small leap of faith—at a

time when Americans' trust in public health is already low.

America has had its share of COVID-vaccination victories. Hundreds of millions of people have gotten at least one dose.

Distribution and administration have been streamlined. Communities have come together to bring shots to people in all sorts of venues. The local experts I spoke with felt confident that they'd rise to the challenge of this autumn, too. But if the shots themselves are not in demand, an infusion of supply-side resources alone won't be enough.

Read: America created its own booster problems

With two years of data on COVID vaccines' safety and efficacy, the case for dosing up has only strengthened, scientifically. But the public's interest and trust in the shots has

fallen off as recommendations have shifted, often chaotically, and the number of necessary shots has ballooned. Even Americans who lined up for their first doses are now over the idea of rolling up their sleeves again. Abdul-Mutakabbir hears often: "I got the two doses; that's what you told me I needed to do. I'm not doing anything else." In Camden County, New Jersey, a team led by Paschal Nwako, the region's health officer, has "knocked on doors, given out freebies and gift cards, visited people in all areas: grocery stores, shops, restaurants, schools, churches, shows," he told me. "We have exhausted all the playbooks." Still, people have refused.

The shifting culture around COVID in the U.S. has undoubtedly played a role. "We don't have the same sense of desperation that we did in December of 2020,"

Maldonado, of Stanford, told me. Americans are eager to put the pandemic behind them. And boosters are a tough sell in a nation that has dispensed with nearly all other COVID-prevention measures, and where political leaders are triumphantly declaring victory. "We start talking about COVID, and people's eyes glaze over," says Nathan Chomilo, a pediatrician and health-equity advocate in Minnesota. "The messaging will have to be fundamentally different, even, than last year's conversation about boosters."

Read: Don't wait to get your kid vaccinated

When the vaccines were fresh, the popular narratives were tantalizing: The shots could permanently stop transmission in its tracks. But that was probably never going to pan out, says Luciana Borio, the FDA's former acting chief scientist. "Everybody that worked in the vaccine space," she told me,

knew that the safeguards against infection "were not going to last. Their voices did not get listened to." Instead, the more appealing story took root, setting "expectations that could not be sustained." Disappointment ensued, fracturing public faith; mis- and disinformation seeped into the cracks. And no one, including the nation's leaders, was able to offer a compelling enough counternarrative to put the matter to rest.

An upgraded shot could be enticing to some pandemic-weary folks. "I know a lot of people, including my family members, who say, 'If it's the same vaccine, why would I have to get it?" Nwako told me. "They want something different." Chomilo suggested that it may also be wise to stop counting how many shots people have gotten: "I hope no one 15 years from now is saying, I'm on my 15th booster." But nothing about these new

vaccines promises to unify Americans around the why of COVID vaccines. At April's advisory meeting, Marks said the FDA knew that the U.S.'s current vaccination strategy couldn't go on forever. "We simply can't be boosting people as frequently as we are," he said. And yet, the nation's leaders now seem keen on okaying another round of original-recipe shots for adults under 50—without emphasizing other tactics to lower transmission rates.

Getting COVID shots, too, can be a chore. With so many brands, doses, schedules, and eligibility requirements in the matrix, it's "the most complex vaccine we have," says Erik Hernandez, the system director of clinical-pharmacy services at the University of Pittsburgh Medical Center. The fall will introduce even more snarls: Boosters are switching to an Omicron blend, but, contrary

to what the FDA had initially planned, primary-series shots will be sticking with the original recipe. "That has massive operational implications," Maine CDC's Shah said, and could "increase the risk of errors." Nor have federal officials offered clarity on how long people getting shots now will have to wait before they're eligible for yet another this autumn. And Loma Linda University's Hogue thinks that it's very unlikely that children, especially the youngest ones, will be greenlit for bespoke Omicron doses this fall—another caveat to juggle. Some experts also worry that different states will once again select different rules on who can sign up for shots first. "You almost have to have a computer algorithm" to figure out what shots you need, Chen, of the University of Maryland, told me. Recommending an updated dose for everyone at once could be

less confusing, but if shots are truly scarce, broad eligibility could simply put the privileged at the front of the queue.

Read: Vaccines are still mostly blocking severe disease

Less funding already means less community outreach, and less support for the people most vulnerable to COVID's worst. The country could easily default back to many of the failures of equity it's rehearsed before. Abdul-Mutakabbir, who's the lead clinician and pharmacist for the COVID-19 Equitable Mobile Vaccination Clinics, serving Black and Latino communities in San Bernardino County, says she's "very nervous" that large swaths of the country will once again "end up in this place where people of minority groups are going to be those that suffer, and people of lower socioeconomic status are going to be those that suffer."

An infusion of dollars would allow the government to purchase more vaccines; it would furnish states with the funds to hire more workers, expand their community clinics, and reach people who might otherwise never get their shots. But the underlying issue remains: The U.S. does not have a strong, coordinated vaccination plan. Experts still can't agree on how many shots people need, how often we'll need to update them, even what the *purpose* of a COVID vaccination should be: stopping just severe disease and death? Blocking as much infection as possible? "We don't really have a grand unified theory of what we're doing when we vaccinate," Shah told me, at least not one that's been properly messaged—a deficit that will keep hamstringing the country's immunization efforts.

Without a clear plan, this fall, contra Marks's prediction, may actually be a definitive one for COVID vaccines—just not in the way that the nation's leaders once hoped. A bad precedent, too, could be set, and make Americans' trust in these shots, and the people who offer them, even tougher to recoup.