COMMENTARY

THE AMERICAN JOURNAL of MEDICINE®

Newest Guidance and Evidence for Health Care Providers: COVID-19 and Other Vaccines

On September 2, 2022, the US Food and Drug Administration (FDA) issued emergency use authorizations and the Centers for Disease Control and Prevention immediately endorsed use of new boosters created to combat the most recent and highly prevalent omicron variants of coronavirus disease 2019 (COVID-19), namely BA.4 and BA.5.[1,2] Fortunately, these most recent and most highly prevalent variants, while more communicable, are less lethal. Health care providers should be aware that more widespread vaccinations with these boosters now can avoid the specter of future and more lethal variants becoming realities.

In this commentary, we provide the most updated guidance to health care providers concerning COVID-19 and other vaccines as well as the evidence.

Health care providers are, with good reason, the most trusted professionals by the US general public, especially for the most updated and reliable information about COVID-19.[3] Health care providers are uniquely positioned to help their patients understand the applicability of the vaccine to their personal life circumstances, including addressing feelings of COVID and booster burnout. Such efforts by health care providers will assist their patients to feel empowered to participate in their medical care and make the most rational clinical decisions.[4] Health care providers already have and will continue to play crucial roles in reducing preventable morbidity and mortality from COVID-19, but these most recent updates create new challenges.[1,2,5]

The most simple and straightforward newest guidance we can now offer to health care providers is that all individuals 12 years of age and older should receive a booster shot every 4 to 6 months. Specifically, based on the recent emergency use authorizations issued by the FDA on September 2, 2022, those 16 and older may receive Moderna or Pfizer boosters, and those 12 and older should receive Pfizer only because the data from Moderna are still forthcoming. While the absolute risks of severe COVID-19 are low in youths, the benefit-to-risk ratio was deemed to be favorable in a 13 to 1 vote of independent external advisers to the FDA.[1]

In the most recent guidance from the FDA and the Centers for Disease Control and Prevention, unvaccinated US adults aged 50 years and older, when compared with those receiving at least 1 COVID-19 booster, have about 14 times the death rate. In addition, compared with those who have had 2 boosters, those 50 and older who have received only 1 booster have 3 times the death rate.[1,2]

Large numbers of volunteers have participated in more than 800 large-scale randomized, double-blind, placebo-controlled COVID-19 trials in the US and worldwide, and the results show markedly favorable benefit-to-risk ratios for the Moderna and Pfizer vaccines. In addition, postimmunization surveillance of millions of vaccine recipients have shown that the Moderna and Pfizer COVID-19 vaccines are as safe as or safer than most other common vaccines that are routinely administered to millions of children and adults. Further, their benefit-to-risk ratios, far exceed those of the influenza or pneumococcal vaccines, which have been widely accepted by the vast majority of adults in the US who have received them.[6]

On a daily basis, health care providers try to prevent and treat illness based on a sufficient totality of evidence that allows rational clinical decision-making for individual patients as well as policy making for the health of the general public.[5] Rejection of the COVID-19 vaccine, despite

Funding: None.

Conflicts of Interest: AR, VJ, MJDC, and DGM report none. SKW reports that she serves as an independent scientist in an advisory role to investigators and sponsors as a member of a data monitoring committee for Amgen. CHH reports that he serves as an independent scientist in an advisory role to investigators and sponsors as chair of data monitoring committees for Amgen, British Heart Foundation, Cadila, Canadian Institutes of Health Research, and DalCor, to the Collaborative Institutional Training Initiative (CITI), the US Food and Drug Administration, and UpToDate; receives royalties for authorship or editorship of 3 textbooks and as coinventor on patents for inflammatory markers and cardiovascular disease that are held by Brigham and Women's Hospital; has an investment management relationship with the West-Bacon Group within Truist Investment Services, which has discretionary investment authority; does not own any common or preferred stock in any pharmaceutical or medical device company.

Authorship: All authors had access to the data and a role in writing this manuscript.

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https://doi.org/10.1016/j.amjmed.2022.09.018

the aforementioned totality of evidence on benefit to risk, also poses an "ethical quagmire."[6] First, levels of protection and safety exceed those for other vaccines. Second, previous vaccines have been mandated and are widely accepted by the vast majority of adults, including health care professionals. Third, >90% of Americans have been vaccinated against other generally less common and less serious diseases, but fewer have been vaccinated against COVID-19. We believe health care providers have the potential to avoid the expected seasonal increases of premature deaths and hospitalizations by advising their patients right now about the need for full vaccination and periodic boosters.

In 2021, collegial, collaborative and coordinated efforts of academia, industry, federal, state and local governments as well as regulatory authorities in the US led to the almost miraculous development of effective and safe vaccines that have been widely distributed in record time. Most vaccines take up to a decade or longer to develop and prove their efficacy and safety, whereas multiple effective and safe COVID-19 vaccines have been developed and widely distributed throughout the US in <1 year.

Health care providers may wish to emphasize to their patients that, compared with influenza, the mortality rate from COVID-19 is about 30 times higher. Further, a patient positive for COVID-19 is likely to transmit to about 6 people compared with 1 or 2 for influenza. The efficacy of COVID-19 vaccines are 95% against hospitalizations and death. These reassuring data are significantly higher than for conventional influenza vaccines. Finally, the reported side effects are no greater and are likely to be less than for most other vaccines.[6] It is also important for health care providers to acknowledge that fears of patients are understandable but, fortunately, do not derive from the reliable evidence about COVID-19 vaccines.[2]

The war on COVID-19 is being fought most successfully, valiantly, and selflessly by all health care professionals in communities and in hospitals. Dedicated and conscientious health care providers are doing the most good for the most patients, while placing themselves and their loved ones at increased risk. As competent and compassionate health care professionals, we must redouble our efforts to promote evidence-based clinical and public health practices that should include vaccination of all US adults and eligible children based on the most recent guidelines.

Health care providers may also wish to emphasize that many patients with "vaccine hesitancy" believe in their individual right to remain unvaccinated. In this circumstance it may be informative to discuss the issue of balancing individual rights with personal responsibilities when vaccine hesitancy is driven by this concern. For example, cigarette smokers have the right to die from lung cancer and cardiovascular disease but also have a responsibility not to increase these risks to others.

Of the 10 richest countries in the world, the US ranks last in vaccination rates and first in both numbers and rates of deaths from COVID-19. The US has experienced >1 million or >16% of worldwide deaths from COVID-19 and constitute <5% of the world's population.[1,5] While today the US is experiencing about 500 daily deaths from COVID-19, this number will surely increase in the fall and winter. Further, health care providers may wish to emphasize to their patients that we are basically accepting the numbers of deaths that would accrue from the crashing of a 747 with no survivors each and every day.

Vaccines to prevent common and serious infectious diseases have had a greater impact on improving human health than any other medical advance of the 20th century. It may be helpful to create a dialogue about the experiences concerning the eradication of smallpox. Alarmingly, in the US today the vaccination rates against COVID-19 remain low and suboptimal in the general population.[7]

Since 2019, the percentages of US children unvaccinated against common and serious childhood diseases has decreased. For example, diphtheria-pertussis-tetanus (DPT) immunizations have decreased in the US from 85% in 2019 to 67% in 2021.[7] Recently, a young adult unvaccinated against polio in Rockland County, New York, where there is opposition to vaccinations,[8] contracted paralytic disease, raising concerns that the loss of herd immunity may portend new epidemics.[9]

Ironically, virtually all Americans would seek effective and safe therapies for any communicable disease. Most individuals routinely accept major surgery, toxic chemotherapy, or radiation therapy for cancer. At present, in the US, vaccines provide the *best opportunity to combat* COVID-19. Health care providers may also wish to apply the Benjamin Franklin axiom that "an ounce of prevention is worth a pound of cure" by increasing vaccination rates in their patients.

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