MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention (CDC)
Virtual Emergency Meeting
January 27, 2021

Excerpt: Public Comments

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Overview

The floor was opened for public comment during the January 27, 2021 ACIP emergency meeting at 4:30 PM ET. Given that many more individuals registered to make oral public comments than could be accommodated, selection was made randomly via a lottery. The comments made during the meeting are included here. Members of the public also were invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket No. CDC-2021-0002. Visit http://www.regulations.gov for access to the docket or to submit comments or read background documents and comments received.

Lindsay Clarke, JD
Vice President
Health Education and Advocacy
Alliance for Aging Research

Thank you so much. Good afternoon. I'm Lindsay Clarke, Vice President of Health Education and Advocacy at the Alliance for Aging Research. The Alliance is one of the convening members of the COVID-19 Vaccine Education and Equity Project, along with Healthy Women and the National Caucus & Center on Black Aging (NCBA). We are joined by more than 125 partner organizations representing patients, caregivers, families, diverse communities, health care professionals, older Americans, veterans, frontline workers, and scientists. The project is focused on promoting widespread and equitable access to COVID-19 vaccination information, particularly among those on the front lines and the communities that have been hit hardest by the pandemic. You can learn more and join us at https://covidvaccineproject.org/

While we are excited to see vaccine administration ramping up in recent weeks, we also need to continue to be aware of and look out for those that may be left behind. Vaccine hesitancy still exists in many communities, but as discussed earlier, the primary obstacle right now seems to be access. Older adults, Black Americans, and other vulnerable populations are more eager than ever to get vaccinated. However, in order to make vaccine appointments, they often are asked to go online, download, apps, and check back frequently for availability. Those who don't have internet access or are uncomfortable with technology or who don't have the time to devote to getting an appointment are being left out. We're glad to see the committee addressing this and encourage use of the CDC Social Vulnerability Index (SVI) to offer vaccines according to zip codes. Just because a COVID-19 vaccine clinic is set up in an underserved area does not ensure vaccine access unless appointments are limited to those residents. We also need more targeted outreach on the ground in underserved communities, as well as appointment assistance. All of these strategies will help get vaccines into the arms of the most vulnerable in the communities that have been hit the hardest.

Even if they are able to navigate the appointment system, there are still many who are reluctant to get a vaccine. According to a survey that the Alliance recently conducted on behalf of the Vaccine Education and Equity Project, when asked about preferences on where to receive a COVID-19 vaccine, the majority of responds (64%) indicated that they would prefer to get it at their health care provider's office, 29% prefer a pharmacy, and 20% a drive-through vaccine clinic, while only 13% would like to receive the vaccine at a grocery store pharmacy. Older adults are much more likely to cite a preference for COVID-19 vaccine administration in their health care provider's office. Those preferences seem to relate to trust and familiarity, with nearly two-thirds of respondents saying they would prefer to get vaccinated from a healthcare provider they know. While the focus is primarily on large-scale distribution sites in these early

phases of administration, we encourage the ACIP and CDC to consider these barriers and preferences in future phases so that we can reduce barriers for individuals who are harder to reach or who are reluctant to actively seek out a COVID-19 vaccine. We are ready and willing to help the committee in any way, so please reach out. Thank you for the opportunity to comment.

Mark Gibbons
President/CEO
RetireSafe

Mr. Chairman. Good afternoon. My name is Mark Gibbons. I'm the President and Chief Executive Office (CEO) of an organization called RetireSafe. RetireSafe is a non-profit grassroots organization whose mission is to educate and advocate on behalf of older Americans. We address many key issues, including Social Security, Medicare, Medicaid protecting our health, and financial wellbeing by making sure the concerns as well as the wisdom of older generations are given voice. The COVID virus has impacted all of us in many unexpected and devastating ways, but the stats for those over 65 are harsh, indeed. Approximately 1 in 7 adults in the United States are over 65, but CDC reports that 6 out of every 8 COVID-related deaths have occurred in this age group. That is 6 out of 8. Older persons also have higher infection, hospitalization, and death rates from other infectious diseases, such as influenza and also pneumonia. In short, advanced age tragically also means advanced risk.

RetireSafe thanks ACIP and its advisors for their tireless work for being invited to speak today. As new vaccines for COVID and other diseases are developed, it is so important that the high-risk status of more than 50 million older Americans be addressed. We respectfully ask that ACIP consider the addition of adding a few more gerontological experts to its membership. I understand that 4 new members have been added; however, none were from this category. This is a little disappointing for my membership. I attended a meeting back in 2019, and one of the members stated that the committee's only concerns were younger children and young adults—not the aging adults. I don't think that is really what was meant to be said, but that's what was said. So, please consider adding some more doctors that handle the aging. Thank you for your time and have a good afternoon.

Dr. Justin Gregory
Division of Pediatric Endocrinology
Vanderbilt University Medical Center

Good afternoon. My name is Justin Gregory. I'm a Pediatric Endocrinologist at Vanderbilt University Medical Center (VUMC). Currently, the CDC categorization has Type 1 diabetes as a condition that *may* increase risk for severe COVID-19. In light of recent clinical evidence, I urge my colleagues on this committee to recommend revising this categorization to a condition that *does* increase risk for severe COVID-19. At present, the CDC appropriately list Type 2 diabetes as a high-risk condition. As we summarized in an article in the *Annals of Internal Medicine* published yesterday, clinical evidence unequivocally suggest that CDC should likewise categorize Type 1 diabetes as a high-risk medical condition. In our prospective cohort study of COVID-19 outcomes at Vanderbilt, originally published last month in *Diabetes Care*, we found hospitalization with COVID-19 is 4.6 times more likely to occur in patients with Type 1 diabetes than patients who do not have diabetes. By comparison, hospitalization is 3.4 times more likely to occur in patients with Type 2 diabetes than patients who do not have diabetes. Moreover, we found that even when patients with Type 1 diabetes maintain blood sugar at ideal levels, they were still 3 times more likely to be hospitalized than patients without diabetes.

Our international colleagues similarly found having Type 1 diabetes increases the risk of mortality. A recent population-wide study of England published in *Lancet Diabetes and Endocrinology* found COVID-19 mortality was 3.5 times more likely among patients with Type 1 diabetes than patients without diabetes By comparison, COVID-19 mortality was 2 times more likely in patients with Type 2 diabetes. Fortunately, randomized clinical trials (RTCs) showed that both currently approved vaccines were just as efficacious in preventing COVID-19 complications in people with diabetes as they were in protecting the entire study cohort. Moreover, severe COVID-19 occurred only once among all of the vaccinated participants. Thus, while patients with Type 1 diabetes are at greater risk for severe COVID-19, the vaccine appears to have a profoundly protective effect against this outcome in these patients.

In conclusion, the data are clear. I join the Juvenile Diabetes Research Foundation (JDRF), the largest charitable supporter of Type 1 diabetes research to urge this committee to recommend that CDC revise its categorization of people with certain medical conditions to reflect that individuals with Type 1 diabetes are at increased risk of severe illness from the virus which causes COVID-19. As individual states will soon transition into Phase 1c of COVID-19 vaccination, this revision can play a critical role in appropriately prioritizing patients with Type 1 diabetes for immunization. Such action will allow the medical community to maximize the benefit of the vaccine by protecting over 1.6 million Americans with Type 1 diabetes through an increased risk for morbidity and mortality from this virus. Thank you.

Michaela Jackson, MS
Prevention Policy Manager
Hepatitis B Foundation

My name is Michaela Jackson. I am the Prevention Policy Manager for the Hepatitis B Foundation. On behalf of the hepatitis B and liver disease communities, I am speaking today to encourage ACIP to share available subgroup data, particularly for people living with hepatitis B and liver disease that has been presented by companies developing COVID-19 vaccines. ACIP has responded to the coronavirus pandemic swiftly and we applaud the dedication to ensuring the safety and efficacy of each vaccine. However, there remains great uncertainty and confusion among patients and providers about who should receive the vaccines. Lack of publicly available data plays a large role in this uncertainty. We are aware that people living with HepB and liver disease have been included in clinical trials, but representation matters little if the groups represented are not able to see the information relevant to them. Establishing trust in the efficacy of these vaccines is absolutely critical to ending the pandemic. While the public health community has made great strides with this endeavor, there is still a long way to go. Throughout the course of this pandemic, an increasing number of people living with HepB have approached us with questions about how effective the vaccine is for them and if they should even receive it given their health condition. Simply put, these communities have expressed an interest in getting immunized against COVID-19, but are hesitant due to a lack of information currently available to them. Presenting evidence on people living with HepB and liver disease from clinical trials will help improve access to approved vaccines and will broaden trust and acceptance as well. Too often, the medical community has neglected to listen to the concerns of under-represented groups and the consequences have been devastating. We must remember that data is one of the most powerful tools we have to build back some confidence among vulnerable populations, and it's one that we must fully utilize in order to earn the trust of consumer communities. Thank you for your time today.

Kelly Shanahan, MD
Member at Large
METAvivor

I'm Kelly Shanahan. Before my metastatic breast cancer diagnosis, I was an OB/GYN. Now, I'm an advocate on the Board of Directors of METAvivor, which raises money for metastatic breast cancer research, including the $4.4 million dollars we awarded in the midst of this pandemic. I'm speaking for the adult cancer community as there is no such representation on ACIP. From the first paper from the COVID-19 Cancer Consortium published online in *The Lancet* last year, it has been clear that people with cancer are at increased risk of severe illness and death if infected with SARS-CoV-2. This is true whether the cancer is active or not, although people currently being treated for cancer with a metastatic diagnosis fared the worst. Work from the United Kingdom Coronavirus Cancer Monitoring Project (UKCCMP) confirmed this. Desai et al, in an article from December, performed a meta-analysis of people with cancer hospitalized with COVID-19. Thirty percent of those hospitalized died. For studies that included a mix of in- and outpatients, the mortality rate was 15%. Currently in the US, the case fatality rate of COVID-19 is 1.7%. We know that the risk of dying increases with age. Levin et al in the December *European Journal of Epidemiology* calculated an infection fatality rate of 0.4% at age 55, 1.4% at 65, and a staggering 15% at 85. What does that 15% remind us of? The 15% to 30% mortality of people with cancer who also have COVID-19. It's not just death that we need to consider. People with cancer who become ill with COVID-19 are more likely to require hospitalization at 47% according to an analysis of electronic health records (EHRs) by Wang et al published in *Jama Oncology* in December—almost double the rate of people without cancer and almost 4 times the rate of people with cancer who did not also have COVID-19. People with cancer have increased exposure risk because staying home and skipping treatments and scans is not an option for us. If the goal is to vaccinate those at greatest risk of severe illness or death should they contract COVID-19, shouldn't people with metastatic and active cancers who die at a rate equal to and perhaps twice as high as octogenarians be vaccinated with that group? I've heard experts say that we should move to vaccinating based on age alone—that it's just too hard to prioritize by risk. They said it was too hard to go to the moon, but we did that. It's not rocket science to devise a system where people with metastatic and active cancers are vaccinated at their cancer center or oncology office. We're going for treatments and scans and follow-ups already. Our oncologists know our diagnosis. Who gets vaccinated when is all over the map. State and local public health organizations look to you for guidance. If you truly believe that the most vulnerable must be prioritized for vaccination, then that must include people who have a 15% to 30% chance of dying—the active and metastatic cancer population. Thank you.

Allison Winnike, JD
President & CEO
The Immunization Partnership

Good afternoon Chair Romero and members of the committee. My name is Alison Winnike. I'm President and CEO of the immunization partnership. Our nonprofit mission is to eradicate vaccine-preventable diseases by educating the community, advocating for evidence-based public policy, and supporting immunization best practices. Thank you for developing vaccine recommendations to keep all Americans safe and healthy. Your scientific recommendations are an important tool that states use to carry out their constitutional duty to protect the public's health. Today, I have two recommendations for the committee. First, I recommend giving greater weight to vaccine availability through the supply chain in the priority-based group recommendations. ACIP recommendations should be a solid data-driven guide for states as

they implement their COVID-19 vaccine administration plans. However, it is notable that outside of the Phase 1a recommendations that were recommended by ACIP, and that were nearly universally adopted by the states, only a small minority of states are exactly following the Phase 1b and 1c recommendations. Many were frustrated by the committee's prioritization of essential workers in Phase 1b over those at high-risk for severe COVID-19 at a time when vaccine supplies were so limited and deaths were mounting in those aged 65 and older and people with high-risk medical conditions.

With nearly 425,000 deaths so far and a surge impacting our most vulnerable, states need more detailed recommendations to help them prioritize within phase groups as we struggle with such limited vaccine supply. My second recommendation is to continue your practice of transparency and deliberations for forthcoming COVID-19 vaccines. We were very fortunate that the first two vaccines authorized for emergency use demonstrated extremely high efficacy rates for the adult population, but future vaccines may not meet the efficacy levels of our current vaccines or they may have varying rates for different age groups. I am concerned that as new vaccines enter the market, people may fear they are receiving an inferior product if the efficacy rates do not meet the vaccines that are currently available. The community should take extra efforts to sufficiently explain the science behind your recommendations, both to states executing their vaccine plans and to the public. Americans are frustrated, they're scared, they're sick, and many feel forgotten if they wait their turn to be vaccinated against this novel coronavirus. Please make sure that future COVID-19 vaccine recommendations take into account the vaccine access and equity issues Americans face. Strong communications from the committee on the science may help combat the perception that future vaccines may be of lower quality or rushed through to distribute to those with high social vulnerabilities and few resources. Thank you so much for your important work and the opportunity to share our comments.

Edward Nirenberg
Vaccine Advocate

Hello. Thank you for the opportunity and privilege you granted me today in permitting me an oral public comment. My name is Edward Nirenberg and I am a vaccine advocate who focuses primarily on debunking and pre-bunking harmful disinformation and misinformation pertaining to vaccines. I am immeasurably grateful for your labors in ensuring the safety of the American people and your transparency of these proceedings, as they have helped me personally tremendously. I'd like to call out a few issues to the attention of ACIP in this short window of time. Firstly, the Pfizer-BioNTech vaccine in preclinical and clinical data showed robust activation of CD-8 T-cells, while for Moderna's vaccine the response was undetectable. Notably, efficacy for both vaccines in the Phase III trials were very similar. Due to the exigency of our present crisis, people should absolutely take the first vaccine offered to them provided they have no contraindications. However, preclinical models in macaques implicate CD8 T-cells as important correlates of recovery from COVID-19. Epidemiological data show low CD8 T-cells are associated with poor prognosis. Many patients with certain blood as well as those with certain autoimmune diseases are placed on anti B-cell therapies such as Rituxan, Rituximab, or Ranibizumab. Operating under the assumption of a neutralizing antibody-mediated mechanism as a correlate protection, this presents many patients without protection against COVID-19. I ask that the committee consider, in light of the evidence available, a recommendation that those patients on anti-B-cell therapy should whenever possible preferentially receive the Pfizer-BioNTech vaccine over Moderna as a way to recognize of the evidence-based considerations.

Secondly, increasingly I'm seeing concerns regarding apparent functional movement issues following the receipt of COVID-19 vaccine. These have gone viral and several videos are provoking profound anxiety. The Functional Neurological Disorder Society (FNDS) has issued a statement describing the nature of these reactions. I believe it would be valuable for the committee to enhance communications regarding possible cytogenic issues related to immunization as this has been observed before with, for example, the human papillomavirus (HPV) vaccine. Lastly, the anti-vaccine movement sees the pandemic an opportunity to undermine vaccine confidence and is thus working tirelessly to correlate any adverse outcomes from anyone who receives the vaccine as a causal relationship to vaccinations. I believe it would be helpful for the committee to put out communications elucidating the inadequacy of temporal associations in establishing causality and adverse event following immunization. I have been able to rely on several excellent summaries such as one from Dr. Bob Walker showing how many adverse health outcomes can be expected in any given 2-month window for 10 million people irrespective of vaccination status. These are subject to the assumption of vaccine distribution stories with statistical average across the entire population, which as the committee is aware, would represent an underestimate with vaccine preferentially going to the elderly and those with comorbidities since such outcomes are at baseline much more likely. Thank you for your time.

Peter Matz
Director, Food & Health Policy
Food Industry Association

Good afternoon. My name is Peter Matz and I'm here representing FMI, the Food Industry Association where I'm the Director of Food and Health Policy. By way of background, as the Food Industry Association, FMI works on behalf of the entire industry from retailers who sell to consumers, to producers who supply the food, to supermarket pharmacies and beyond. The total FMI member companies operate around 3000 grocery stores and 12,000 pharmacies, touching the lives of more than 100 million US households per week and representing an industry with nearly 6 million workers. First, FMI strongly supports ACIP's recommendation to prioritize food and agriculture industry essential workers in Phase 1b. However, states and jurisdictions should be strongly encouraged to adhere to the federal recommendations. As a result of many states developing their own prioritization frameworks in the face of federal guidance, food industry essential workers are struggling to access vaccinations. For manufacturing and production employees working in close proximity, to grocery workers who have a higher contact rate with the public, to certain transportation workers and food safety auditors who ensure food, beverages, and packaged foods are safe for consumer consumption our industry's essential workforce has gone above and beyond in demonstrating their continued resilience. But to keep supply chains operating and Americans nourished until all can receive the vaccine, it is imperative that they receive vaccinations.

Furthermore, as supermarket pharmacies across the country step up in support of vaccinations plans, changes to federal prioritization guidelines across states are impeding efficiency in vaccine delivery causing confusion and undermining the national vaccination effort. With that in mind, FMI urges the Biden Administration to designate a Federal COVID-19 Vaccine Coordinator in each state and jurisdiction to coordinate at all levels of government and help ensure the deployment of vaccines among priority populations. Also, to the extent that jurisdictions have already made revisions to federal vaccine allocation guidance, FMI asks that the CDC compile and store all state plans so the information is easily accessible to all stakeholders. Separately, supermarket pharmacies administered roughly 25% of the nation's flu vaccinations this year and now they stand ready to play an expanded role in increasing access

to COVID vaccines. A number of FMI pharmacy members have been providing vaccinations through the Federal Pharmacy Partnership (FPP), and a majority are enrolled as providers in the states where they operate. All of them have pharmacists prepared to administer COVID vaccinations in their stores and many pharmacists available and ready to provide vaccinations off-site as well. Many are also utilizing their parking lots and outdoor tents as COVID vaccination clinics capable of administering nearly a 1000 shots in a day. However, our members are not yet receiving vaccine supplies anywhere close to their capacity. Finally, in order for vaccine providers to fully utilize the Limited supply of vaccines they do receive, they must have visibility into the expected availability of future doses. We really appreciate the opportunity and thank you to ACIP.

Claire Hannan
Executive Director
Association of Immunization Managers

Good afternoon. I'm Claire Hannan, Executive Director of the Association of Immunization Managers (AIM). AIM members are the dedicated public health immunization directors currently working to help coordinate the COVID vaccine roll out, fighting to maintain and increase other immunization rates, writing grants on both the COVID response and routine immunization, and coordinating response to state legislation, including an array of bills threatening to compromise school requirements and add barriers to vaccination. It is a critical time. I'd like to thank the committee and CDC for their dedication to thoroughly reviewing all pre-decisional data and post-authorization safety data, building public trust and vaccines. The vaccine campaign, in the use of second doses, must be driven by science. Our success in just 5 weeks of vaccinating is incredible, with more than 23 million doses administered, more than 3 million people fully vaccinated, tens of thousands of private providers enrolled and trained. But, in the context of people dying of the virus and people suffering anxiety and frustration searching for the vaccine, our accomplishments don't feel incredible. So, we will continue to address our challenges and learn from them.

Vaccination strategies are evolving as jurisdictions work to improve efficiency and reporting. Large scale, high throughput vaccination clinics are more common. Jurisdictions are benefiting from public and private partnerships, collaboration with large companies such as Starbucks, and local and chain pharmacies. In our rush to improve efficiency though, we cannot lose sight of equity. Program managers are driven to ensure this vaccine receives widespread acceptance and protects everyone in all of our communities. Listening to the discussion today, we are so pleased to hear ACIP focusing on equity as well. State and local health agencies have received funding and resources to support COVID vaccination. We are grateful, but we also see these resources as just a down payment on the needed larger investment in our future in information technology (IT) modernization, public health workforce, routine adult vaccination, and continuing the critical work of building confidence in all vaccines in all communities. The key to COVID vaccination success is increased supply, increase transparency and communication, and most importantly, increased collaboration. Federal, state, and local public health must work together, not in competition, united by the same vision and goals. Our country is in a COVID emergency, but our entire immunization infrastructure is at stake. Combating myths and dangerous legislative initiatives require all of us. Let's start with the scientific expertise of this committee and the CDC. Thank you for your continued guidance and expertise.