MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention (CDC)
Virtual Meeting
December 1, 2020

Excerpt: Public Comments

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Aly Hargrave, RN
Pediatric Registered Nurse
Minnesota Nurses for Informed Consent

Thank you. My name is Ali Hargrave. I am a working Pediatric Registered Nurse in the State of Minnesota and a Combat Veteran of the United States Air Force. I am no stranger to witnessing vaccine injury. I came to this meeting to bring questions that, in my opinion, deserve to be answered before it can be deemed appropriate to distribute the fast-tracked to COVID vaccine to frontline healthcare workers. Why are roughly 36% of nurses planning to refuse this vaccine and 31% of nurses unsure if they will take it? How do we know that there will be no long-term health consequences from receiving the COVID vaccine? Long-term injuries and ailments are a possibility from any pharmaceutical product. Therefore, it is questionable how the label of "safe" can be given to the COVID vaccine when long-term studies and monitoring have not been done. Is it possible that we will be sacrificing or risking widespread injury among our essential population of healthcare workers for this pandemic and potential future pandemics? What about paradoxical immune enhancement? You must remember the phenomenon that created lethal inflammation during the 2012 animal studies of previous coronavirus vaccine trials, when all the vaccinated ferrets were exposed to the natural infection, then died from the overly robust immune response. How can we possibly know that this will not occur again when animal trials were forfeited for the sake of an accelerated timeline? Again, is it possible we are risking our essential healthcare workers by not having these questions answered? What about health care workers who have already recovered from the natural COVID infection? How will this vaccine act with the existing antibodies that they have? Is it safe to give this mRNA vaccine to people who have already recovered from a natural infection? Was this considered during the fast-tracked trials, especially considering how widespread the natural infection is amongst out healthcare workers? Finally, as a nurse, I am legally bound to give informed consent prior to giving any medication or intervention. How will it be possible for me, as a recipient, to receive informed consent when the CDC website states that ingredients of the COVID vaccine may be withheld due to proprietary concerns and the Phase III of the trials is still in progress? How can I receive informed consent without all the information available? With these questions, does it make sense for our frontline healthcare workers to receive this adequately tested, liability-free vaccine when the nation is literally depending on them to guide us through this pandemic? How can you call yourself an advisory council when you don't have all of the adequate information to advise us? Thank you.

Enrique Ricardo
Comments were unable to be transcribed due to sound quality.

Athanasia Anagnostou
Senior Director Corporate Development, Immunomic Therapeutics
Co-Founder & Board Member, Why We Vax

My name is Athanasia Anagnostou. I have worked for nearly a decade heading corporate development at a company called Immunomic Therapeutics. We work on nucleic acid vaccines quite similar to the technologies that underlie the COVID vaccines being discussed today, but we are focused on things like allergy and cancer. I am also Co-Founder and a Board Member of Why We Vax. This is a nonprofit that is dedicated to supporting vaccine education, awareness, and countering vaccine misinformation. I want to thank you all for having this meeting today and for your individual and collective hard work and dedication to support the use of vaccines in the US. I want to also note that amongst all the complications of this pandemic, the committee has been working to hold these meetings and be transparent and inclusive in your deliberations, and

for the overall process for how you make these recommendations. I support that you continue being transparent and inclusive. I think it will continue to, or at least try to instill confidence in the process and in COVID vaccines in general, which we know is so important. Also, as a mother of young children, I see one of the challenges to public confidence in vaccines, and I think we are seeing some of that today, and we might in a couple minutes, is the influence of people and groups that continue to spread misinformation and disinformation. We haven't always taken a very seriously, but I think we continue to see the deleterious effects. Before just on general vaccine uptake, but now with COVID misinformation is going to cast new types of doubt and you know, we've been seeing it about the safety and effectiveness. This is possibly going to be harmful to all Americans and even the ones that we've been talking about today who are most vulnerable to COVID-19. I think just in general, the motion put forward today obviously has been done with extensive deliberation and consultation. It is a great first step to protecting Americans from COVID and for the safe and adequate operations of healthcare providers and services. I strongly support voting for the motion. But, I also want to encourage CDC to continue to conduct education activities and outreach, and to be entrusted public source of information, because I think your credibility goes a long way to promote confidence in use of COVID vaccines. I think we all need to try to directly address some of the concerns that Americans have about these vaccines so that we can do our best to ensure widespread uptake so we can all get back to normal life. Thank you all for the hard work that you do.

Harald Schmidt, PhD
Assistant Professor
Department of Medical Ethics and Health Policy
University of Pennsylvania

Thank you very much. My name is Harald Schmidt. I am an Assistant Professor in the Department of Medical Ethics and Health Policy at the University of Pennsylvania. I'd like to start by congratulating the committee members and especially also their staff for their work. The complexity of data integration and the pressure, political and otherwise, is just intense. I frankly have no idea how you do it, but evidently you do. All the best as the initial finish line comes into sight. I'd like to make three brief points that focus on promoting equity, both within priority Phase 1 and beyond the consideration given to priority groups. I'd like to note that these comments build on collaborations with a number of colleagues, but in particular an outstanding Economist. So the first point is that allocating vaccines to states according to population does not help reduce inequities, which I take to be a central goal of the framework. For example, in New Hampshire a little over 1 in 10 people is among the most disadvantaged nationwide, but in New Mexico it is more than 3 and 10 using the SVI standard that the committee also draws on. There are similar variations in the populations of healthcare workers, of course. So if we send vaccines to states based on the population, disadvantaged groups in states with above-average shares face more rationing, but that's not fair. It would be helpful to encourage more fair allocation to jurisdictions that takes into consideration their shares of disadvantaged. Second, and related, the committee can still recommend that jurisdictions set aside extra vaccine amounts for disadvantaged populations. The National Academies of Sciences, Engineering, and Medicine (NASEM) report, which called sought to assist ACIP specifically with addressing equity recommended setting aside a 10% reserve at the federal level. While there is much other similarity between NASEM overall and ACIP, this proposal seems not to have carried over. This is regrettable as we have shown in a study that a 10% federal reserve is the most beneficial for disadvantaged groups, including healthcare workers. But we've also shown that a 10% reserve at the state level can still meaningfully help disadvantaged populations dramatically. Given where we are, it would be helpful if ACIOP took up the NASEM's work and recommended that states and other jurisdictions strongly consider a 10% percent reserve based on SVI or a related

measure to further promote equitable allocation within each population group. In a separate study that will launch tonight, we compared all 64 jurisdictions' initial allocation plans and can report that the State of Tennessee already plans to do this set aside of a 10% reserve. So other jurisdictions can likely learn from this approach, as well as from 17 other states that plan to use the SVI to promote equity for worse off populations in different ways. Lastly, technology can of course also enable in inequity. At an early meeting, ACIP suggested that the SVI could be integrated in the Tiberias software. From the tenor of the discussion then, I assumed that this would be to enable jurisdiction plans using Tiberias to prioritize disadvantaged groups using this SVI, but this seems unclear. Our analysis of the plans also show that 23 states currently plan on using Tiberias, including 15 that don't otherwise plan to use SVI for equity-promoting purposes. So the index may need more here and it would be helpful to have clarity on this point. So in summary, aside from considering equity in the sequence of priority populations, ACIP can still promote equity further by recommending allocations to jurisdictions not by population but by their share of disadvantaged within healthcare workers or otherwise, recommending 10% reserves for disadvantaged communities at the state level, and building SVI into the Tiberius platform.

Kermit Kubitz
Individual

Yes, I am Kermit kibbutz. I was a polio pioneer in the 1954 vaccine trials, which ultimately reduced polio cases from 55,000 to 5000 in the next 2 years. The recommended vaccine allocation priorities are well thought out based on goals of maximizing benefits, protecting public health and the health care system, and providing equity. You will vote on providing vaccination priority to health care workers in Phase 1a. You may want to clarify the firefighters, who act in many cases as healthcare workers and roll out to provide EMT services, are included as healthcare workers for Phase 1a purposes. My second recommendation, similar to the last speaker, is that geographic and state allocation of vaccines must recognize population densities and the availability of ultra-cold storage, and allocate less stringently storage vaccines to states and rural areas within states without deep cold storage if two different kinds of vaccines are available. Third follow-up of vaccines should include not just safety, but studies of effectiveness based on different populations and groups, potential flaws in logistical distribution and handling of vaccines, delays in dosing, or other issues which can affect effectiveness. So, there should be follow-up. Fourth, and I emphasize this, remember and plan to avoid laxity in non-pharmaceutical interventions such as masking and distancing by vaccinated persons interacting with unvaccinated populations. The vaccine may limit symptoms and illness, but may still allow infection and transmission. So, you must have a plan to ensure masking and distancing are still implemented until vaccines are widely available and used. Finally, as essential workers, I do recommend giving some priority to people who have participated in vaccine trials and received a placebo. Once an approved vaccine is available, those who receive the placebo should get the vaccine even at the cost of less follow-up of a placebo group, because the trial participants are truly essential workers. Just to clarify on EUA fact sheets for everyone involved, it is my understanding is one thing about an EUA vaccine is that people do have the right to choose not to use a vaccine approved through an EUA; that is, EUA vaccines are voluntary. Thank you.

Dorit Reiss, PhD
Professor of Law, Hastings College of the Law, University of California
Member, Vaccine Working Group on Ethics and Policy

My name is Dorit Reiss. I am a Professor of Law at the University of California Hastings College of the Law and a member of the Vaccine Working Group on Ethics and Policy. I have four points to make. ACIP plays a critical role in making recommendations that public health departments and healthcare providers recognize as authoritative and fact-based. ACIP recommendations are always critical, but even more so in a public health emergency, particularly the kind of emergency we are in now. While the public may not be aware of all that ACIP has done, the public benefits from the deliberations of this committee and relies on its expertise. It is critical that ACIP continue to play this critical role for COVID-19 vaccines. Second, in previous commenting sessions, members of the Correctional Officers Association asked you to consider including their members in the highest tier. I support the recommendation and am clearly too late for this, but I want to reinforce the message that while the level of outbreaks in jails and prisons were not as bad as in LTCF, they were high. In both cases, we have a captive population and many in prisons and jails are at high risk. Correction officers are the bridge to the community and may bring in COVID-19, but they are not healthcare workers and are not covered in the first tier. Maybe they should be because prisoners are exposed to COVID-19 through no choice of them. Many are in prison for things that don't deserve COVID-19 as a penalty, and some are in jail innocent. Third, and this is a bit of response to the previous comment, although the FDA and CDC have previously categorically stated that EUAs do not allow mandates, I think that is a misreading of the statutory language. The statutory language allows the Secretary discretion on whether mandates are allowed, and the categorical provision on mandates by private business may be vulnerable to Legal challenges as the misuse of discretion. I think advisory committees need to consider to what extend an EUA should allow mandates. That is more to FDA and to you, but you need to be aware of us. Finally, to echo comments I made in the past, I think ACIP should make public participation and its deliberations written only, at least for the near future. As you all know, all commenting before you has been used by anti-vaccine activists to create propaganda movies for their own community under the heading of “These are our comments to CDC.” Transparency is important, participation is important, but contributing to anti-vaccine propaganda is not a legitimate role for ACIP. You are promoting transparency by having this public discussion. You should keep doing that. You are providing an opportunity to public participation by having easily accessible written comments. You do not need to also provide a platform for making anti-vaccine pieces. Thank you very much.