

AMA webinar series: CDC Update on COVID-19 vaccine development

On Oct. 13, 2020, the AMA hosted the second webinar in the "COVID-19: What physicians need to know" series.

About the event

Hosted by AMA physician leaders, each installment of this webinar series aims to gain fact-based insights from the nation's highest-ranking subject matter experts working to protect the health of the public, particularly during the COVID-19 pandemic.

The second episode provided a comprehensive overview of the CDC's role in vaccine review and immunization programs.

Host

- Susan R. Bailey, MD, AMA President

Guests

- Nancy Messonnier, MD, Director, National Center for Immunization and Respiratory Diseases (NCIRD) at the Center for Disease Control (CDC)
- Amanda Cohn, MD, Acting Chief Medical Officer, NCIRD and Executive Secretary for the Advisory Committee on Immunization Practices (ACIP)

Transcript

Dr. Bailey: Hello everyone and thank you for joining us for the second AMA led discussion about the process that will eventually lead us to a vaccine for COVID-19. I'm Dr. Susan Bailey, president of the American Medical Association. The purpose of this call is to help physicians and the public have a

better understanding of the vaccine development process, as well as allocation and distribution of a vaccine, or vaccines, when they become available. We appreciate all of you for taking the time to be a part of today's call and we kindly ask that if you're not a health care provider that you log off from the session at this time. Thanks.

Dr. Bailey: Now, if you weren't able to join us for last week's call with Dr. Peter Marks, director of the Food and Drug Administration Center for Biologics Evaluation and Research, I encourage you to watch a video replay of our conversation, which can be found in our online COVID-19 resource center on our website. You can Google AMA COVID-19 resource center, or just type in ama-assn.org/COVID-19.

Dr. Bailey: Before I introduce our special guests for today's call, I want to take a moment on behalf of everyone at the AMA to send out my most sincere and heartfelt thank you to physicians everywhere who've responded so heroically to this pandemic. 2020 has tested us in ways that few could have imagined, but time and again, physicians, nurses and our entire health care community, have risen to the challenge of this moment. We still have a lot of work to do ahead of us to defeat COVID-19, but we know that the development of a safe and effective vaccine is a critical step toward a return to normalcy. The AMA has championed the widespread use of vaccines since the early 1960s, when the Sabin oral vaccine was developed to combat polio, and vaccines remain among the safest and most effective ways to prevent illness and protect public health.

Dr. Bailey: Of course, all of us are eagerly awaiting a vaccine for COVID-19, but we cannot rush the development of a vaccine at the expense of rigorous safety oversight. Rushing an unsafe or ineffective vaccine to market would compound the devastating effect of COVID-19. It was so important to hear from Dr. Marks at the FDA last week about the rigorous evidence-based safeguards in place during this accelerated vaccine development process.

Dr. Bailey: So today our guests will share their unique insights and perspectives into the planning and framework for successfully allocating and distributing a COVID-19 vaccine or vaccines. They'll discuss the role of the Advisory Committee on Immunization Practices, or ACIP, and providing recommendations for use of vaccines in the US civilian population. And they'll talk about the work of the CDC to ensure, once we have a safe and effective vaccine, that it's distributed across the country and that the appropriate data collection system is in place to track the vaccine supply, administration and monitor its safety.

Dr. Bailey: And they'll discuss the role physicians play in vaccine administration, and in promoting vaccine confidence. In a time of heightened concerns about this pandemic and with so much information, and disinformation, on vaccines in general, spreading online, the process we use to engage a skeptical public is critical to understand and discuss. Nobody understands this better than our two guests today. Dr. Nancy Messonnier is director of the National Center for Immunization and Respiratory Diseases, the NCIRD, at the Centers for Disease Control and Prevention. Dr. Messonnier

has held a number of prominent leadership positions within the CDC, including serving as deputy director of NCIRD and leading the agency's meningitis and vaccine preventable disease branch from 2007 to 2012. An expert in global health and surveillance initiatives, Dr. Messonnier has spearheaded prevention and control for bacterial meningitis in the U.S. and in hotspots around the world.

Dr. Bailey: And we also are glad to have Dr. Amanda Cohn, the acting chief medical officer at NCIRD and executive secretary for the ACIP. Dr. Cohn, who's board certified in pediatrics, has led or played integral roles in multiple domestic and international meningococcal disease outbreak response efforts since joining the CDC in 2004.

Dr. Bailey: We're delighted to have both of these amazing physicians, these experienced infectious disease experts, with us today. After their remarks, we will have some questions that have been submitted in advance by the audience. So please join me in welcoming Dr. Nancy Messonnier and Dr. Amanda Cohn. Thank you. Dr. Messonnier, it's all yours.

Dr. Messonnier: Great. Thank you Dr. Bailey and thank you to the AMA for inviting us here today. Dr. Cohn and I, in our day jobs, work on a variety of vaccines, but we are now both deployed to the CDC emergency response to work specifically on planning for COVID vaccines. You can go on to the next slide. You all are true heroes in everything you've done this year. What I'm going to talk to you today is really the next step in those roles and I will start by saying that we understand your incredible importance in this planning around COVID vaccine delivery. The U.S. government has made a huge investment in developing and manufacturing safe and effective COVID vaccines, and yet, a vaccine that is safe and effective sitting on a shelf, is not helpful. For these vaccines to be useful, need to be used safely and effectively, and that's what we're going to talk to you about today.

Dr. Messonnier: We are in a complicated vaccine landscape and there are many types of vaccines in development that could possibly be authorized by FDA. And we don't come to you today able to talk specifically about the vaccine that we expect to get there first or second. There's a lot of information that isn't available yet because it's not known. But no matter how quickly vaccines are developed, CDC and FDA will deploy the routine processes and procedures and systems to ensure vaccines are safe and effective, and to ensure appropriate oversight of those vaccines. It's great timing that Dr. Marks spoke to you last, and if you haven't heard his talk, I've certainly heard him speak eloquently on this issue. I agree with Dr. Bailey that it would be worthwhile to go back and listen to him, because what we're going to talk about today is sort of the natural next chapter in that story about what happens after FDA's role and what happens after FDA either authorizes or approves a vaccine.

Dr. Messonnier: Now, one of the major questions we get asked when we talk about this topic is who's going to get vaccine, and truthfully that will evolve over time. Our partners in operational warp speed, the initiative that I spoke about between DOD and HHS, assure us that some vaccine will be available this calendar year in 2020, but we expect that the quantities of vaccine will be limited, and therefore it will be important to target the vaccine. However, because the vaccine is being

manufactured even while the clinical trials are ongoing, we expect in calendar year 2021 for the supply to increase, and in fact it could increase quite quickly. And so we could rapidly be in the situation where we actually have enough vaccine for everybody, and that would be great, but it also offers lots of additional challenges to ensure that that vaccine is used efficiently and get to the people at highest ... only be authorized or recommended for adults, though I know we're all looking forward to having a vaccine soon that will be available for kids.

Dr. Messonnier: The COVID vaccine planning is changing very rapidly and that's frustrating for all of us, as well as I'm sure for you and for our state and local health department partners and the partners all over the country and all over the globe who are planning for it. I wish we could have all the certainty that we'd all like upfront, but if we wait for that certainty, it means that our planning will be delayed, and so we have to have plans that are, as ... it becomes available. And you'll hear that as Dr. Cohn goes through in more detail our planning. But finally, my upfront message and our last message would be this last one.

Dr. Messonnier: Even in this era of uncertainty and of myths and misinformation spreading so easily in social media, in any group when we ask patients about their most trusted source of information when it comes to vaccines, we are told that they will look to their own health care providers. You will play a critical role in helping to build confidence in COVID-19 vaccination. Our goal today is to be as upfront as we can about what we know and we don't know. But what we'll keep coming back to is despite all the uncertainty, we are going to be relying on the systems that we always rely on to ensure that the vaccines that are being recommended are safe and effective, and that oversight on those vaccines is rigorous, but also transparent.

Dr. Messonnier: And we hope that by talking this through, we will build your confidence, not only in these vaccines, but in the systems that are in place. Your confidence is crucial, I understand, if you're going to be able to talk confidently to your patients about these vaccines.

Dr. Messonnier: I'll turn it over to Dr. Cohn who will go through our planning in more detail, and then I'll be back at the end if there are any questions. Again, thank you again for taking time out of your busy days to join us for the seminar. Amanda.

Dr. Cohn: I am now going to take these main points that Dr. Messonnier just shared with you and give you the sort of underlying data that we have now to help you with your thinking on COVID-19 vaccines. There are multiple critical components to vaccine implementation. These are all the steps, as Dr. Messonnier described, that have to happen after FDA authorization and ACIP recommendations.

Dr. Cohn: So vaccines have to be prioritized and allocated, and that's where we're going to start right now. But then after that, vaccines have to be distributed, administered, which is where all of you play a key and critical role, and then we have to monitor for safety and effectiveness and to make sure that

patients come back and get their second dose. Throughout this whole process, as you can see in green at the top, communication and stakeholder engagement is critical for success, but really the public health impact of COVID vaccines on this pandemic relies on rapid, efficient and high uptake of a complete vaccine series.

Dr. Cohn: Next slide. I just wanted to share with you briefly, how FDA licensure and ACIP recommendations connect. This is a slide for the normal vaccine process, which demonstrates, and many of you may have heard Dr. Marks talking about this last week, that the pharmaceutical company will submit to FDA for a BLA. In this case, those will be EUA, emergency use authorizations. Then there will be a subsequent VRBPAC meeting, and Vaccines and Related Biological Products Advisory Committee is the counter, or the sister of the ACIP. They advise the FDA director, who then authorizes the emergency use authorization. The ACIP process next to that. So FDA authorizes vaccines, ACIP recommends vaccines, and people frequently ask what the differences is and I'd like to think of this as being FDA makes decisions about which blood pressure products you can use and we look to provider organizations to make recommendations for clinical use for how to best use blood pressure medications, in the context of an individual's blood pressure.

Dr. Cohn: ACIP is making decisions about who should get vaccinated in particular situations, or across the board. The ACIP advises the CDC director, and then on the CDC director's approval, those become CDC recommendations.

Dr. Cohn: Next slide. Just to give you a high-level perspective of the incredible work that ACIP does, there are 15 voting members, one includes a consumer representative, and the other 14 members have expertise in different disciplines. We have four year overlapping terms and all of the individuals on this committee essentially relinquish any potential conflict of interest. They all announce their potential conflicts of interest at every ACIP meeting.

Dr. Cohn: This has been incredibly complicated, as you can imagine, since pretty much every pharmaceutical company is developing a COVID vaccine, and these are experts in vaccinology. So many of these members support getting vaccines to market. So these members include expertise in medicine, state and local public health, nursing, immunology, vaccine research and policy, and economics and cost effectiveness.

Dr. Cohn: We do have a consumer representative to represent consumer concerns. Next slide.

Dr. Cohn: Importantly, one of the key things that which makes ACIP work so well is that we have 31 organizations that have broad involvement with immunizations, and they liaise at the ACIP meeting so every one of these professional organizations has a liaison member to ACIP. And while they don't vote, they provide critical input and work through their organizations and with ACIP for so that our ACIP recommendations reflect organizational input. We also have ex-officio members. Next slide.

Dr. Cohn: But the real work happens on a very regular basis through the ACIP work groups. The COVID work group started work in March or April and has been meeting weekly. These work group meetings are not public. ACIP meetings however are public, and that's the time when all of the work that is happening at this work group level is presented to ACIP for deliberation and consideration. These organizations are also represented on the ACIP work group for COVID vaccines, including AMA, and ACP, AAFP, ACOG and AAP among many, many other organizations. Next slide.

Dr. Cohn: ACIP uses the grading of recommendations, assessment development and evaluations for COVID-19 vaccines. This is the same process we use for all of our other immunization decisions. There's a review of the evidence, and then that evidence is put into a recommendation framework, which incorporates issues such as comparing the benefits and harms, understanding the values, the acceptability, the feasibility and the resource use. Then finally there are ACIP recommendations. ACIP can decide to recommend a vaccine or to not recommend a vaccine. They also will make recommendations around prioritization of vaccines, as well as provide clinical guidance for how to use vaccine.

Dr. Cohn: Those are the questions such as if an individual got a flu shot in the last 30 days, can they get COVID vaccine? What's important is that GRADE is a transparent framework for developing and presenting summaries of evidence, and provides a systematic approach for making clinical practice recommendations. We have used this approach for over 10 years in ACIP decision-making, and we are implementing all of this ... we're using all of these same approaches for recommending COVID vaccines. We're just doing it at rapid speed by meeting much more brilliantly. We have had monthly meetings of the ACIP virtually since June of 2020, and our next meeting as at the end of October. Next slide.

Dr. Cohn: As Dr. Messonnier just described, distribution will adjust as volume of vaccine doses increases. We do anticipate limited doses being available. That will be challenging during that period of time because we will want to ensure that the prioritized groups, that groups of individuals who ACIP, with the input of multiple other organizations such as the National Academy of Sciences has ... those groups that are prioritized are the groups that actually are vaccinated early.

Dr. Cohn: This will include tightly focused administration. And for example, may occur at a large hospital where health care workers can come in and get vaccinated, as well as other emergency response workers. We'll talk about critical workforce in a minute, but I just wanted you to carry this slide through with you through the rest of the presentation. The middle section of this is when we anticipate that a large number of doses will be available. And at that time, our thinking really shifts on how we want to get vaccine into people's arms.

Dr. Cohn: We want to make sure that there is a broad administration network which can ensure that all individuals have access to vaccine. This would expand beyond our initial populations and would

use all of our private sector partners including pharmacies, and doctor's offices and clinics very similar to how the H1N1 was implemented. But we would also administer a vaccine through public health sites such as mobile clinics, FQHCs and targeted communities. Because as we are all way too well aware, it is communities that may have the least access to health care that have been overly impacted by the COVID-19 outbreak. Next slide.

Dr. Cohn: These are the way that we describe the different critical populations to ensure access critical infrastructure of which include health care workers and emergency response workers, and I'll go more into detail on that in the next slide. People at increased risk for severe illness. People at increased risk for COVID-19, such as people who are incarcerated or living in homeless shelters. And then people with limited access to vaccines. People in rural communities and people with disabilities, for example. We're framing out how to reach each of these types of groups of people independent of when they're recommended or when they're prioritized for receiving vaccination. We want to make sure that as soon as there's vaccine available, we can get it to these different groups. Next slide.

Dr. Cohn: This is a very detailed view of the critical infrastructure workers. We have many, many groups ... have always been included in critical workforce infrastructure workers. But even during this pandemic, it's been very clear that there are different types of groups, such as poultry workers who are clearly essential. In the last iteration, education, school teachers and the other people working in schools has also been added to this list, as well as correctional and detention facility staff. Next slide.

Dr. Cohn: How do we get vaccine to those individuals? Now I'm going to talk about distribution. Next slide. We will want to get vaccine out everywhere we possibly can. The manufacturers have been contracted by Operation Warp Speed to produce up to a hundred million doses each of vaccine. We are also contracting out the putting together what we call kitting of ancillary supplies, which includes PPE. Both of those, both the vaccine product and the ancillary kits will be sent to a centralized distributor. So that when vaccine shows up at your office, not only is a vial. It's all of the ancillary materials, such as needles and syringes that you will need to administer those vaccines.

Dr. Cohn: This is really important, because one clear message we want to tell providers is that we do not need people to stockpile needles. The needles and syringes for all of these doses has been secured. With the centralized distributor, we will then be shipping the vaccine directly to all of these different groups that you see in this last column. Early in vaccination, we anticipate that this will be more limited. For example, we might administer to hospitals if health care workers are prioritized, which we do anticipate. And there might be more mobile vaccination clinics or onsite vaccination clinics in places where critical infrastructure workforce can come to vaccination.

Dr. Cohn: Another really good example is how we're giving long-term care staff vaccinated. That we are developing a way to access long-term care staff, which is an incredibly hard group to get vaccinated. We're working with long-term facilities as well as public health. It might be a mobile vaccine clinic go into multiple facilities in a day. We want to have plans in place for all of these

different ways to access a vaccine. And vaccines will be distributed based on state allocations of vaccines.

Dr. Cohn: At the national level, we prioritize large groups such as health care workers, or essential workforce, or residents living in long-term care facilities. But at the state and local level, we're going to have more people in those groups than we will have vaccine early. So, state and local health departments who understand their communities much better can prioritize and allocate directly to the groups that they think are most critical for vaccination early. Like we said before, we hope that this is a very short period of time and that this will rapidly shift to getting vaccine out through all of these different groups, and directly through pharmacies and other private partners to augment vaccination. Next slide.

Dr. Cohn: So, how do we get vaccine in people's arms? And this is one of the places where all of you will be critical partners. Next slide. Right now, the state health departments are engaging in efforts to enroll providers to be COVID-19 vaccinators. Early on, these state health departments are focusing on providers that can rapidly vaccinate initial populations as the focus as soon as vaccine is available. Like I said, these might be large health care systems in some areas. Different approaches in more rural areas. Getting those providers on board early is really critical.

Dr. Cohn: But for subsequent planning, which is right around the corner ... as in the next couple of months, these health departments will be trying to recruit broadly vaccination providers to expand equitable access to remaining critical populations. And eventually, the general public. I'll give you some more information in a little bit, but we do anticipate having vaccine product not at the end of this year, but over time next year, that can easily be administered in a provider's office. And we hope that all of you will consider signing the provider agreement, which just makes sure that you understand your roles and responsibilities as a provider to administer the vaccine. The vaccine will be free of cost. The product will be sent at no charge. And providers will be able bill for the reimbursement per administration of that vaccine, and additional information about that will be available in the next couple of weeks.

Dr. Cohn: We know that training all of our COVID vaccine vaccination providers is really critical to ensure the success of the vaccination program. These vaccines will be distributed under an EUA. As soon as we have information about how to administer and the requirements for administration, we will be rapidly communicating that with all of our providers. Next slide.

Dr. Cohn: This is just an example for considerations for vaccine administration. Infection control and social distancing measures will be important. Storage and handling capacity will be important. Some of these vaccines do require ultra-cold storage early, and those requirements, as Dr. Messonnier indicated, are shifting and hopefully going to be more ... vaccine will be able to be stored at more reasonable and feasible temperatures. But all of these things will have to be in place in order to administer a vaccine successfully.

Dr. Cohn: This is an example of more of a mass vaccination clinic where you would also need to have security and the ability to administer the EUA requirements. To translate this into an office setting, for example, you may set up a time of day where you vaccinate when you're not seeing other patients, or you may set up a different entry or some other way to vaccinate while socially distancing. We're also supporting this effort with things like tools, applications to schedule your appointments for vaccination, and more information will be available on that. Next slide.

Dr. Cohn: We do have information on guidance on how to safely provide immunization services, and this correlates with the CDC framework for providing non-COVID-19 clinical care, and discusses PPE and considerations of the various different clinical settings where you could be vaccinating. This document focuses on priority populations for influenza vaccine, but is actually about to be updated with additional considerations for COVID-19 vaccine. It will still be at that same link at the bottom of this slide. You can also just Google CDC COVID immunization and this will appear. Next slide.

Dr. Cohn: I'm going to move on to talk about the safety and effectiveness that happens after administration. This really focuses on a key aspect. We're mostly going to be talking about safety. Because at the end of this when I'll focus on vaccine confidence, really having strong safety surveillance systems in place is critical to ensure confidence in the program.

Dr. Cohn: Next line.

Dr. Cohn: Once again, I just want to remind everyone that communicating about our safety monitoring to providers, to health care workers, to the public, is one of the things that we recognize is ... needs to start now, and it needs to happen regularly and often, in order to reassure the public that we are doing everything we can to monitor the safety of these vaccines, even after use.

Dr. Cohn: Next slide.

Dr. Cohn: So this outlines our vaccine safety strategy for COVID-19 vaccines. We are using our established systems to implement heightened safety monitoring for COVID-19 vaccines. These are systems like VAERS, the Vaccine Adverse Event Reporting System, which providers and the public can submit reports of adverse events to VAERS. We're doing a lot of work to understand background rates of different conditions in the setting of COVID. As you know, things have really changing in

terms of what types of health conditions are being reported, so we want to have a really good baseline to be able to detect signals that may be related to COVID-19 vaccines.

Dr. Cohn: Additionally, we're developing new platforms and leveraging other federal data sources to complement these existing systems. So new platforms are things like, and I'll go into this in the next slide, but things like V-SAFE, which is a text messaging and mobile application that we anticipate using early, as health care providers and other critical infrastructure who are likely to be prioritized early for vaccination can report adverse events to this system, and will be reminded and asked if they've had any adverse events. So this is more active monitoring of individuals who are vaccinated early in the program.

Dr. Cohn: And then, as I said before, communicating clearly on the vaccine safety process and systems now, and then as soon as data become available, we need to provide vaccine safety data and monitoring results frequently and clearly.

Dr. Cohn: Next slide.

Dr. Cohn: This is a slide which just demonstrates the vast collaboration happening between the FDA, the VA, the Indian Health Service, DOD and CDC to really look at vaccine safety monitoring after COVID-19 authorization and implementation very broadly. So we have, as I said before, the systems that we always use, such as VAERS and VSD, the Vaccine Safety Datalink, which is at the top of this slide. We're also going to be able to harness Medicare data to rapidly assess claims and do active surveillance through claims data. And, yes, that will be administration claims. We also are going to be harnessing an FDA system called BESS, which is the Biologics Effectiveness and Safety System.

Dr. Cohn: And then, just to go down to the bottom of the slide, these are all of our normal existing systems at the top. We're adding V-SAFE, which is a smartphone-based active surveillance with text messaging, web surveys and telephone follow-up of clinically important adverse events. We're also using NHSN, which is our National Health care Safety Network, to assess acute and long term care facilities for adverse events in those populations, which we particularly want to monitor very closely because of the underlying conditions present in patients in those settings, and will stimulate reporting to VAERS.

Dr. Cohn: Next slide.

Dr. Cohn: I'm going to end off by saying, and then I'm going to move into vaccine confidence, but I just, these are some actions that health care organizations and personnel can take now to prepare for vaccine administration. At the organizational level, when supply of vaccine is constrained, prepare for the possibility of health care personnel as an early priority group. I keep sort of indicating this, but ACIP has not seen data on safety or effectiveness to make final decisions about prioritization, but all of the frameworks for prioritization do include health care personnel very high up in frameworks, in

terms of prioritization, and that coincides with all of the public engagement that we've done, where the public really supports administration of vaccine early to health care personnel.

Dr. Cohn: So we want large and small health care organizations to identify critical staff and tier staff. For example, staff that are working on billing and potentially still working from home may not be a first-line for vaccine, but janitorial staff, across-the-board staff that engage with patients and that interact daily at the hospital should be tiered for early vaccination.

Dr. Cohn: We'd like for health care organizations to determine if their facility can conduct vaccination clinics that reaches all the critical health care personnel. We're hoping that in the next couple of weeks, health departments will start to work closely with health care organizations to ensure that plans are in place to vaccinate in many of these systems. Some of the facilities will not be an early vaccination site, and so they'll have to plan for alternative sites where staff can access vaccine early. As soon as possible, as soon as there's more information available, communicate your organization's vaccine plan to staff and provide staff education to decrease hesitancy.

Dr. Cohn: When supply of vaccine increases, we hope health care organizations will work with jurisdictions to expand access to vaccine, as well as to implement communication strategies to encourage vaccination and remind patients to come back for their second dose. There will be several systems in place for monitoring second dose administration. We anticipate being able to do reminder recalls through text-based applications, but many health care systems have their own systems that already work very well, and those should be used as well.

Dr. Cohn: Additionally, we want to ensure that EHR as an alternative system is in place to provide administration data into the state IISs. For those of you who work in smaller clinics or practices, connecting with your state IIS will be a really important part of onboarding you as a COVID-19 vaccinator.

Dr. Cohn: For health care personnel, know where to go for the latest accurate information. We are launching a COVID-19 vaccines webpage at CDC, hopefully by the end of this week or early next week, and we anticipate updating that frequently. For more product-specific information, that will be available soon. Things like what the EUA looks like, some of that data and some of that information won't be available until closer to vaccination, but we'll be providing more general data about COVID-19 vaccines on this webpage for providers to use. Understand your facility's plan for vaccination and be prepared to educate your patients about vaccine.

Dr. Cohn: Next slide.

Dr. Cohn: Which leads us to the last few minutes of this talk, where I want to reiterate what both Doctors Bailey and Messonnier started with, which is that health care providers are the linchpin really, in a successful COVID-19 vaccination program. We know that concerns and misinformation about

vaccines are not new. This is a cartoon from 1802.

Dr. Cohn: Next slide.

Dr. Cohn: And these are additional ways that vaccine misinformation has been shared through pamphlets and other paper-based ways throughout history, really. What's different now is the rapidity of which information can become viral and can spread well beyond a single community, and with just a small group of individuals, can really expand the anti-vaccine or vaccine disinformation.

Dr. Cohn: Next slide.

Dr. Cohn: So, we know from research what factors influence decisions about vaccination, and we've lumped them into three different groups. The first is contextual. So, media and public communication, local politics, religion, culture, how easy it is to access vaccine. We always say access should never be a reason why somebody can't get vaccinated. We need to have clinics open in the evening time. We need to catch people coming out of 24-hour shifts or 12-hour overnight shifts, and get them vaccinated when they can get there and in the places they can get to.

Dr. Cohn: And then, really, trust in authorities is really important. In a time where there's a lot of lack of trust in authorities, I think transferring that to local authorities, and local community leaders and health care providers is really critical. Individuals and group influences can also inform decisions about vaccination. This is beliefs and attitudes about health and disease prevention, knowledge and awareness, and previous experiences where they've received poor quality health care.

Dr. Cohn: The last part is vaccine-specific issues, and we'll go into this more, but there's a lot of really valid concerns about COVID-specific vaccines, such as how these vaccines were made, how they were approved so quickly, things like the mode of administration, the source of the vaccine, the vaccine schedule, are there going to be costs, and the knowledge and attitudes of health care professionals.

Dr. Cohn: We saw this a lot with HPV vaccine. It wasn't just the doctor who needed to recommend the vaccine. The vaccine needs to be recommended from the second an individual, a patient enters the facility. Early discussions about vaccines can really inform a parent or an individual's decision to get vaccinated.

Dr. Cohn: Next slide.

Dr. Cohn: So, there's a large vaccine demand continuum. There is a very small number of individuals who absolutely refuse any type of vaccine. As individuals hear more about COVID-19 vaccines and do understand the processes and the data better, we're hopeful that we will be able to increase acceptance of COVID-19 vaccines, as well. But there's a wide spectrum of vaccine-hesitant

individuals. Some of whom will accept, some will delay, and some will refuse, and that's the group of people who we really need to increase confidence in, in order to increase the number of those individuals who accept and don't delay vaccination.

Dr. Cohn: Next slide.

Dr. Cohn: Finally, we have to contain vaccine misinformation. There are both valid concerns about COVID-19 vaccines that we need to address with empathy, but there's also vaccine misinformation, and this has raised more questions among individuals about the safety and benefits of COVID vaccines. So these false claims about vaccines have to be effectively countered with accurate information, and this really requires a particular focus on the patient-provider interaction. As Dr. Messonnier said earlier, health care providers are the most trusted source of information by patients.

Dr. Cohn: Next slide.

Dr. Cohn: So, finally, I'm just going to touch on COVID-19 vaccine confidence considerations.

Dr. Cohn: Next slide.

Dr. Cohn: This is a new pandemic, a new vaccine and really will be primarily adult-focused, which really means shifting our tactics on how we reach groups to get vaccinated. Individuals across the spectrum will have concerns about COVID vaccines. These concerns are understandable and need to be addressed with empathy and transparency.

Dr. Cohn: But what we've also heard that is very different is that we have heard increased vaccine hesitancy among health care providers. This is a real risk for the overall vaccine confidence, and one of the reasons why it is so important for you to hear from us and for us to hear what concerns are among health care providers, as much as possible.

Dr. Cohn: Finally, communities will have unique experiences which inform COVID-19 vaccine perceptions. So engagement with community organizations and leaders will expand our access to communities, to clear and accurate information on COVID-19 vaccines.

Dr. Cohn: Next slide.

Dr. Cohn: We have to rise to the challenge of increasing uptake and confidence of COVID vaccines. This is a slide that demonstrates influenza vaccination coverage by race and ethnicity. We are hardly at over 50% among adults for any adult population, but when you look at Black non-Hispanic and Hispanic populations, there are clear disparities in immunization coverage. We need novel and more robust strategies to increase uptake among both the influenza vaccines, as well as COVID-19 vaccines as soon as they're available.

Dr. Cohn: Some of the work that we've been doing over the last several months is really laying the groundwork for increasing influenza vaccine during this pandemic, which we hope leads to directly increase trust in COVID vaccines, as a lot of what we've been doing is engaging with non-traditional immunization partners to reach communities of color.

Dr. Cohn: Next slide. We have done some formative research to inform our messaging, and I'm going to give you a very high-level overview of some of the key findings. We specifically did do research in essential workers, non-medically trained as well as nurses. Next slide. What we found overall is that almost all were aware of vaccines. Many were uncertain about when it would be available. But these individuals in these focus groups want to understand safety and effectiveness, and side effects, and the testing processes and timelines for approval. They want to know if the timelines compromised the process? And they want to know who the vaccine was tested on? And was it tested in that particular demographic? These are really good questions. And in questions that we need to provide information to providers who can then share that information with their patients, as well as share publicly. Next slide.

Dr. Cohn: The sources of information on this slide, just to show you at the bottom, individuals do rely on different kinds of media. As you can imagine, older individuals rely on news establishments. Their personal doctor was especially trusted. And younger segments frequently relied on social media. But individuals cited widely, including, besides Dr. Fauci, relatives who were health care workers was one of the key groups that many, many people identified as someone who they would trust. So we want you to increase confidence not only among your patients, but also among your web of your community and your family. Next slide.

Dr. Cohn: What we heard from many of these individuals is that they were open to getting vaccinated, they just wanted to wait till there was more information. And many people cited six months or a year. So what you don't see in some of these surveys that, where the data keep being in the news, is that people may not want to get vaccinated right when it becomes available. And we've got to shift that timeline and we've got to increase trust earlier. Because the only way we will have any impact on this pandemic is if people get vaccinated over a shorter period of time, than at this time people appear to be willing to get vaccinated. So we have to start applying risk communication strategies now. Given the unknowns and potential risks, we have to communicate early and often in ways that people trust. We have to communicate clearly and with compassion and attend to low health literacy levels. We have to acknowledge and communicate what we don't know.

Dr. Cohn: And that's, I think, a really important lesson that we've learned over this pandemic, as well as from other outbreaks. And in situations like this, we need to be transparent and honest and disclose more. For example, if there is a vaccination safety signal, we should lean towards being clear that there is a signal and that we're evaluating that signal and we're doing something about it rapidly. We need to listen and respond to specific concerns of stakeholders, which is why I hope we hear

concerns from you. And we need to deliver messages through multiple media modes. Next slide.

Dr. Cohn: I want to wrap up. But I just wanted to share with you the Social Vulnerability Index, which can be used to identify communities at risk, is a tool that identifies, even within a county, census level tracts that are more vulnerable to things like the pandemic or natural disasters and things like that. I have the link at the bottom of this page for you to learn more about that. But that's going to be a strategy we can use to target certain communities that may be at risk for impact from COVID vaccine. And then what you need to achieve high vaccination coverage. Next slide.

Dr. Cohn: But finally, I just wanted to share with you this draft of a “Vaccinate with Confidence Strategy to Reinforce Vaccine Confidence in COVID-19 Vaccines.” This is really different than the way that we build confidence for childhood vaccinations, for example. And the three pillars of this strategy are to reinforce trust, to empower health care providers. So we want to promote confidence among health care provider personnel in their decision to get vaccinated and to recommend vaccination to their patients. And then the last pillar is to engage communities and individuals. Next slide. And that is it. Thank you so much for taking the time to listen to us. And we would love to hear some questions.

Dr. Bailey: Thank you so much, Dr. Cohn, that was an amazing presentation. We do have a few questions in our time remaining. You mentioned provider enrollment in the vaccination process. And we know that the “COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations” was released last month and that states are currently working on their plans. So you mentioned providers getting enrolled. Where do providers find that information? What do physicians need to be doing now to ensure that they are enrolled and have the data systems in place to administer COVID-19 vaccines to patients once they're available?

Dr. Cohn: That's a great question. I would recommend at this time ... So each state will be different in terms of how they're enrolling providers. And so states are submitting, they've been working on these plans since the playbook was released. And I think the next step is to implement these plans rapidly. And so I anticipate that providers will be hearing directly from their jurisdictions about what systems need to be in place. It varies by which IIS and, which IIS they would be reporting to. And they will be getting more direct information about enrollment. Dr. Messonnier, do you want to have anything to add?

Dr. Messonnier: Yeah. Just that I think something that folks should understand is those two phases that Dr. Cohn showed and that the hard part here is this initial phase that is the thing that's going to be upon us really quickly. We expect there to be limited doses of vaccine, and therefore the vaccine would need to be targeted. So we believe that health care workers will be in that first set of priorities. But the way that the initial vaccines are going to be delivered, it's not going to be conducive to basically sending it out to every provider's office. And so for that phase, we would definitely suggest that health care providers should be talking to their health care system. Because that is probably who

the health department is working with to try to figure out a solution to maximize the reach of a campaign to health care providers.

Dr. Messonnier: Now when we get to the second phase, that's the phase where we expect to get a rapid increase in vaccine, and we're going to need everybody on board vaccinating. And some of the vaccines that we'd expect to be available next calendar year will actually be easier to put in each provider's office. So if you haven't heard, it may be because the solution for your initial vaccination is what the health department is working on. So please go through your health department, but also frankly, talk to your health care system. And it may require a little patience, because again, you may be on that first line to get vaccinated early, but they may not be asking you to actually become a vaccinator until we get into next calendar year.

Dr. Bailey: And there are a lot of us private practice physicians out there that are part of health systems that will make ... the AMA will be sure to make sure physicians are aware working with the state and county medical societies on how they can get the vaccine. Now, I have a question just about the initial approval process. Now, once the ACIP approves its recommendations for vaccine administration, the next step I'm guessing, is for that to be signed off by the CDC. But then, is that going to have to be signed off by HHS or? Because my understanding is, is typically when the CDC signs off, it's ready to go.

Dr. Cohn: Yeah. So we anticipate that our normal processes will be in place, and when the CDC director signs the approval to accept ACIPs recommendations, that will become official policy. We've already been thinking about how we will need to communicate to providers that minute or within hours after that happens. But we do anticipate that the HHS secretary will be informed about the decision, but that the CDC director will accept the recommendations.

Dr. Messonnier: And I just want to add one thing that, again, Amanda sort of skirted over, but it's really important to me. Typically, when the ACIP makes a recommendation and the CDC director signs off on it, it's frankly weeks or months before it's actually out in your hands to get vaccinated, or we're asking you to roll up your sleeves. These timelines are really compressed. So we are going to be, for example, as soon as FDA authorizes a vaccine under an EUA, pushing out information about the vaccine, and the storage and handling, which may be frankly, more complicated than one would hope. But the initial vaccines haven't been optimized for storage and handling, they've been optimized to get them out quickly. So some of those initial vaccines require a diluent at the bedside. That's not something that we would typically say for our routine vaccines.

Dr. Messonnier: So we're going to be pushing out that information quickly. And then the night or the morning that the CDC director signs off on the recommendations, we really need to make sure that we have the pathways set up to get that information to your community, your health care community really quickly. And so we're going to be working with AMA and other provider organizations, as well as a health care sector and try to put those plans in place, that as soon as information becomes

available, it gets to you. Because frankly, the vaccine, the physical vaccine, may be moving more quickly than happens in routine times.

Dr. Bailey: Very good. Well, there are more questions, but we're running out of time, and maybe we can do this again. But I want to thank both of you and thank our audience for joining us for this very important information session on the vaccine development process. Thank you to Drs. Messonnier and Cohn for their insights and your candor, and to all of those who asked questions. From the information that we received today, I anticipate that it may be around the first of the year, by the end of the year, that there may be limited quantities of vaccine available, probably for a frontline health care workers. And because of the cold storage requirements, it's likely that administration will be in a large health center that has that type of cold storage. But soon as 2021 goes on, the vaccine will be available at many more places.

Dr. Bailey: It's not going to be as easy as it was back in the early sixties when the doctor of my county medical society just set up tables in front of ... and handed out sugar cubes. It's a little bit more complicated these days. But we are eagerly awaiting the vaccine that finally brings an end to this difficult pandemic. And there's so much to be encouraged about in the vaccine development process. But all that really matters is that what is produced and whenever it becomes available, it's got to be safe and effective, and that the public at large as well as physicians have total confidence in the process that got us here. So thank you again to all of you for joining us. Everybody stay healthy, stay safe and we'll talk again soon. Thank you.

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COVID-19 vaccine development webinar series

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