Watch the AMA’s daily COVID-19 update, with insights from AMA leaders and experts about the pandemic.

**Featured topic and speakers**

In today’s COVID-19 update, AMA Chief Experience Officer Todd Unger speaks with James Kublin, MD, MPH, about the COVID-19 Prevention Network (CoVPN) and its recruitment efforts for vaccine trials, which includes a PSA of testimonials from registry participants, narrated by actor Harrison Ford.

Learn more at the AMA COVID-19 resource center.

**Speakers**

- James Kublin, MD, MPH, executive director, COVID-19 Prevention Network (CoVPN)

**Transcript**

**Unger:** Hello, this is the American Medical Association’s COVID-19 update. Today, we’re talking with Dr. Jim Kublin about the COVID-19 Prevention Network or CoVPN and its recruitment efforts for vaccine trials. Dr. Kublin is executive director of CoVPN and principal staff scientists in the vaccine and infectious disease division at Fred Hutchinson Cancer Research Center in Seattle. I'm Todd Unger, AMA’s chief experience officer in Chicago. Dr. Kublin, why don’t we start by telling our viewers what CoVPN is and why it was created.
Dr. Kublin: Thanks, Todd. Well, the CoVPN was started earlier this year by the National Institute of Allergy and Infectious Diseases, of course, led by Dr. Tony Fauci. Building on the foundation of a lot of the vaccine network activities that have been supported by NIAID for decades. The CoVPN is really founded on the HVTN. The HIV Vaccine Trials Network, and some of these other clinical trials networks that conduct vaccine clinical trials around the world.

Unger: And will you elaborate a little bit more on the mission of CoVPN?

Dr. Kublin: Sure. So very specifically CoVPN is focused on the phase three efficacy trials for COVID vaccines and monoclonal antibodies. We work to develop and conduct studies to ensure rapid and thorough evaluation of these US government sponsored vaccines and monoclonal antibodies for the prevention of COVID-19 disease.

Unger: We’re hearing a lot about the trials right now, and I’m sure you’re thoroughly familiar with the challenges of enrolling people in these vaccine trials. How are you addressing those challenges and managing them?

Dr. Kublin: Well, indeed it is a very challenging time right now to address much of the misinformation that's in the media, in press and perpetrated by many public figures. Vaccine hesitancy continues to be a major issue and really addressing the fears and the uncertainty that people are facing today has been a major focus of our community engagement and outreach efforts.

Unger: What are you finding particularly effective in addressing some of those challenges?

Dr. Kublin: Well, we have to speak directly to the uncertainty that people are feeling and how vaccines and improved therapies and prevention will address that uncertainty, address the fears. We have to speak to the mistrust that exist historically in many of these populations, there are quite a few challenges that we have to overcome, but fortunately at preventcovid.org, people can find the facts and also volunteer.

Unger: Excellent. As you know, COVID-19 has had a disproportionate impact on minoritized communities. Why is it so important to have diversity in vaccine trials and what are you doing to help achieve that?

Dr. Kublin: Well, as the CoVPN really has built on the community engagement efforts that we've had for decades with our HIV vaccine and TB and malaria vaccine efforts, we think that it really is foundational to the ethical conduct of these clinical trials to ensure that we're including individuals who are most impacted by COVID-19. And that unfortunately is disproportionally impacting these minority populations. Again, focusing on the transparency of our efforts, communicating the facts of what we're doing engendering trust with these communities are all top priorities for us.
Unger: Are there any specific channels to reach this audience that have been effective for you?

Dr. Kublin: We have a number of consultant groups and panels that we've worked with, with extensive representation from the Black and African American, Hispanic, Latinx populations, Native American communities, and Alaskan tribal communities. And the elderly, of course, who are also very tragically disproportionately impacted by this epidemic. We also have faith based initiatives knowing that not only physicians who are represented here in the AMA, but also the community leaders that people trust and how we can mobilize individuals to preventcovid.org, to volunteer with information from these trusted individuals.

Unger: How is enrollment in these trials going in general?

Dr. Kublin: I think, quite remarkable. We have over 440,000 individuals who had volunteered on preventcovid.org, but we literally need millions because we need to ensure that those people representing the most at risk populations are participants in these clinical trials. Now, the Moderna study has almost a completed enrollment. The Pfizer study has almost completed its enrollment, but it'll continue to be a challenge throughout the end of the year and into 2021 to enroll the numbers that we need, which range from 30 to 60,000 people per clinical trial.

Unger: Well, many physicians and physician scientists are concerned that safety and efficacy standards will be sacrificed in rushing a vaccine to market. What do you tell them to help alleviate those concerns and how are we able to get a vaccine to market so much quicker than with a past vaccines?

Dr. Kublin: Well, we are still relying on the critical milestones of both safety and immunogenicity to move forward into these large vaccine efficacy trials or phase three trials. We're not cutting any corners or skipping any steps, but we are speeding and accelerating this entire process. So rather than it being a completely sequential stepped process, some of these areas are overlapping to accelerate the testing and evaluation of the efficacy of these vaccines. We're also conducting these very large studies of 30 to 60,000 people to ensure that we have sufficient safety monitoring ongoing. And I think recent study pauses have demonstrated that the safety monitoring is working very well in these large efficacy trials.

And then of course there's a tremendous financial incentive and investment that the US government has made to ensure that these studies can proceed as quickly as possible. And that has required a lot of preclinical work, a lot of manufacturing and optimization of getting these vaccines to the point where they can be released and confirm sufficiently safe to be testing in humans. And then we have tremendous oversight by the data safety monitoring board that we work with. That's founded by NIAID at NIH. There's also the FDA. And I know many people claim these groups are under a lot of political pressure, and I'm not saying that they're not, but I think they've done a tremendous job in clarifying the critical steps that are necessary to confirm safety, immunogenicity and ultimately efficacy of these vaccines.
Unger: Yes, we had a chance a couple of weeks ago with a webinar and to talk with Dr. Marks at the FDA, and he echoed a similar sentiment about that. Just to track back on one of the things you mentioned in terms of the normal sequential approach. In terms of the manufacturer of these vaccines right now, while this testing process goes, is that unprecedented or have we ever seen that before?

Dr. Kublin: We've never seen a concerted effort like this and in such a massive scale. I mean, the scale of anticipating that globally billions of people will need a vaccine is one of the reasons why we're also relying on multiple platforms. We have three main platforms that we're looking at, the nucleic acid vaccines, such as Moderna and Pfizer with their mRNA platform. The viral vector vaccines that AstraZeneca and Johnson are both pursuing. And then the more standard, typical protein adjuvant vaccines, that typically take a little bit longer to get through this large manufacturing process, but routinely may be the most successful. We'll see, at the end of the day.

Unger: Well Dr. Kublin, you mentioned a bit ago about HIV, and I know you bring a lot of experience, as does Dr. Fauci, from HIV research. Is there anything that we know from other diseases like HIV that's informing our efforts with vaccine development for COVID-19?

Dr. Kublin: Well, I'd say, I mentioned these different platforms that are being tested for COVID vaccines. Many of these have really relied on foundational work in HIV vaccine development to get to where we are today. The viral vectors that are being evaluated. These adenovirus vectors have really been tested extensively by different developers focused on an HIV vaccine. And we've learned very much about how to optimize manufacturing, how to test these most efficiently in humans, what type of safety signals we may have to look out for. And that is truly foundational work that goes back over decades that has provided real support to how we can accelerate these efforts today.

Unger: Well, given where we are right now, how do you hope to partner with physicians to get the word out about vaccines and the importance of enrolling in these trials? What do you see as the physician's role in doing this?

Dr. Kublin: Well, I think physicians are often, as are faith-based leaders and many other leaders in the communities, held as sources of tremendous trust and confidence. And I think communicating clearly the potential benefits of these vaccines and also potentially the civic duty or social responsibility that we all may have to participate in some of these efforts. However, that may be, however, individuals decide to do that. And I think at preventcovid.org, we outline very clearly some of the benefits and potential risks of participating in these clinical trials. I think physicians can clarify or answer questions that individuals may have about their participation in a clinical trial and overall support the scientific endeavor that we're all in engendering here and trying to ultimately discover, develop and deploy effective COVID-19 vaccines.
Unger: Well finally, if someone is interested in enrolling in a vaccine trial, what should they do?

Dr. Kublin: Well, as I mentioned it at preventcovid.org, we have a registry, you can volunteer now. It takes about four and a half to five minutes on average, as I mentioned, we have over 440,000 people who have completed that registration. It doesn't obligate you to participate in a clinical trial, expressing that interest is a fantastic first step. And then with that contact information, our clinical trial sites within those catchment areas, in which people reside, would then reach out to individuals they deem to be best eligible for these particular clinical trials. And so that's a tremendous way for people to step up and at least take that first step.

Unger: Well, thanks so much Dr. Kublin. And again, that's preventcovid.org. I also understand that you have a PSA that's been recorded with Harrison Ford that features testimonials from those participating in the vaccine trials, and we'll post a link to that as well. Thanks so much, Dr. Kublin, for being here today and sharing your perspective.

We'll be back with another COVID-19 update soon. For more resources on COVID-19 visit ama-assn.org/COVID-19. Thanks for joining us and please take care.

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