Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Booster Shot: Enhancing Public Health through Vaccine Legislation"
June 15, 2021

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The Honorable Robin Kelly (D-IL)

Could you please speak to the importance of vaccines for new mothers, especially those who did not receive recommended vaccines during pregnancy? What insurance coverage barriers might new mothers face?

Since 2004, the Advisory Committee on Immunization Practices (ACIP) has issued recommendations on the importance of maternal immunization, and currently recommends that all pregnant women receive the influenza, tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines. Unfortunately, a recent survey by the Centers for Disease Control and Prevention (CDC) found that "many pregnant women are unvaccinated, and they and their babies continue to be vulnerable to influenza and pertussis infection and potentially serious complications including hospitalization and death." Additionally, CDC and the American College of Obstetricians and Gynecologists (ACOG) strongly recommends that pregnant persons also receive COVID-19 vaccination and unfortunately, even as the COVID-19 delta strain circulates, the coverage rate for pregnant people 18 – 49 years of age is below 40%.

When mothers get vaccinated, especially during pregnancy, it does increase the safety of the infant through passively acquired maternal antibodies that are transferred to their infant, for example, for Pertussis and influenza. Vaccinations also protecting mothers from infectious diseases herself during a vulnerable period and helps to cocoon the child, protecting the child from infections. While the benefits of maternal vaccinations are clear, unfortunately, many pregnant women and nursing mothers do not receive all of the recommended vaccines to protect themselves and their infants from influenza and pertussis infection, even when vaccination is offered. Furthermore, maternal populations of color are less likely to be vaccinated than their white counter parts – with only 23% of black women, 25.4% Hispanic women compared to 46% of white women.[1]

The National Vaccine Advisory Committee (NVAC) issued a report in 2014 looking at ways to reduce patient and provider barriers to maternal immunization.[2] Currently, the NVAC Maternal Immunization Working Group is in the process of updating these recommendations. In the interim, a recent white paper outlines additional factors that may be driving and contributing to

[1] https://www.cdc.gov/mmwr/volumes/69/wr/mm6939a2.htm#T1_down

https://www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvac_reducing_patient_barriers_maternal_immunizations.pdf

the persistence of these longstanding barriers, even though maternal immunization barriers are well-understood and many legislative, programmatic and community level efforts to address them exist. It provides an overview of the current landscape, limitations, and impacts of challenges related to maternal immunization data collection/reporting and implementation, as well as a discussion that details potential solutions that could strengthen existing efforts in place to address longstanding barriers to vaccinations among pregnant individuals.[3]

One concern to highlight is that maternal populations in Medicaid have lower vaccination rate than privately insured due to costs to the patient, vaccine hesitancy, low reimbursement rates, or lack of a strong recommendation from providers. An additional challenge that we have is that it does cost providers a lot of money to start vaccinating. Family physicians have been vaccinating forever. Pediatricians have done this very well for a long time, but when we started expanding to providers of health care to pregnant women, internists, we need to figure out ways to incentivize them to absorb, to take on these costs to start up to vaccinate people and I think that is one of the most important things that we can do, in addition to removing costs to the patient. It is especially important to recognize that one of the major reasons why a pregnant person gets vaccinated is a health care provider recommendation. It is because of that recognition that a lot of work was done to bring on board OB-GYNs to become immunizers, to provide recommendations for immunizations, and to administer the vaccines.

There is legislation in the Senate, the Maternal Immunization Enhancement Act (S.1114) and the Maternal Immunization Coverage Act (S.1117) that would help improve access to and utilization of maternal vaccines by ensuring first dollar coverage of vaccines for perinatal women enrolled in Medicaid; adopting the recent prenatal immunization quality measure; and requesting much sought-after data on obstetric patients and providers. It is in our nation's interest to improve immunization coverage rates to improve maternal health outcomes. With several promising new vaccines in the research pipeline for life threatening conditions that could provide important health benefits to pregnant women and their children, we must focus on improving immunization rates in the perinatal population.

Passing the Helping Adults Protect Immunity (HAPI) Act is critical to ensuring access to vaccines. I thank Rep. Soto for his leadership here, and also continue to push for the MOMMA's Act, which would mandate Medicaid programs to expand postpartum coverage from 60 days to one year. Together, these changes will ensure that both pregnant people and new moms can receive the vaccinations they need.

I agree with your assessment of the HAPI Act. Medicaid, along with the Children's Health Insurance Program (CHIP), is a federal-state insurance partnership that provides coverage to over 70 million low-income children and adults. Medicaid covers low-income older adults, persons with disabilities and chronic conditions, and pregnant women. Many of these same populations have been hit hard by the COVID-19 pandemic. These high-risk health groups are also extremely vulnerable to serious adverse health consequences of other vaccine preventable illnesses. Hospitalizations, increased morbidity and mortality, loss of independence, the ability to engage in activities of daily living, and reduced quality of life are but a few of the devastating,

[3] https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:bbef3987-626e-4fea-bb75-387572263032

but avoidable, direct and indirect costs. Vaccine preventable conditions add over $8.3 billion in costs to the health care system overall, according to a 2016 study of just four vaccine preventable conditions (influenza, pneumococcal disease, herpes zoster and pertussis).

The HAPI Act (H.R. 2170) seeks to provide a baseline of consistent and reliable Medicaid coverage across the country. Currently, access to vaccines under Medicaid varies, depending on where you live and your Medicaid eligibility status. Medicaid enrollees who are covered through Medicaid expansion programs are guaranteed access to all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) with no cost sharing requirements. By contrast, not all vaccines recommended for adults are covered by traditional Medicaid programs and those that are covered may have cost sharing requirements that put access to the vaccines out of reach. The HAPI Act seeks to ensure that all Medicaid enrollees have access to this important preventive health service and do not face insurmountable financial hurdles to receive a recommended vaccine.

The Honorable Michael C. Burgess, M.D. (R-TX)

Vaccines are one of the most effective and safest ways to prevent and even eradicate diseases. One of the biggest barriers to vaccinations in the United States is hesitancy. What have we learned about vaccine hesitancy over the past several months, since the COVID-19 vaccines received Emergency Use Authorization and were made available to the public?

As you state, immunizations are a cost-effective (and sometimes cost-saving) means for reducing illness, hospitalization, and death. They protect individuals across the life course from vaccine-preventable diseases and outbreaks. At-risk populations, including older adults, persons with disabilities, and those living with chronic health conditions such as heart and lung disease, diabetes, and cancer, are extremely vulnerable and at increased risk of suffering serious adverse health consequences if infected with vaccine preventable illnesses.

Despite tremendous safety and effectiveness of vaccines, most adults in the United States are missing one or more routinely recommended vaccines. The most recent published data on all routinely recommended vaccines from the 2018 National Health Interview Survey (Table 1) found that at least 3 out of every 4 adults are missing one or more of four routinely recommended vaccines [influenza, pneumococcal, zoster (shingles), and tetanus toxoid-diphtheria (Td) or tetanus toxoid-diphtheria-pertussis (Tdap)].[4] Many adults are missing other vaccines recommended for them based on their age, medical conditions, occupation, or other factors.

We have seen misinformation about vaccines increase since the authorization of the COVID-19 vaccines and as a result vaccine hesitancy has also have grown. Unfortunately, the anti-vaccine voice has been capitalizing on this situation to also expand the disinformation to include all vaccines, and created mistrust in vaccination more broadly. Hesitancy may result from misinformation that they might have heard from friends and/or family about the potential or

[4] http://dx.doi.org/10.15585/mmwr.ss7003a1.

alleged side effects of a vaccine. Trusted providers and on the ground community leaders need to convey accurate information about vaccines, and make sure people understand that vaccines are safe and effective. That is why members of the National Adult and Influenza Immunization Summit (NAIIS), which IAC co-chairs, have put out a call to action to providers across the healthcare spectrum to take actions to improve routine and catch-up vaccination of adults.

Specifically, NAIIS calls on all clinicians and other healthcare providers, such as pharmacists, occupational health, and clinical subspecialists, to follow the National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice including:

- Assess the vaccination status of patients at all clinical encounters, even among clinicians and other providers who do not stock vaccines.
    - Utilize a jurisdiction's immunization information system (IIS) to view patients' prior vaccinations to support vaccine needs assessment.
- Identify vaccines patients need, then clearly recommend needed vaccines.
- Offer needed vaccines or refer patients to another provider for vaccination.
- Document vaccinations given, including in the jurisdiction's IIS.
    - Many electronic health record (EHR) systems already link to jurisdiction's IIS – providers should check with their EHR administrators.
    - Providers not already utilizing an IIS should contact their local or state immunization programs to inquire about enrolling in their jurisdiction's IIS.
- Measure vaccination rates of providers' patient panels; make changes to clinic patient flow and take other steps to address barriers to patient vaccination.

Taking these actions will help protect adults across the U.S. against preventable illness, disability, and death.[5]

In response to the measles epidemic that surfaced in 2019, Dr. Schrier and I worked on the VACCINES Act together. I am grateful this bill was signed into law, as it provides the CDC with important resources to understand the driving force behind vaccine hesitancy and barriers to immunization. How can we work to better educate our communities on the safety and importance of vaccinations, and do you think legislation like the VACCINES Act will help address hesitancy?

The VACCINES Act (H.R. 2862, 116 Congress) will provide a heightened focus on addressing vaccination hesitancy concerns and increase public confidence in the safety and efficacy of vaccines as a potentially lifesaving medical countermeasure. Importantly, it can help provide better education to our communities to address hesitancy by providing funding to develop, scale, and evaluate local initiatives to promote recommended vaccinations during this pandemic. These investments are particularly important for building confidence around the COVID-19 vaccines as evidence of their safety and efficacy has emerged.
Indeed, there is a lot of new work at developing trusted partnerships at the community level between public health and other community leaders to improve understanding of the needs of the

[5] https://www.izsummitpartners.org/call-to-action-adult-immunizations/

community to better address vaccine misinformation. While vaccine hesitancy is a national problem, national solutions need to be adapted to fit the needs of the local community.

Moving forward, it will be critical to continue communication and engagement with the public not only on the Covid-19 vaccines, but also on the need to continue to stay up to date with the immunization schedules recommended by the Advisory Committee on Immunization Practices (ACIP), including the receipt of vaccinations for flu, pneumococcal disease, shingles, and hepatitis.

The Honorable Neal P. Dunn, M.D. (R-FL)

Over the past several months, multi-specialty medical groups and integrated delivery systems have expressed frustration around their lack of inclusion in initial vaccine distribution discussions. Multispecialty medical groups and integrated delivery systems (IDSs) are an untapped resource in the national vaccine administration strategy. These organizations play a critical role in the delivery of healthcare in this country and have long standing relationship with their patients and the communities they serve. They also have tools, such as electronic health records to identify patients at higher risk which allows for prioritization for vaccinations and testing. How can we ensure we leverage the expertise and experience multispecialty medical groups have with vaccine administration in any national vaccine distribution strategy and continue to work together on this current pandemic?

As you note, there are indeed many healthcare systems and multi-specialty groups that have important roles to play to improve access and administration of vaccines, particularly to the adult population. IAC, working through the NAIIS has made healthcare systems a focus. We have established strong working relationship with the AMGA and indeed, we serve on the steering committee of the AMGA's new 4-year initiative to improve adult immunization coverage rates, titled "Rise To Immunize."

Additionally, IAC has a collaboration with Becker's Hospital News where we have published numerous articles and hosted webinars to increase understanding of the burden of adult vaccine preventable diseases, improve awareness of the cost benefits to implementing adult immunization programs, and leveraging their health information technology to facilitate assessment of their patients for recommended and needed vaccines (see: https://www.izsummitpartners.org/content/uploads/2017/06/making-preventative-priority-becker-hospital-review-2017.pdf).

There is a long-standing vaccine distribution process in place involving medical groups and pharmacies. The Influenza vaccine, for example traditionally reaches 45-50% of the US population. What do you think about defaulting to this tried-and-true process for COVID-19 going forward? This allows the providers who already have vaccine systems in place to best put shots in arms rapidly, instead of sending half the population to non-healthcare locations, and having medical groups competing with other non-providers who received initial batches of COVID shots.

You raise an important point regarding assess to vaccination services. That remains one of the challenges (in addition to cost and payment to providers) in getting adults vaccinated. The more assess points for vaccination that we can provide an adult, the better the chance that that adult will receive an assessment for, and a recommendation to get, a needed vaccine. Thus, what I believe is optimum to improving adult coverage rates is utilizing all available providers to vaccinate, and removing any barrier that would make it difficult for one sector of providers to provide vaccinations over another sector.

Thus, I agree with your comment that we need to remove challenges that get in the way of the more "traditional" vaccinating providers offering all recommended vaccines to their patients, AND we need to also increase the complementary access points for receiving vaccinations so that members of the public who may not be able to get vaccinated easily at a "traditional" clinic, can still get access to vaccines at complementary settings, such as mass immunization clinics. IAC has developed a resource to help understand and harness the potential in mass immunization clinics (see: https://www.mass-vaccination-resources.org/).

There is rapidly mounting evidence about the important role of T cells in COVID-19. In fact, a recent study showed that T-cell responses to certain vaccines remain unaffected by common variants, while neutralizing antibodies are significantly diminished. Given the complementary information T-cell testing can provide, should the FDA require T-cell information from vaccine developers when assessing immunogenicity or when determining how frequently booster shots may be needed in different populations? Do you agree it is important for researchers and vaccine developers to incorporate measures of T-cell response when assessing vaccine response and duration and give physicians the tools they need to make appropriate clinical decisions in treating patients?

It's hard to disagree that we need more accurate surrogates of immunity beyond antibody response. The challenge with T cell assays is that they are difficult to do and are not well suited to public health laboratories. Many developers of vaccine technology are already looking at T cell responses, minimally CTL and helper T cell responses. I believe that where possible, T cell responses to a vaccine would be useful additional data for the FDA to ascertain the efficacy of a vaccine. It is important to note that antibody responses are still important in providing that broad protective immunity upon first exposure to the pathogen.

How can the National Institutes of Health (NIH) support additional research to build on existing evidence on the use of T Cell testing for COVID-19? To assess the long-term effects of COVID infection? To examine the cellular immune response as it studies vaccine efficacy and duration? For other known diseases? To prevent or mitigate future pandemics?

A more standardized and consistent assay for measuring vaccine-specific T cell response would be very helpful.

"Long" COVID is now proving to be an important long-term sequalae for COVID-19 disease. First, improving surveillance for "long" COVID is important so that we can get a better sense of

what the condition is and getting to potential underlying risks. Understanding the mechanism for this condition is critical. There are many multi-system impacts of long COVID and so each symptom (fatigue, dyspnea, cardiac implications, mental fogginess) will need to have the specific etiology further defined. There is a nice review recently published that highlights potential areas for study: https://www.bmj.com/content/374/bmj.n1648.

Finally, the role of T cells in the vaccine response is something that continues to be studied as cellular immunity certainly has a role in both duration of immunity and the breadth of the immune response to the pathogen. Research in these areas is needed as it may pave the way to not only more efficacious vaccines, it may also pave the way to improved vaccine platforms, especially when it is clear that a cell-mediated immunity may be critically important.

As for future pandemics, I like to say that "annual readiness equates to pandemic preparedness." We must continue to sustain our investment (as a result of COVID-19) in our public health infrastructure and in our vaccination infrastructure. Our ability to deliver flu vaccines to all those in our population recommended (6 months of age and older) for vaccination predicts our success to deliver pandemic vaccines to our entire US population effectively. Conversely, and this is where we were when COVID-19 hit us, our inability to do deliver flu vaccines to all recommended predicts our failure to deliver pandemic vaccines rapidly during a pandemic.