Hearing Title: Booster Shot: Enhancing Public Health through Vaccine Legislation

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Chairwoman Eshoo, Ranking Member Guthrie, Members of the Committee, thank you for the opportunity to be part of the hearing today to talk about this important issue. My name is Rebecca Coyle. I serve as the Executive Director of the American Immunization Registry Association, known as AIRA. I began my work in the immunization community in 2002 as the School & Childcare Immunization Coordinator for the Idaho Immunization Program. I later worked in the Minnesota Department of Health as a Centers for Disease Control and Prevention (CDC) public health advisor before I returned to Idaho as the Immunization Program Manager. In 2010, I became the Executive Director of AIRA.

AIRA is a membership organization that promotes the development and implementation of immunization information systems (IIS) as an important tool in preventing and controlling vaccine-preventable diseases. AIRA members include IIS and immunization program staff working in health departments and organizations, such as IIS implementers, nonprofits, and others interested in IIS. There are currently more than 700 individuals representing 85 member organizations.

AIRA collaborates closely with CDC and jurisdiction IIS to develop guidance and standards, test IIS regarding their alignment with those standards, and provide education and technical assistance to support program improvements.

Background

IIS, often known as immunization registries, are confidential, population-based, computerized databases that record all immunization doses administered by participating vaccination providers to persons residing within a given geopolitical area. At the point of clinical care, an IIS can provide consolidated immunization histories to determine appropriate patient vaccinations for use by a vaccination provider. At the population level, an IIS provides aggregate data on vaccinations for use in surveillance and program operations and to guide public health action.

IIS have existed for the past 30 years, and pre-date broad adoption of electronic health record (EHR) systems. In response to concern over low immunization rates in preschool children and the measles resurgence of the late 1980s, the United States, largely through early efforts of the Robert Wood Johnson Foundation[1] [2] and the CDC, invested in the development of monitoring and follow-up systems for vaccination. Initially known as immunization registries, IIS offer a centralized repository of consolidated records to reduce record fragmentation and support appropriate and timely immunizations.

Present day landscape
Prior to COVID-19 vaccine administration, IIS had established more than 100,000 electronic interface connections with private and public immunizers that allow data to be smoothly exchanged between EHRs and pharmacy systems to IIS. It is this data exchange that has helped facilitate robust participation in IIS. Nationally, 96% of children, 82% of adolescents, and 60% of

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[1] Watson WC, Saarlas KN, Hearn R, Russell R. The all kids count national program: a Robert Wood Johnson Foundation initiative to develop immunization registries. Am J of Prev. Med. 1997;13(2):3-6(Suppl).
[2] Inkelas M, Wood D, Borenstein P, et al. Lessons learned in planning for community child immunization registries. Am J of Prev. Med. 1997;13(2)(Suppl): 7-11.

adults have immunization records in the IIS as of 2019. I have enclosed several education resources about IIS and a recent landscape analysis that we completed on IIS Adult Vaccination Data Capture and Data Utilization.

IIS are primarily funded through federal investments using Cooperative Agreement funds from the CDC immunization program (317 program), some funds from the Vaccines For Children (VFC) program, and fewer than half of states use any state resources. IIS support the administration of the VFC program, with a majority of VFC vaccines being ordered by providers using the IIS. However, no overarching federal policy requires VFC providers to record these doses in an IIS. Many jurisdictions have implemented reporting requirements, but policies vary by jurisdiction. States have different laws and policies for data exchange, vaccine reporting, documentation, access and data usage, and consent for IIS participation.

It is important to note that IIS are required to protect the privacy of all system data. Standards set by CDC state that all IIS must have a written privacy policy that clearly defines the type of information contained and how it will be used, participation parameters, who has access to IIS information, what constitutes a breach of confidentiality, and the period of time that information in an IIS will be kept. In addition to privacy, system security is paramount and is expected to be updated to mirror industry standards.

IIS are a powerful tool for managing immunization records and supporting healthier communities. IIS are part of the immunization program infrastructure and are used to:

- Consolidate immunization records. IIS records contain immunizations administered at a previous provider's office, hospital, pharmacy, a school clinic or elsewhere. Access to comprehensive IIS records prevents patients from receiving too many or too few vaccines.

- Order vaccines and manage inventory. Vaccine ordering, tracking, and administration are all managed in one tool. Ensuring every vaccine dose is accounted for minimizes waste and saves money.

- Conduct coverage assessments. Population-level vaccine coverage data provides a clear view of communities at risk.

- Provide vaccine forecasting (clinical decision support). Through automated vaccine forecasting and alerts, IIS provide meaningful information to guide both clinical and patient decision-making.

- Remind patients when vaccines are due. Using IIS data to send reminders to individuals who are due for immunizations promotes on-time vaccination, improves geographic-wide coverage rates and increases vaccine series completion.

- Respond to outbreaks. IIS are proven tools for responding to outbreaks of vaccine-preventable diseases. During an outbreak or pandemic response, access to near real-time data for decision making is essential to managing a public health emergency.

Examples of how IIS are being leveraged across the United States

North Dakota currently has the third-highest HPV vaccination rate in the country (the HPV vaccine is a cancer-prevention vaccine). Through primary care provider support and a combination of evidence-based interventions, including IIS reminder/recall efforts, school-located immunization clinics, and collaboration with health systems, North Dakota's HPV vaccination rates have soared. In 2019, nearly 90% of adolescents in North Dakota had received at least one dose of HPV vaccine, putting them on track to eradicate cervical cancer in the state.

In **Colorado**, data from the Colorado Immunization Information System (CIIS) are used at the state and local levels to identify gaps in vaccination coverage and inform and target interventions at the county and sub-county levels to improve vaccine access, awareness, and education. CIIS data has helped communities identify where to place members of Colorado's Immunity Corps, an AmeriCorps VISTA program that enhances capacity at local public health agencies for immunization efforts, such as education, planning vaccination clinics, and visualizing data. In Colorado's rural Delta County, their Immunity Corps members recently used CIIS data to determine adolescents not up to date on vaccines and then carry out individual outreach as vaccination reminders.

In addition to these activities in North Dakota and Colorado, there is great potential to leverage IIS to improve vaccine equity first by identifying gaps, then by understanding why gaps exist and then developing targeted strategies that address the challenges experienced by specific at-risk populations.

Desired Systems

As mentioned above, IIS are proven tools for responding to outbreaks and pandemics as mentioned above. IIS have been used in nearly all vaccine-preventable disease outbreaks in the past decade, the 2009 H1N1 pandemic, and the current COVID-19 pandemic. IIS have evolved to include additional functionalities unique to outbreaks. These functionalities are often included as part of current IIS capabilities or as separate mass vaccination systems that may connect to the IIS.

COVID-19 vaccination efforts have highlighted multiple areas where investments in IIS are critical. Without an investment now, IIS will continue to face scaling and capacity issues.

Capacity. In one state in the pre-COVID-19 vaccine era, 17,000 doses of vaccine were reported to the IIS each day. This past March, that same IIS saw 507,000 COVID-19 vaccine doses + 70,000 routine vaccine doses reported in just one day. The ability to process and store this much data highlights the need for systems to move to cloud-based hosting with scaling and surge capacity capabilities.

Volume. Large-scale vaccination events, particularly the COVID-19 vaccine efforts, can generate significant amounts of data. The same IIS noted above moved from 26 servers to 98 servers to manage the incoming data and huge demand for queries from exchange partners that need access to those data. While the volume of incoming data may decrease, the existing data will remain. IIS have a responsibility to manage data, preserve the quality and integrity of these data,

and safeguard the access and use for intended purposes. Systems should be rearchitected and move to the cloud to address performance and volume issues.

Interoperability. Meaningful Use (MU) and Meaningful Use financial incentives played a significant role in helping establish provider interfaces with IIS. The Office of the National Coordinator for Health Information Technology (ONC) determined that, as a result of MU, the percentage of participating Medicare professionals who vaccinate and report to an IIS increased from 51% in 2011 to 72% in 2014. Among the IIS community, it has been noted that these efforts disproportionately benefited high-volume providers and pediatricians/family practices who vaccinate children. Additional efforts are needed to identify and expand bi-directional data exchange, including the onboarding of small volume providers often located in rural areas and the many unique and varied entities administering vaccinations to adults.

Workforce. System management and data quality management require a skilled and knowledgeable team to employ industry standards for maintenance and usage. It is critical to have a workforce that can support and perform functions and leverage new technologies and increase efficiencies.

Policy. The present pandemic is the first time near real-time vaccination data has been shared with CDC to provide comprehensive surveillance at the federal level. These data are primarily coming from IIS. Special policies were instituted to allow for this sharing of data. However, these policies do not extend to other vaccines and this limits our nation's public health agency's ability to monitor outbreaks and routine vaccine administration from a national perspective. Additionally, federal systems (e.g., Bureau of Prisons, Veterans Affairs, Department of Defense) that provide vaccinations do not report to IIS. This limits the comprehensive record capabilities of an IIS. A national policy framework is needed to align reporting and consent requirements, authorized use and data access. Strong national leadership is needed to establish baseline requirements and capabilities and ensure IIS meet them through rigorous, third-party testing.

Summary

Congress has an opportunity to improve, enhance, and expand the ability of IIS to securely exchange real-time immunization data while securely protecting personal information. The **Immunization Infrastructure Modernization Act, H.R. 550,** legislation by Representatives Annie Kuster and Larry Bucshon will provide the needed national framework for IIS operations. Providing resources and supporting policies to modernize IIS will allow better management of routine immunization efforts and enhance public health's ability to respond to pandemics and outbreaks of other vaccine-preventable diseases. Specifically, this legislation will allow for:

- An assessment of current information technology capabilities and gaps among immunization providers
- Expanded enrollment and training of a wide range of immunizing providers (including settings, such as pharmacies; long-term care; specialty care; community health centers; and organizations caring for adults, the homeless, and incarcerated populations)
- Support of standardization of IIS across jurisdictions
- Improve secure data collection, maintenance, and analysis of immunization information

- Support for real-time immunization data exchange and reporting across jurisdictions
- Improved bi-directional exchange of immunization data and interoperability of IIS with health IT platforms

By providing authority to CDC to help jurisdictions modernize their systems, the Immunization Infrastructure Modernization Act of 2021 will provide resources and support for the improvement, enhancement, and expansion of IIS and provide for efficient enrollment and training of health care providers, including pharmacies and other places where immunizations are given.

In summary, the framework with which our public health systems operate needs to be thoughtfully and critically evaluated and evolve to meet the present and future needs. Sustainable and dedicated funding are needed to both modernize and maintain our IIS. IIS programs are well-positioned to build on their decades of experience and existing capabilities to serve as rich data sources for responding to a pandemic or responding to the complexities of routine immunizations.

Thank you again for the opportunity to testify. I look forward to answering your questions.