



December 3, 2020

David Kim, M.D.
Office of Infectious Disease and HIV/AIDS Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services

Comments to be submitted to: NVP.RFI@hhs.gov

RE: Request for Information (RFI): Vaccines National Strategic Plan Draft 2021-2025
Available for Public Comment

Dear Dr. Kim:

On behalf of the American Immunization Registry Association (AIRA), we thank you for the opportunity to submit comments in response to the Office of Infectious Disease and HIV/AIDS Policy (OIDP) Request for Information on the *Vaccines National Strategic Plan (VNSP) 2021-2025*. AIRA appreciates OIDP's coordination of collaborative efforts to develop this plan to strengthen the entire immunization ecosystem on a national level.

AIRA is a national membership organization that promotes the development and implementation of immunization information systems (IIS) as part of critical infrastructure for preventing and controlling vaccine-preventable diseases. With almost 700 members from more than 80 public health organizations, AIRA represents a diverse perspective on issues that impact IIS and related immunization program efforts across the country.

AIRA's comments are organized in response to the questions included in the RFI.

Do the draft Vaccine Plan's goals, objectives, and strategies appropriately address the vaccine landscape?

The goals, objectives and strategies detailed in the VNSP focus on essential issues that span the vaccine landscape ranging from vaccine development and access to acceptance, tracking coverage, and monitoring safety on a national and global scale. This plan will help to build on the progress achieved since the 2010 plan and guide national efforts to support and enhance routine vaccination and emergency response. We support the new plan's



expansion of scope to address vaccination across the lifespan, as well as shortening the timeframe to a five-year window to allow for flexibility in a rapidly changing immunization environment. The forthcoming implementation plan should help to prioritize the many important but competing strategies, guide implementation and help to identify resources and entities responsible for achieving targets and success.

Accurate and complete data are critical for supporting both patient and population health. Immunization information systems (IIS) consolidate disparate immunization records to help ensure complete and accurate vaccination records for individuals within a geographic jurisdiction. IIS, also known as immunization registries, are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area. At the point of clinical care, an IIS can provide consolidated immunization histories for use by a vaccination provider in determining appropriate client vaccinations. At the population level, an IIS provides aggregate data on vaccinations for use in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable disease. IIS also support capabilities for vaccine management through ordering, inventory and accountability, offering a tool to more efficiently manage millions of dollars of publicly purchased vaccine.

In light of COVID-19 and other recent outbreaks, it is more important than ever that we support the infrastructure for IIS in every jurisdiction to be able to supply information on immunization status and needs for diverse stakeholders in real time, including individuals, providers, public health officials and policy makers at the local, state and national levels. Investments in IIS capabilities will ensure these needs are met across the nation. The COVID-19 context is proving the reliance our nation has on invaluable information captured and included in IIS to support critical response efforts including documentation and rapid reporting of all doses of COVID-19 vaccine being administered, ensuring vaccine recipients receive the appropriate 2nd dose of the appropriate vaccine product since vaccine products are not interchangeable, and tracking distribution, inventory and overall vaccine uptake. Data in some IIS will also likely be leveraged to support vaccine effectiveness and vaccine safety studies. IIS have been essential for jurisdiction efforts to carry out catch up campaigns to address the impact COVID-19 has placed on routine immunization.

COVID-19 has also spotlighted areas for improvement that require dedicated resources to sustain and enhance IIS to ensure readiness to respond to future emergencies and





continue to support routine immunization. Examples include the need for federal level policy solutions to enable broad data capture, sharing and exchange, as well as to improve IIS participation for adults through technology solutions that improve interoperability and incentives and resources for providers who vaccinate adults to adopt them. Accelerating the adoption of data exchange standards that support seamless interoperability has and will continue to improve both the quality and completeness of data in IIS.

While the most relevant objectives and strategies related to IIS fall under Goal 4, it is important to recognize IIS have a role in supporting each of the goals of this plan, including many of the respective objectives and strategies. For example, for Goal 3, IIS provide critical information through reports and data visualizations for decision-and policy-makers (**Objective 3.3**), house the necessary data to determine pockets of need and under-vaccinated populations (**Strategy 3.4.1**), and inform vaccine hesitancy studies (**Strategy 3.4.2**). IIS data are essential for knowing where to target interventions and resources to address low areas of uptake and to explore reasons for under-vaccination. While we believe an entire goal could be dedicated to immunization information infrastructure, we are pleased to see the inclusion of IIS in objectives and strategies under Goal 4.

Are there any critical gaps in the Vaccine Plan's goals, objectives, and strategies?
If so, please specify the gaps.

AIRA identified the following gaps, focusing most of our attention on Goal 4 where IIS are specifically called out.

Goal 2: Maintain the highest possible levels of vaccine safety

Page 5 references advanced VAERS reporting capabilities, including transitioning of vaccine manufacturers to reporting using standardized messages through electronic data exchange. There is still a gap in reporters (e.g. providers, pharmacists) reporting through electronic data exchange, as there is no electronic interface to submit a VAERS report.

Strategy 2.2.1 and/or **Strategy 2.3.3** could address this.

In addition to serving as a reliable source for timely, accurate, and complete data for assessing vaccination coverage, IIS are an important data source for studies evaluating vaccine safety. Multiple evaluations of adverse events have relied on IIS vaccine administration data to assess the potential association of vaccine exposure with various outcomes of interest for safety investigations. For example, the Post-Licensure Rapid





Immunization Safety Monitoring (PRISM) program and Vaccine Safety Datalink (VSD) have both linked to IIS for more complete immunization data as part of studies assessing the safety of H1N1 vaccine.¹ IIS also house important details on the vaccine products administered, such as manufacturer and lot number facilitating timely response in the case of safety scares related to the vaccine product that need to be acted on.

As the US prepares to introduce numerous novel vaccines utilizing new vaccine technologies to respond to the COVID-19 pandemic, proving these vaccines are safe is imperative to the success of the mass vaccination campaign and maintaining confidence in all vaccines. Given the variability in strategies used to assess safety, we would like to take this opportunity to call attention to a potential need to evaluate the methods in which vaccine safety is being monitored across the US and to consider opportunities to standardize and modernize these efforts. It may be possible that IIS data can be leveraged on a larger scale to support rapid, population-level studies. For example, IIS could be used to verify what type of COVID vaccine a person received should there be an adverse event. It can also be used to review a person's comprehensive vaccination record. There might be a need to evaluate safety and/or efficacy with co-administered vaccines (COVID + flu) or vaccines administered within a certain timeframe of a COVID vaccine. Fitting in with **Strategy 2.2.1**, IIS enhancements and development of standards to support linking data across systems should be prioritized to ensure readiness of our systems to track safety.

Goal 4: Access to and use of all routinely recommended vaccines

The statement on pages 8-9 related to state and local immunizations programs not having the legal authority to share data across jurisdictions is an extremely important point from a policy standpoint that needs to be addressed to support data exchange necessary to ensure complete records in IIS, particularly for adults. The statement "*state and local*

¹ Selvan, M. S., et al. (2014). "Data sources and structure for post-licensure rapid immunization safety monitoring (PRISM)." *Value in Health* **17 (3)**: A129.

Salmon, D., et al. (2012). "Success of program linking data sources to monitor H1N1 vaccine safety points to potential for even broader safety surveillance." *Health Affairs* **31(11)**: 2518-2527.

McCarthy, N. L., et al. (2011). "Monitoring vaccine safety using the Vaccine Safety Datalink: utilizing immunization registries for pandemic influenza." *Vaccine* **29(31)**: 4891-4896.





immunization programs **do not** have the legal authority to share individual vaccination data across state jurisdictions" should be corrected to say **may not** have the legal authority to account for some states that do have interjurisdictional data exchange agreements in place. **Objective 4.3** or **4.4** should include an additional strategy for advocacy and to overcome policy barriers that inhibit data exchange, data sharing, and complete data capture (e.g. promote opt-out vs opt-in consent policies) to improve data completeness and quality and allow for maximized utilization of IIS and their features. Strategies under **Objective 4.3** get at this, but specific support for a federal framework or model law that promotes effective data capture, exchange and use will provide both uniformity and support toward a nation-wide network of interoperating IIS.

AIRA recommends reworking **strategies 4.3.3 and 4.3.4**. **Strategy 4.3.3** can focus on increasing data analytics capacity to conduct disease surveillance and assessing and reporting on vaccination coverage (including enhanced capacity for integrating data visualization tools). And **Strategy 4.3.4** can focus on increasing enrollment of adult health care providers in immunization information systems (including increased capacity for outreach and onboarding), including providing additional resources, training, and incentives to improve IIS reporting by adult vaccine providers.

Strategy 4.4.3 could be expanded to include encouraging Medicaid programs to collaborate with public health to improve data sharing and integration of data systems to better assess coverage of individuals on Medicaid given disparities that exist (e.g. children and pregnant women on Medicaid).

For **Strategy 4.4.4**, AIRA supports the plan's inclusion of using vaccination as a quality measure in value-based payment models but would also promote the widespread adoption of the Adult Immunization Status (AIS) and Prenatal Immunization Status (PRS) measures as tools to promote quality improvement, adherence and consistent utilization of recommended vaccines. A strong and robust immunization information infrastructure is critical to these efforts, and adoption of composite measures that can be electronically reported will provide reliable and comprehensive means to assess the vaccination status of adults and pregnant women while reducing administrative reporting burden on providers. All stakeholders will benefit from more complete, valid data and more useful surveillance tools and guidance for integrating data sources such as IIS to carry out reporting.



Goal 5: Protect the health of the nation by supporting global immunization efforts

AIRA collaborates with global partners to share best practices on developing and achieving standards for electronic immunization registries to become more complete, accurate, and useful for global immunization programs and ministries of health. **Objective 5.3**, support global partners to strengthen immunization systems, should be expanded to more explicitly state, *including immunization information systems/electronic immunization registries*. IIS could also be called out in **Strategy 5.3.2**. Further, we see an opportunity to add a strategy under **Objective 5.4** related to collaboration around global vaccination data infrastructure to advance how vaccine coverage, safety and effectiveness are monitored globally, including the development of standardize methods and guidance to share and compare these sorts of data.

Table 1: Indicators and Targets for the 2020 Vaccine Strategic National Plan

In reviewing the information included as baseline and target metrics, AIRA has questions regarding why more recent data are not being utilized for baseline figures.

1. Percentage of children aged <6 years whose immunization records are in a fully operational, population-based IIS uses 2017 data while 2019 IISAR data are available indicating **96%** which surpasses the 5- and 10-year targets.²
2. Percentage of adults aged ≥19 years who have one or more immunizations recorded in an IIS uses the 2018 figure. The 2019 IISAR results were recently posted publicly and reflects **60%** for the most recent baseline.³
3. The rows referencing kindergarten MMR, DTaP, and HPV could use the most recent NIS-child, teen, and kindergarten coverage reports.
4. While this is pulled directly from the Healthy People 2030 goals and we agree progress for adult participation in IIS could be better measured, because we know that all IIS are now able to capture lifespan vaccines, *the proportion of Immunization Information Systems that track adult immunizations across the lifespan* under developmental indicators is less meaningful than an indicator that captures the proportion of adult providers reporting to IIS and/or proportion of adults represented in IIS.

² <https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/downloads/2019-data-child-map-508.pdf>

³ <https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/index.html>



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Do any of the Vaccine Plan's goals, objectives and strategies cause concern? If so, please specify the goal, objective or strategy, and describe the concern.

No, AIRA does not have concerns about strategies included beyond the gaps addressed above and need for implementation plans to identify resources and further prioritize these strategies.

AIRA appreciates this opportunity to comment and continue to advocate for the strong role of IIS as foundational to our national immunization infrastructure. We look forward to serving as a partner and supporting our members in implementing the VNSP. Please feel free to contact me with any questions at coyler@immregistries.org.

Sincerely,

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