AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

INFORMATION REQUEST

Topic: FDA's Vaccination and Safety Effectiveness Surveillance Program

Request Date: August 29, 2022

Information Requested:

The Nevada Department of Health and Human Services has been asked by FDA and Acumen, to participate in FDA's vaccination safety and effectiveness surveillance program. Attached you will find an FAQ document about the project. Nevada has not yet agreed to participate and would be interested in IIS programs responses to the following questions:

- Is your jurisdiction actively participating in this project, in the process of agreeing to participate in this project, or not planning to participate?
    - If your jurisdiction is participating, Nevada would like to know about your experience and lessons learned, including whether you intend to continue and the method you chose to employ for file exchange.
    - If your jurisdiction does not plan to participate, what led to that decision?

Requesting Member: Mandy Harris

Responding Member(s): Rachel Odom (AR), Miriam Muscoplat (MN), Alexandra Ternier (NYC), Rex Larson (OR), Ellen Amore (RI), Brett Oakland (SD), Kevin Allen (TX), Jon Reid (UT)

Results:

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AR:

Arkansas has met with the Acumen group and a DUA has been signed to participate in the project; however, we have not started sharing data yet. We have a meeting set up with Acumen on 9.6 to work out the details and determine how the data will be exchanged. An

epidemiologist in our agency will be pulling and sending the file. I can send more information once we get the process started.

MN:

Minnesota opted not to participate directly in this project due to privacy concerns. Our Data practices Statute (MN §13.3805) is pretty clear about data sharing. We could participate with a Commissioners Order, but opted not to go that route as we like to limit use of that option.

Another factor is that health insurers in Minnesota are allowed to utilize our IIS for their clients. Therefore, the participating insurers (which we found out is most if not all) already include IIS data in their numbers. Given the breakdown of insurance coverage in Minnesota, we believe the vast majority of Minnesotan's are already covered with the data they currently have. The only group not covered are those on traditional Medicare.

Happy to answer any follow-up questions.

NYC:

NYC is considering participating in the FDA Vaccine Surveillance Project. We are in the process of reviewing the DUA.

OR:

Oregon doesn't have much to say regarding this project, but we met with Acumen and FDA a couple of times, and they presented to our Data Governance Council which would be our governing body that would approve this request. That group has some questions or concerns, but felt the project was worth pursuing. Unfortunately, we put any decisions on hold as we deal with Monkeypox and COVID bivalent booster rollout. I expect we'll revisit the issue in the fall after things slow down.We'd love to hear what your thoughts on the project are as well though!

RI:

As of now, Rhode Island is in the process of deciding if we will or will not participate. IIS and Immunization Program does not recommend participating for the following reasons:

- We already give data to the CDC through the data clearinghouse. It is not identifiable, but CDC is requiring us to participate in Privacy Preserving Record Linkage (PPRL), which is a huge project for us to establish, so that they can link with outside datasets in the absence of identifying information. We think that would be an appropriate way for FDA to go.

- Their request is specific for Medicare and Medicaid enrollees since 2015. We do not know who those people might be in our IIS.
- Their request is for data for all vaccines. Most of the vaccines have been used for decades and have a long-established safety record.
- This request is for identified data which we do not give out except to other immunization registries or clinical partners for the purpose of care coordination and assuring immunization in our population. Our authority to send PHI includes the Confidentiality of Health Care Act which allows sharing for the purpose of care coordination, which is not the purpose of this request. The FDA argument is that PHI could be shared without consent under the Public Health HIPAA exemption. However, we do not feel this should be entered into lightly and could result in the dismantling of an IIS if public sentiment were swayed that way.
- Our workload is substantial and CDC is constantly requesting that we do large projects with short turn-around times (supplemental IIS budget request, IIS cost estimate, PPRL, data exchange with VHA and other states and jurisdictions through the IZ Gateway, legal agreements to be reviewed and signed, etc) and all of this is on top of our usual workload (not to mention we are down 2 positions which are on hold due to the "FTE cap"). Monkey pox is the latest in the added burden of work for our team.

SD:

South Dakota has agreed to participate, but we have not begun any data exchange yet. We are transitioning to a new IIS platform next year, and we will likely wait to exchange data until then.

TX:

Texas did have a meeting to discuss the project but due to statutory restrictions relating to sharing record-level data out of state, we had to decline.

UT:

Utah received the same request. We decided not to participate. The request is more a research/data visualization project with PII. Acumen is not an authorized participant according to our state rule. We generally don't participate in vaccine safety/effective projects, that is better handled by healthcare providers/researchers. This seemed a little duplicative with CDC efforts, and I would like to see them work with the CDC

first. Also, we could do linkage on our side and send them the results instead of us releasing PII directly to them.