

National Vaccine Registry

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Part 3: Final National Vaccine Registry

1. SCOPE

Meaningful Use and the impetus to implement an Electronic Health Record (EHR) provide an ideal platform for the enactment of a national vaccine registry. Although unsuccessful in the past, the current landscape in health care provides a perfect opportunity for this endeavor. Referred to as Immunization Information Systems (IIS), vaccine registries exist in all fifty states and many exchange this data via Health Information Exchanges (HIE), yet a national network is nonexistent. A National Vaccine Registry (NVR) or National Immunization Information System (NIIS) will integrate with the existing state registries and HIE's allowing for bidirectional transmission of data among providers, states and the EHR.

A NIIS will ensure that the correct immunizations are administered by providers through consolidating vaccine records from multiple sources on a national level. Vaccine information will be bar-coded and may be scanned directly to the NIIS and the EHR. By means of a patient portal this information will provide accurate up to date vaccination records that will be available for the parents to access when needed as well as sending reminder notices when vaccines are due. The accumulation of the data from the registries will allow for better forecasting regarding supply and demand for specific vaccines.

An existing infrastructure will provide the means for the vaccine registry to exchange information on a national level. The Nationwide Health Information Network (NwHIN) was established under the auspices of the ONC and has evolved into a collection of standards, services and policies, which support exchanges among health care participants. (Perelman, Baer, & Garcia, 2012). Viewed as a “network of networks”, the

NwHIN will integrate existing vaccine registries as well as providing access for new participants via several different avenues. Pharmaceutical companies, government agencies, insurance companies, labs are all tied together via the NwHIN network.

Requirements for providers to participation in the NwHIN is the acquisition of a unique Organizational Identifier (OID) which will allow the healthcare system or provider to receive and send messages to trusted entities within the NwHIN through an interface such as MIRTH CONNECT and DIRECT (Perelman et al., 2012).

According to the CMS, to achieve stage 1 Meaningful Use (MU), a provider must perform at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and requires follow up submission if the test is unsuccessful. The anticipation is that Stage 2 MU will require ongoing submission of vaccination records and Stage 3 will likely require bidirectional messaging using HL7 standards. Access to the registry via NwHIN will take the providers all the way to Stage 3 MU.

In order for the exchange of information to be accurate and effective, the correct patient must be entered into the system, or matched with the appropriate record that already exist within the registries. A patient locator system that matches demographic information in order to link appropriate records and avoid duplication will be used to verify to correctness of the match.

2. OBJECTIVES

In order to meet the objectives for the establishment of the NIIS, the ability to consolidate records is paramount. A Patient Discovery Interface will provide guidance to ensure the correct patient is matched within the registry. Demographics are entered into the system, and if a single match is found this is considered reliable, if multiple or no

matches are found, additional information will be requested until a match is reliable.

CONNECT is an open source software package that supports HIE at both the local and national level. In 2008 federal agencies implemented a program to connect their health IT systems into NwHIN, as a means of sharing health care data using nationally recognized interoperability standards such as HL7. DIRECT uses standard message authentication, security and transport via HTTP. Providers who do not have access to NwHIN 's CONNECT, may utilize the DIRECT interface system via a secure email address issued by the ONC, which would allow sharing of information (Perelman et al., 2012). The establishment of patient portal will allow parents access to the registry and retrieve vaccine records. Parents may authorize access for schools, and childcare organization, camps, etc. The providers will have real-time exchange of data once the EHR is integrated into the system, but may have daily batching until that point.

The next objective is to work with the EHR vendors to enable the provider to enter data either manually or by bar code into the EHR and exchange information in a bidirectional manner with the registry. An outcome of this feature is that the provider will be prepared for attestation for Stage 2 MU, in regards to immunization transmission.

In the event of an outbreak of disease, epidemiologist may utilize the information gathered from the registry to identify populations in the outbreak region and determine if patients have been adequately vaccinated. The vaccine supply will be monitored and when limited resources are available, distribution may be targeted to high-risk populations. The vaccine manufacturers will be able to analyze data gathered from the registry to evaluate trends, including effectiveness and adverse events. Supplies may be managed more efficiently, forecasting will become more accurate and a quick notification process will

allow rapid recall of a product if needed. Ultimately as the databases are populated and use of the EHR is widespread, information from the registry may be incorporated into the CDSS, and a risk analysis may assist the physician in making choices regarding immunization recommendations.

3. RESOURCE NEEDS

A survey done by ALL KIDS COUNT evaluated the annual expenditures by schools and health care offices to provide vaccination records, along with the cost of duplicated vaccines, which totaled \$281.2 million. The projected annual cost of a national network ranged from \$78 million (0-5 year olds) to \$100 million (0-6 year olds), leaving a net annual savings between \$181-\$203 million ("Policy Brief Sustaining Financial Support for Immunization Registries," 2000).

The resources required for the parents and the providers are as simple as an Internet connection. The parents will be funneled into the patient portal and the providers to NwHIN via DIRECT or CONNECT, once the EHR is fully integrated the vaccine information will be scanned directly to the EHR via bar code. This will require additional resources for the scanners and training of the users. We will need to work with the IT department to develop the patient portal and patient locator software. Collaborating with the EHR vendors will occur as a means to standardize the immunization format in the programs to match with registry.

Providers may receive financial benefits to offset any cost via the HITECH ACT. Funding for vaccines and registries is fairly widespread and these sources will continue to be tapped, they include The Robert Wood Johnson Foundation via ALL KIDS COUNT, immunization grants, state and local governments, and insurance providers.

4. RISK MANAGEMENT

Both HIPA and HITECH provide a foundation for privacy and security within the NIIS yet there is some flexibility and uncertainty of how privacy is protected across health information exchanges in general. HIE's are not covered by HIPAA since they are not a health care provider, a health plan, or a healthcare clearing house. As a result vaccine registries that utilize information exchanges are subject to unclear legal, regulatory and policy issues. Covered entities (CE) under HIPAA are able to gain access to the HIE's, the HIE provides a service to that CE by allowing them access to a patient's personal health information (if authorized by the patient). The nature of this relationship thus considers the HIE as a Business associate (BA) which is covered by the HIPAA privacy act. HIPAA governs CE along with BA, but FERPA governs the disclosure of information contained within school records and this includes immunization records.

When health care information is exchanged across state lines there is ambiguity as to which regulations should be observed and there is a vast continuum of state laws regarding privacy from extremely rigid to virtually non-existent as seen in Virginia (Fluckinger, 2011). Typically states whose laws are the most stringent are followed but it is open to much interpretation.

Vaccine registries currently exist at the state and regional level, since the NIIS registry is intended to be a national registry it is imperative that the privacy issues are clarified. The NwHIN has in place a collection of standards and regulations that address not only interoperability but also privacy and security on a national level. A key factor to consider in information exchange is trust between the participants. Many HIE's have their own

“trust agreements” between parties. The NwHIN is sponsored by the ONC and it establishes a trust agreement with the participants, which provides a legal framework for participation in the data exchange; access to NwHIN is authenticated and encrypted.

5. ETHICAL GUIDANCE

The core ethical dilemmas particular to the vaccine registry are a result of the ability to track participants. During the Clinton administration an attempt was made to issue a national identification number, public outcry was substantial by a vocal coalition of advocacy groups including the ACLU, Concerned Women for America and American Association of Christian Schools (“Advocates attest national identity debate is here to stay,” 2010). These groups along with private citizens opposed this agenda viewing it as an invasion of privacy and a federal tracking system.

The intent of the Belmont report published in The Federal Register was to provide guidance related to research involving human subjects by developing guidelines for evaluating ethical dilemmas (, 1979). The three ethical principles of Respect for person, Beneficence and Justice all have implications regarding the use of data extracted from vaccine registries for research projects. Respect for person requires consent from the patient to use their health information for reasons that do not relate to the why the information was originally collected. Non-compliant patients in the registry may be stigmatized and pressured to comply with immunization recommendation, this illustrates the concept of beneficence, “do no harm”. Justice requires fairness and equal treatment, which addresses patient privacy, maintenance of dignity and confidentiality.

Steps to mitigate these ethical dilemmas include the patient locator system which will be used to match the individual via demographics thus a national ID will not be

mandated. Clearer guidelines shall be in place regarding the use of the information extracted from the registry for research purposes and informed consent must be obtained. Parents will have the right to opt out of the registry without retribution. Note that even if they exercise this right, a newborn may still be monitored by a tracking system and this must be addressed. In 1995 HHS secretary Donna Shalala posted in The Federal Register, a proposal that newborns are to be issued a social security number, although voluntary hospitals will request to use information from the birth certificate to apply for the social security number ("Federal Register," 1995, p. 12964). The application also requests the Social Security number of the parents, yet this is not mandatory. The Social Security Administration must report the new number to the state health department for use in public health programs, which include vaccine registries.

The philosophy of Utilitarianism determines if an action is right or wrong based on the consequences of the ethical results for happiness of the greatest number of people ("Utilitarianism," n.d). As a society when does this theory trump personal privacy, over public health? When public health is at risk, should officials have access to the registry in order to identify and pursue individuals that are not vaccinated? At what point do we determine the risk is a significant threat and requires intervention, whooping cough, SARS, what about HPV? Where do we as a society draw the line?

6. Stakeholders

The healthcare providers play a significant role in the success of the NIIS, since they must enter the information into the registry either manually or via the EHR. Financial benefits will be appreciated, as the cost to retrieve records will be minimized. The providers will have access to updated vaccine records and the latest recommendations for

their patients, which will improve patient care. Parents will benefit by allowing them access to the registry as needed to retrieve an updated record of their child's immunization history along with receiving reminders when vaccines are due. Schools, day care centers, doctors offices and health clinics will realize a tremendous cost savings if they are allowed access to student records via the computer. Advocacy groups must be acknowledged and assured that the registry will not be used as a tracking system for immigration reason, or targeting parents who forgo vaccinations for their children based on religious reason or personal philosophies. Vaccine manufacturer and the CDC may gather data to forecast supply and demand and anticipate increased demand in areas where outbreaks occur. Insurance companies may benefit by research and information gathered once the system is fully in effect including CDSS by improved outcomes and cost containments.

Consumer buy-in to the NIIS, is not as critical as one may think. Although the information gathered from the registry will be a benefit to the consumer by improved health care, individual buy-in is not critical. Since entrance into the system is opt-out rather than opt-in the majority of people will be entered in to the system. The consumers who will reap benefits are the users exemplified by cost savings for doctor's offices, schools and patients. The registry will become successful as providers and parents use the system and more data is available to measure outcomes.

The vaccine registry is truly patient centered since the patient is the ultimate stakeholder who will receive improved care that is cost efficient especially as the CDSS becomes an integral part of the system and evidence based medicine is integrated.

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