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LEVERAGING IMMUNIZATION DATA IN THE E-HEALTH ERA

Exploring the Value, Tradeoffs, and Future Directions of Immunization Data Exchange

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Table of Contents

Introduction

As a nation, we are at the beginning of a bold transformation of an overly-expensive, disease-oriented and generally disjointed "system" of healthcare into an effective and efficient coordinated system that focuses on the health of individuals and communities. It's clear that the way health information is exchanged and used will be critical to improving the health of individuals and communities, and that health information technology (HIT) is foundational to these overall health reform efforts.

The significant financial investments in health information technology authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act are intended to stimulate a marked increase in the use of interoperable Electronic Health Record (EHR) systems and in the formation of Health Information Exchange entities (HIEs). HIEs are steadily emerging across the country and are expected to grow with the recent appropriation of HITECH funding, especially through the State HIE Cooperative Agreement program.[1] At the same time, Immunization Information Systems (IISs) exist today as fairly mature systems in most states. As of December 2009, 77 percent of all children greater than six years of age in the United States had two or more immunizations recorded in an IIS.[2]

This paper addresses the impact that the growth of HIEs might have on IISs. Specifically, it explores how HIEs and IISs could work together to add value to each other, to build on one another's strengths, and to better and more cost-effectively achieve their overall—and largely shared—missions.

- Would adding immunization data to the portfolio of HIE services increase the value of the HIE to users and strengthen its business model?
- Would enabling access to IIS data through the HIE improve clinician use of the data to make immunization decisions, since access to the data would be more integrated into clinical workflows?
- Would working together reduce costs by minimizing the number of interfaces that need to be created and maintained?
- What would a model of EHR-HIE-IIS data exchange look like?
- What policy and technical issues would have to be addressed?
- What actions are necessary by whom to more fully explore requirements for successful implementation of such a model?

HIEs and IISs: Divergence and Convergence

Despite striking similarities in the overall purposes and functions of HIEs and IISs, they do have important differences. HIEs are an emerging model for securely consolidating and delivering a potentially broad range of clinical health information to the point of care. IISs are a well-established model for consolidating and delivering immunization history and decision support information that also feature functionality such as vaccine inventory management, immunization coverage reports and reminders. So from a clinician's perspective, HIEs are intended to deliver a broad range of relevant clinical information through a single interface, whereas IISs most often provide a single type of clinical data through a stand-alone, web-based application but with a wide range of functionality.

In addition to differences in breadth versus depth, HIEs and IISs differ in how records are created. While HIE records are patient-based and driven by clinical processes, IISs are population-based, with records

[1] Information on the HITECH programs can be found at http://healthit.hhs.gov.

[2] Centers for Disease Control and Prevention. Immunization Information System Annual Report. Available at http://www.cdc.gov/vaccines/programs/iis/rates/2009-child-map.htm. [cited 2010 Sept 23]

originating from birth-record information. This means that the IIS not only has records on those who have sought health care/immunizations, but also on those who have not presented for care ("slipping through the cracks"). As HIEs mature and expand the number of participating provider sites and the range of clinical data they offer, they may also be able to identify who and how many individuals within communities are "slipping through the cracks." This capability, regardless of who performs it, will be critical as efforts expand to improve overall population health, reduce health disparities, measure the impact of increased health insurance coverage, and encourage the use of medical homes.[3]

With so much emphasis being placed on improving clinical workflows, effective use of decision support tools, and patient-centric care, it's natural that clinicians will prefer to use integrated sources of information that meet as many of their needs as possible. As a result, the reliance on stand-alone applications that require separate logins and patient queries, such as an IIS, will likely diminish.

Moving Forward

The HIE and IIS communities now stand at a crossroads. The IIS community has an opportunity to enhance its mission by more seamlessly interfacing with emerging HIEs. Furthermore, if a chief aim of IISs is to improve immunization practice and thus improve clinical and population health outcomes, it only makes sense for IISs to collaborate with HIEs, which share a focus on improving healthcare quality, continuity, cost, and safety. On the other side of the benefit equation, an HIE can increase its overall value, and its business case, by adding high-value immunization data that has already been deduplicated at the patient and vaccine levels. And an HIE could increase its value to the clinician even more by facilitating ongoing data submission to the IIS under the Centers for Medicaid and Medicare Services EHR Incentive Program ("meaningful use").

Collaboration between HIEs could also help to reduce the cost of maintaining separate interfaces and, in the long run, can lead to improved sustainability and potentially lower overall costs for both public health and healthcare organizations.

Scope

Immunizations are administered and/or recorded in increasingly diverse settings, including private provider offices, public health clinics, pharmacies, grocery stores, retail-based clinics, schools, and Personal Health Records. However, this document focuses on immunizations provided in the traditional primary care setting, where the majority of electronic immunization transactions are generated, and where HIEs may facilitate further electronic exchange of the data. To the extent that the new immunization providers support the EHR-HIE-IIS workflow and transactions described herein, those entities may also be considered in scope.

The Indiana Network for Patient Care (INPC) is used here as an example of an existing and mature HIE. The INPC includes clinical data from over 35 hospitals, local and state public health departments, laboratories and imaging centers, and a few large group practices closely tied to hospital systems, with plans underway to expand these efforts. Appendix B provides additional information on the INPC. This document does not necessarily represent how the Indiana statewide IIS would implement these data flows, nor does the document cover the range of existing policy and technical issues in bidirectional EHR-IIS exchange, which are increasingly commonplace across the country. In an alternative model, the HIE

[3] For more on this issue, see Immunization Registries Can Be Building Blocks For National Health Information Systems, Hinman and Ross, Health Affairs, 2010; 29: 676-682

retrieves, consolidates and delivers health information but does not store it once it has been delivered to the provider. This paper does not discuss that model, although many of the processes and issues presented here would still apply.

Further, this document does not describe architectures for an HIE network or issues around transport. Lastly, state privacy laws have a significant impact on how health data are exchanged, particularly if consent is required. Because of the variability in those state laws, privacy issues are not addressed here.

Organization of the Paper

- Section 1 of this paper describes the processes and data flows that would be involved in EHR-HIE-IIS data exchange, using the tools of business process analysis.
- Section 2 explores the many technical and operational issues that are likely to arise in undertaking such an endeavor.
- Section 3 discusses possible barriers to implementation, offering a perspective on various policy and design issues, so that planners are aware of and become versed in these important issues.
- Section 4 provides recommendations to the HIE and public health communities.
- Appendix A provides additional information on the business process analysis tools used here.
- Appendix B provides additional background information on the Indiana Network for Patient Care.

Section 1: Analysis of EHR-HIE-IIS Data Flows

Although the term “business process” has been widely used in industry to describe the way in which organizations conduct their activities and achieve specific goals and objectives, the term is not commonly used in healthcare and public health. A business process describes a set of activities and tasks that logically group together to accomplish a goal or produce something of value for the benefit of the organization, stakeholder or customer. In the context of health and public health, a business process will contribute a valuable service for the benefit of an individual, the community, a provider or healthcare organization, and/or a health department.

Emphasizing business processes instead of specific services or programs is a key principle of health and public health informatics. By understanding a business process and its multiple components, including triggers, inputs, outputs and objectives, we begin to understand how an information system — that is, a tool that supports work — must perform to deliver value to the users. Once business processes are defined, one can define in detail the specific *things the information system is required to do* in order to make the process achieve its purpose and be efficient. We refer to these as *information system requirements*.

For readers unfamiliar with the tools of Business Process Analysis, Appendix A provides an introduction to the tools as used here.

Functional Groups

This table represents the key individuals, groups, and organizations involved in the business processes of EHR-HIE-IIS immunization data sharing and synchronization.

ID	FUNCTIONAL GROUP	POOL	DESCRIPTION
1	Patient	Patient/Family	Recipient of immunization. In the case of an infant or child or any patient unable to care for him/herself, this is the parent or guardian who authorizes the administration of vaccines
2	Provider Administration	Healthcare Site	Non-healthcare provider who interacts with immunization data, patient registration, and other clinical workflow
3	Clinician	Healthcare Site	Healthcare provider who reviews and acts on immunization information; administers immunizations
4	Electronic Health Record System	Healthcare Site	A system to manage a longitudinal electronic record of patient health information generated by one or more encounters in any care-delivery setting.
5	Health Information Exchange (HIE)	Health Information Exchange (HIE)	Electronic network intended to help multiple healthcare organizations (such as hospitals, labs, radiology centers, etc.) in a given area to securely exchange health and patient data
6	Immunization Information System (IIS)	Public Health	Confidential, population-based, computerized information systems that collect vaccination data about all children (and, increasingly, across the life span) within a geographic area, providing vaccine forecasting/decision support, vaccine inventory management, reminder-recall, and various individual and summary reports

Business Process Matrix (See Appendix A for a definition of each component)

BUSINESS PROCESS	GOAL(s)	OBJECTIVE	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
Immunization Data Exchange and Synchronization	• To ensure patients and populations are age-appropriately immunized. • To ensure immunization providers can access complete and accurate immunization history and recommend-dations on any patient at any time. • Public Health Surveillance	• To ensure immunization providers have accurate, complete, patient-specific information to inform immunization decisions. • Reduce provider data entry burden • Reduce cost of system interfaces • Leverage HIE infrastructure	• Patient data security and privacy (state/ local immunization data sharing law; HIPAA). • Data sharing agreements between entities. • National policy recommendations and guidelines (ACIP, NVAC, CDC). • Standards-based implementation guides, profiles or interoperability specifications for immunization data. • AIRA/CDC Functional standards and best practice guidelines for IIS.	• Patient is registered for a clinical encounter (e.g., clinic appointment) • Patient needs certificate for school, child care, or camp • Immunization occurs at another provider site	1. Patient is registered at a clinic. 2. Registration message triggers request for immunization information from HIE. 3. HIE requests immunization information and recommendations from IIS. 4. HIE formats and forwards the immunization history and recommendations to the provider. 5. Provider administers vaccines based on recommendations. 6. Provider sends updates to HIE and IIS.	• Immunization information coming into the HIE and the IIS from a variety of sources. • Child's DOB, gender, contra-indications, and exemptions	• Consolidated, patient-specific immunization record. • Patient-specific immunization recommen-dations based on known immunization history and patient age.	• Proportion of a clinic's patient population age-appropriately immunized. • Proportion of a population in a geographic area age-appropriately immunized. • Proportion of record queries to the HIE for which a match is found. • Proportion of record queries from the HIE to the IIS for which a match is found. • Number of transactions exchanged among IIS HIE, and EHR. • Completeness of HIE and IIS repositories and EHR.

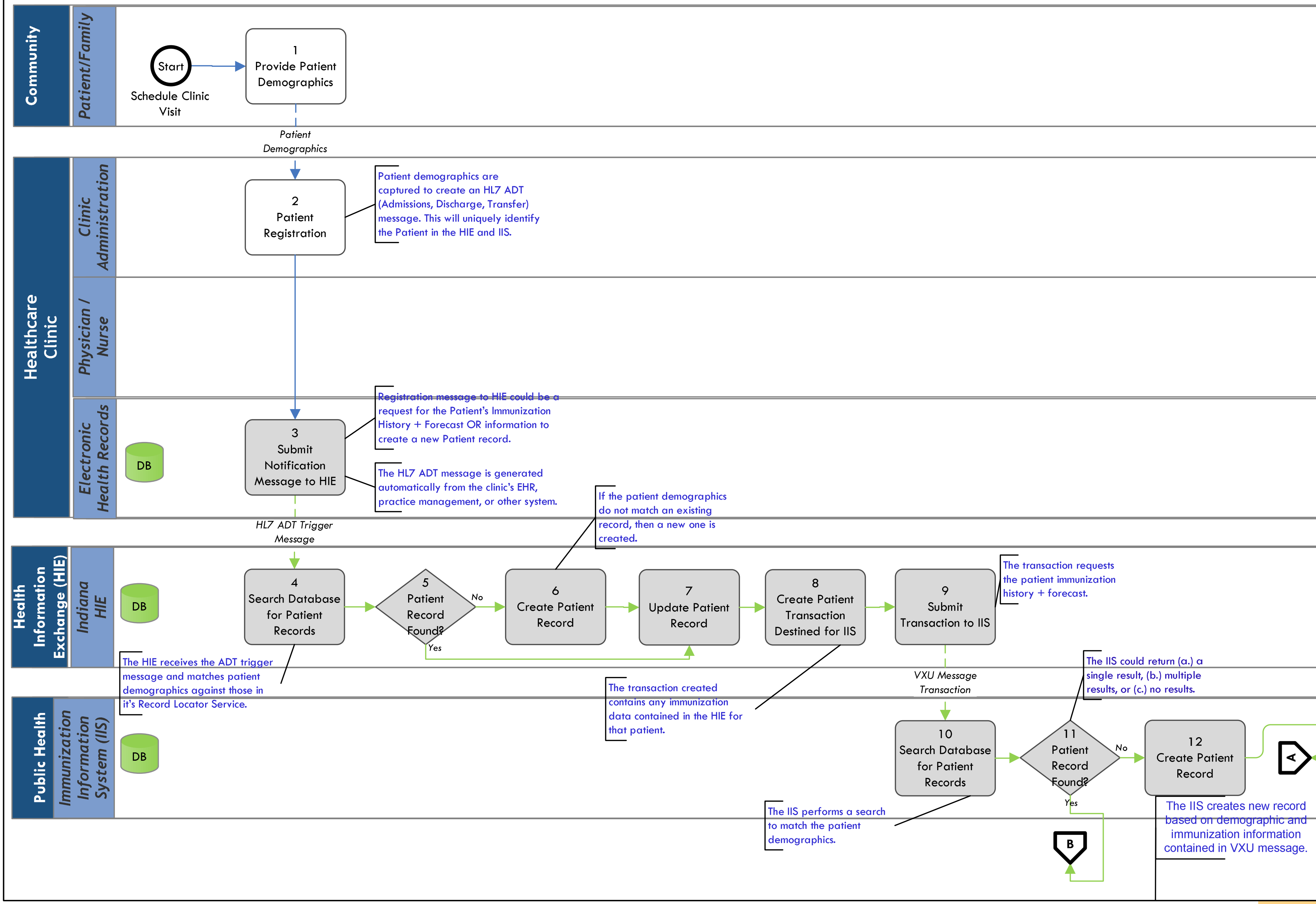
Immunization Data Exchange Process Map Narrative

Synchronizing three data sources

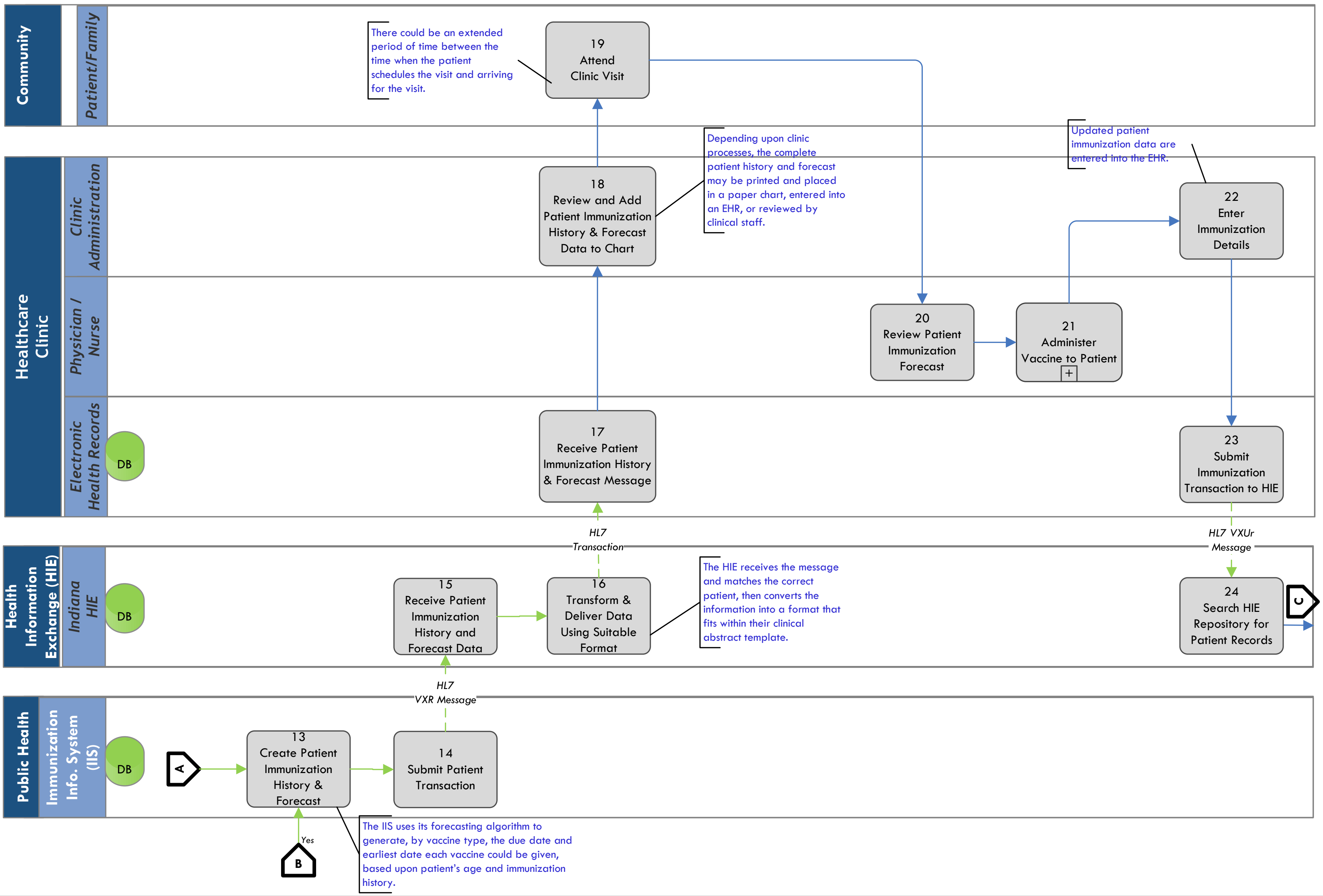
The process map on pages 7-10 addresses the challenge of handling immunization data that is scattered across different systems and may not be synchronized. When incomplete portions of immunization records are spread across multiple sources, the clinician cannot accurately determine what vaccines could be given today. Delivering the most complete and accurate information to the clinician at the point of care is the purpose of this information exchange and synchronization.

There are three types of data sources for this workflow: they include the electronic health record (EHR), which can be instantiated in a variety of forms; the health information exchange (HIE); and the immunization information system (IIS, also known as an immunization registry).

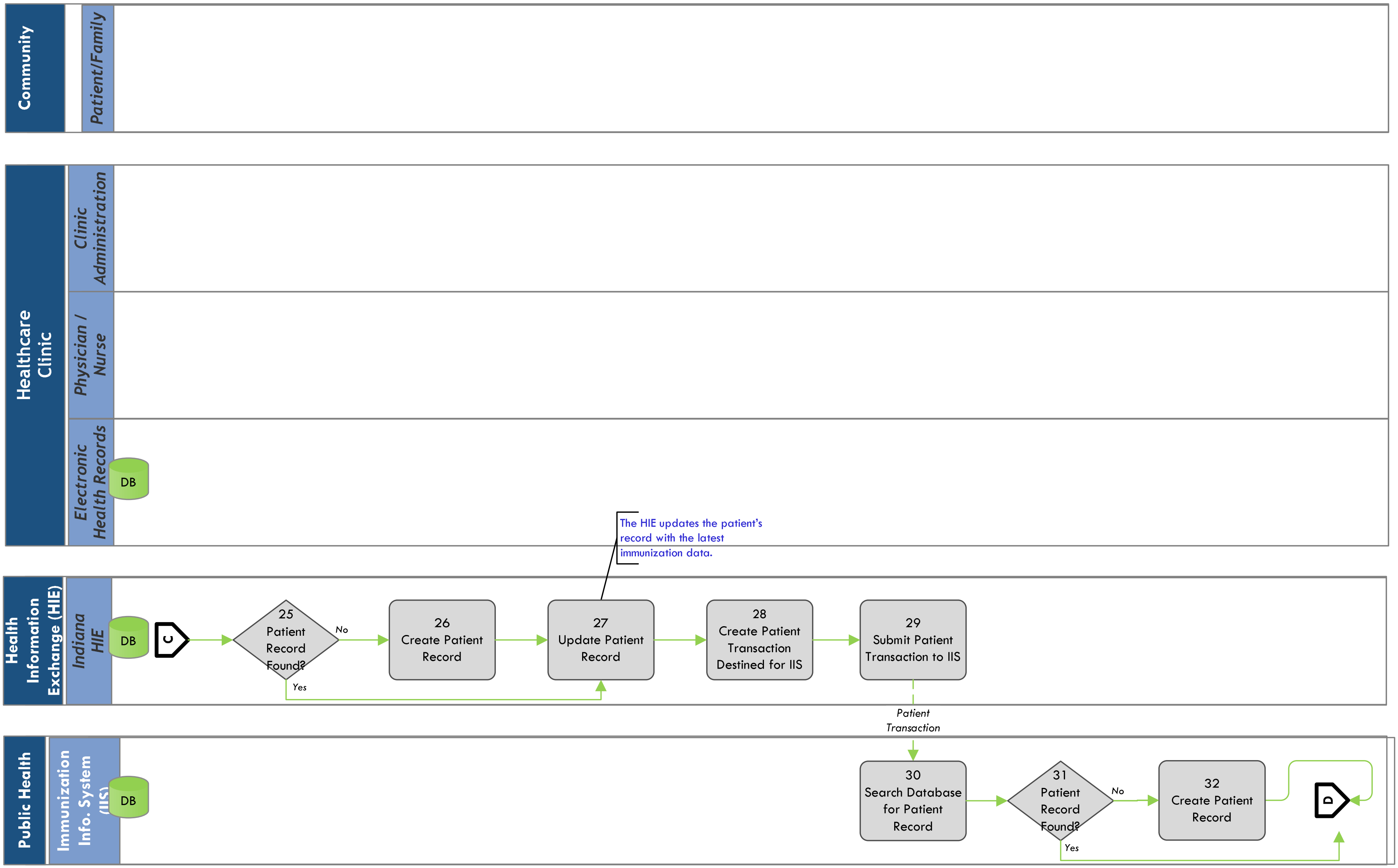
EHR-HIE-IIS Immunization Data Exchange



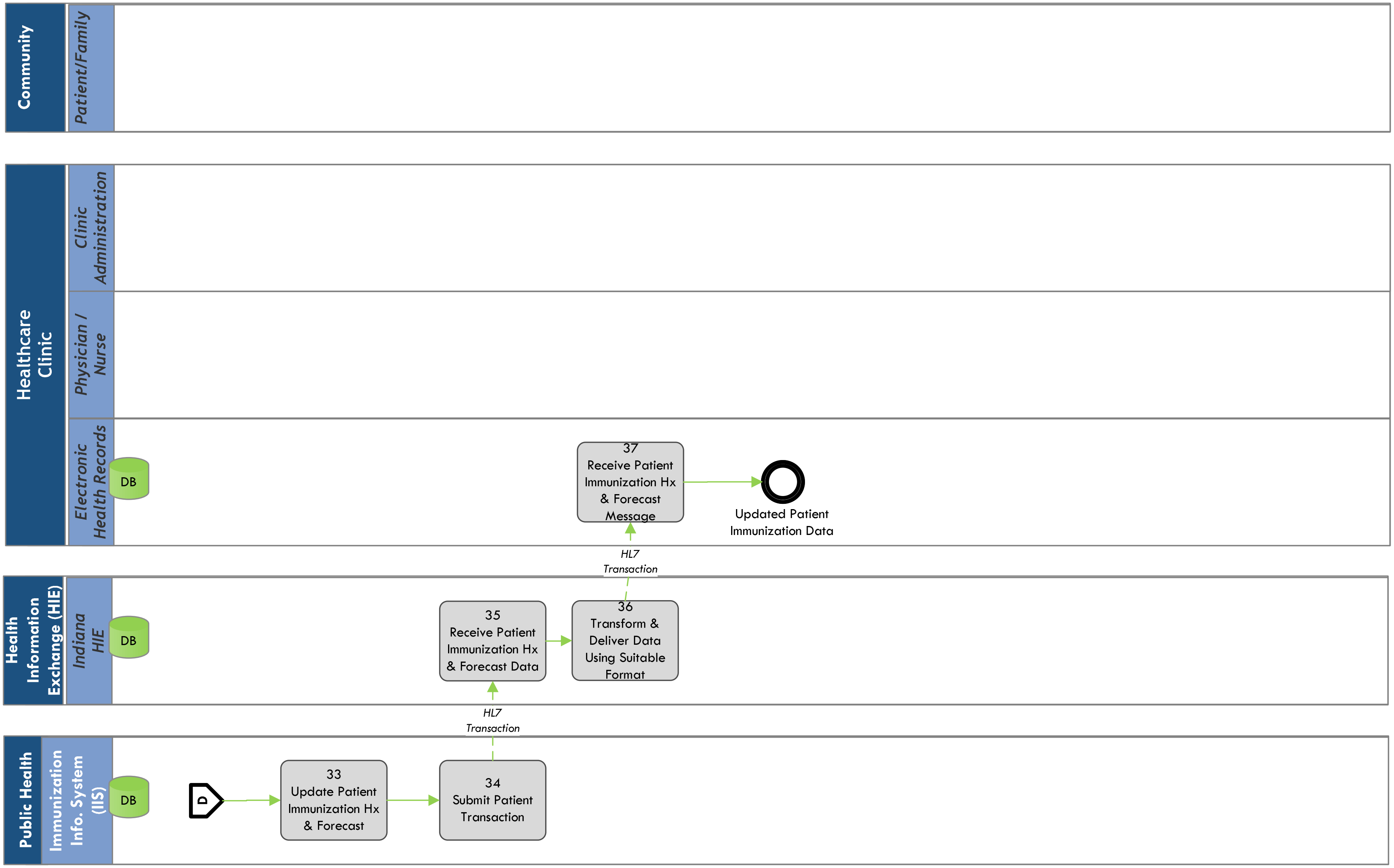
EHR-HIE-IIS Immunization Data Exchange (cont'd)



EHR-HIE-IIS Immunization Data Exchange (cont'd)



EHR-HIE-IIS Immunization Data Exchange (cont'd)



Step-By-Step Process Map Narrative

1. ***ACTOR***: Patient ***ACTION***: Provide patient demographics

Patient demographics are likely already recorded in the EHR system; if not, they may be provided either when scheduling a clinic visit days or weeks in advance of the actual visit, or when alerting the clinic that the patient has physically arrived for a pending visit.

2. ***ACTOR***: Clinic Administration ***ACTION:*** Patient registration

In most outpatient clinical care settings, patient demographic data are entered electronically well before the actual visit. Therefore, there is ample time to submit a transaction to the HIE and the IIS to retrieve any missing data. However, outpatient EHR systems may lack mechanisms that allow a preemptive query or trigger message to be sent. For the Indiana Network for Patient Care (INPC), the trigger messages are commonly sent at the time the patient arrives. Consequently, there is a need for fast-turnaround, low-latency responses from the systems being queried, so that the information is available at the point of care when the patient is being seen. Alternatively, EHR systems may implement appropriate batch-mode immunization data transfer processes on a routine (e.g., nightly) basis.

3. ***ACTOR***: EHR ***ACTION:*** Submit notification message to HIE

Patient-identifying information and vaccine administration data are sent from the EHR to the HIE. This information may be sent in real time or delivered in routine batch mode.

4. ***ACTOR***: HIE ***ACTION:*** Search database for patient records

The INPC master patient index, or global patient registry, aggregates patient-specific data across multiple care settings using a sophisticated matching algorithm. This crucial HIE sub-system is used to identify and aggregate immunization data from multiple data providers.

5. ***ACTOR***: HIE ***ACTION:*** Decision point: Patient record found? (Yes or No)

The INPC master patient index, or global patient registry, aggregates patient-specific data across multiple care settings using a sophisticated matching algorithm. This crucial HIE sub-system is used to identify and aggregate immunization data from multiple data providers.

6. ***ACTOR***: HIE ***ACTION:*** Create patient record (if patient record not found)

If patient demographics do not match an existing record in the HIE, a new patient record will be created automatically. Processes for *creating* a new patient record and *adding* or *updating* clinical data for that patient record are distinct activities. A new patient record must be created *before* clinical data can be added to, or updated for that record.

7. *Actor*: HIE **_Action:_ Update patient record**

If immunization data is contained in the notification message, those data are added to the HIE's clinical data repository. This step is included because *updating* clinical data for an existing patient record is distinct from *creating* a new patient record. This is an unlikely scenario, but is included for the sake of completeness.

8. *Actor*: HIE **_Action:_ Create patient transaction destined for the IIS**

This transaction will contain demographic data destined for the IIS, as well as any appropriate updated immunization data, according to the business rules agreed upon by the EHR stakeholders, the HIE, and the IIS. An example business rule is that the immunization date must include the day it was given, not just month and year.

Note: For optimal performance in patient record matching, both the HIE and IIS must store each other's local unique patient identifiers, and include these in all transactions. If the HIE supports a Master Patient Index (MPI), the IIS identifiers would be among those referenced and matched against the MPI.

9. *Actor*: HIE **_Action:_ Submit query transaction to IIS**

Query transactions containing patient demographic data are transmitted to the IIS.

10. *Actor*: IIS **_Action:_ Search database for patient records**

The IIS identity resolution mechanism searches for an existing patient.

11. *Actor*: IIS **_Action:_ Decision point: Patient record found? (Yes or No)**

The IIS must establish business rules to accommodate the case when a unique record match cannot be made. For example, options may include returning an "insufficient data to match" message; return a list of possible matches; or simply respond with "no record found." This is a critical issue for both IISs and HIEs, and must be given careful consideration. Overly strict matching rules risk user frustration and decreased utility and use. Rules that are too loose risk a proliferation of duplicate records.

12. *Actor*: IIS **_Action:_ Create patient record (if no patient record found)**

If patient demographics do not match an existing record in the IIS, a new patient record will be created. The IIS will have to establish business rules for the absolute minimum information needed to create a new record during such transactions, since the trigger message originating from the clinic may not contain all the data fields required by the IIS.

13. *Actor*: IIS **_Action:_ Create patient immunization forecasts**

Combining information from the IIS, EHR and HIE, the IIS will create a list of forecasted immunizations (that is, what vaccines could be given today or, if not today, the earliest date on which they could be given) based on the known immunization history and patient age. Forecasting business rules are informed by recommendations from the Advisory Committee on Immunization Practices, as accepted by the

Centers for Disease Control and Prevention (CDC)[4]. Note: while immunization forecasting may be closely coupled to the IIS as described in this workflow, close coupling is not necessary. Some immunization stakeholders contemplate a universal forecasting service that could exist independently of any particular IIS and may service a broader constituency. A variety of IISs may desire to use such a system, and other entities such as HIEs and EHR systems may also seek to access a loosely-coupled forecasting system. This particular workflow action will change if a more loosely-coupled forecasting system is desired.

14.	***ACTOR***: IIS	***ACTION:***	Submit patient transaction

The IIS sends the immunization history and immunization forecast, ideally using the HL7 VXR format.

15.	***ACTOR***: HIE	***ACTION:***	Receive patient immunization history and forecast data

16.	***ACTOR***: HIE	***ACTION:***	Optionally transform and deliver data using a suitable format

In addition to delivering a broad variety of integrated clinical data to providers, the HIE transforms (when necessary) and then delivers immunization forecast and history data to the requesting healthcare clinic. While there is substantial variation in file formats used today, two approaches that use national standards would be to pass along the VXR message received from the IIS; or convert the VXR into a *Continuity of Care Document* (CCD - an emerging standard) format, and transmit that.

17.	***ACTOR***: EHR	***ACTION:***	Receive patient immunization history and forecast message

This step assumes that the EHR receives the data, but neither assumes nor excludes the possibility that the provider views the data at this point.

18.	***ACTOR***: Clinic Administration	***ACTION:***	Review and add patient immunization history and forecast data

The workflow for this step may be variable. For example, information may be printed, reviewed on paper and placed in chart, or may be reviewed and stored electronically in the EHR system.

Note: This step is included in part because patient immunization details may be captured from additional sources, such as historical vaccinations recorded on a public health or school immunization card. Ideally, the process for entering historical and current immunization data should be similar.

19.	***ACTOR***: Patient	***ACTION:***	Attend clinic visit

Note: The electronic reconciliation and sharing of vaccine data among EHR-HIE-IIS, and creating and sharing the immunization forecast, may begin either prior to the patient visit, when the appointment is scheduled, or not until the patient arrives at the clinic for the visit, depending upon clinic workflow and policy; hence, the need for responsive systems at the HIE and IIS levels. For pediatric patients still receiving their primary vaccination series, which are very time-sensitive, the healthcare provider should obtain an up-to-date forecast based on the date of the actual clinic visit, and not rely on a forecast generated at an earlier time, such as when the clinic appointment was made.

[4] http://www.cdc.gov/vaccines/recs/acip/default.htm

20. ***Actor***: Physician/Nurse ***Action:*** Review patient immunization forecast

Provider will review current immunization status and assess need for further immunizations.

21. ***Actor***: Physician/Nurse ***Action:*** Administer vaccine to patient

22. ***Actor***: Clinic Administration ***Action:*** Enter immunization details

In the absence of an EHR, the most feasible option for electronically recording immunization transactions is to use the IIS data-entry interface. In such a case, the provider may find that some or all of the information is already in the IIS, presumably from the source that administered the vaccine(s). For any data that the provider enters into the IIS, synchronization between the IIS and the HIE would occur the next time a request for information on that patient was routed through the HIE.

23. ***Actor***: EHR ***Action:*** Submit immunization transaction to HIE

This transaction will update the HIE, and subsequently the IIS, following a clinic visit where new vaccines are administered. This requirement suggests that an automated process within the EHR can identify newly entered vaccination information.

Steps 24-37 correspond to steps 4-17, and are necessary to synchronize data across all sources.

24. ***Actor***: HIE ***Action:*** Search HIE repository for patient records

25. ***Actor***: HIE ***Action:*** Decision point: Patient record found? (Yes or no)

Given the earlier steps 4-7 it may seem that steps 25-27 are unnecessary. However, the former steps reflect an initial patient registration (which can occur minutes, days or weeks *before* an appointment), while steps 25-27 allow immunization data generated *after* registration (during the office visit) to be transmitted to the HIE and IIS. In this model, each immunization transaction must be reconciled against the HIE MPI because patient identifying data can change, and we cannot assume that previous identifying information is sufficient to match transactions separated in time.

26. ***Actor***: HIE ***Action:*** Create patient record (if no patient record found)

27. ***Actor***: HIE ***Action:*** Update patient record

28. ***Actor***: HIE ***Action:*** Create patient transaction destined for the IIS

29. ***Actor***: HIE ***Action:*** Submit transaction to IIS

30. ***ACTOR***: IIS ***ACTION:*** Search database for patient records

The IIS identity-resolution mechanism searches for an existing patient.

31. ***ACTOR***: IIS ***ACTION:*** Decision point: Patient record found? (Yes or No)

32. ***ACTOR***: IIS ***ACTION:*** Create patient record (If no patient record found)

33. ***ACTOR***: IIS ***ACTION:*** Update patient immunization history and forecast

34. ***ACTOR***: IIS ***ACTION:*** Submit patient transaction

35. ***ACTOR***: HIE ***ACTION:*** Receive patient immunization history and forecast data

Because this portion of the process was initiated by recent immunizations sent by the EHR, immunizations will likely be up-to-date. The history and forecast data will be of interest at this stage if the patient has received additional immunizations at another site prior to the EHR submitting their most recent data.

36. ***ACTOR***: HIE ***ACTION:*** Optionally transform and then deliver history and forecast data

37. ***ACTOR***: EHR ***ACTION:*** Receive patient immunization history and forecast message

This last step ensures that the EHR system has the latest patient immunization information stored and available.

SECTION 2: Technical Perspectives and Options

This section is intended to provide greater details related to: (1) perspectives that influence the technical approach implied in the process map and process map narrative (Section A, below); (2) the HIE (Section B, below); and (3) more detailed technical perspectives related to the process map (Sections C-G, below).

A. Perspectives Influencing Technical Strategies

1. ***Support for HIE Involvement in Immunization Data Exchange.***
   HIEs have the potential to add value to the immunization data exchange process for a variety of reasons. To be successful and sustainable, HIEs by their nature must efficiently implement and maintain data interfaces to a broad variety of clinical data sources, and many sources may also maintain interfaces to the IIS. These data sources can include clinic encounters, including well-child visits; multiple medical issues can be addressed at well-child visits, with immunizations being but one aspect of the visit. The ability to combine a range of clinical data into a unified view is compelling for a provider because IISs lack the broader, integrated patient view afforded by HIEs. Further, enlisting HIEs to deliver information from multiple immunization data sources via a single interface may ease technical and administrative burdens, by minimizing the overall number of required IIS data interfaces, not to mention costly provider recruitment, training and support activities.

2. ***Architectural approaches to EHR-HIE-IIS data exchange*.**
   General approaches to exchanging immunization data between EHRs, HIEs, and IISs include the following models:

   a. ***IIS-preferred***—The IIS serves as the preferred source of immunization data in the first model. EHRs query the IIS either directly or by going through the HIE. EHRs and the HIE transmit immunization data to the IIS with the expectation that the IIS will, in turn, deliver reliable, authoritative and comprehensive data. One advantage of this model is that the IIS is population-based; that is, it has records on all children within its jurisdiction (typically the state, derived from birth records) regardless of where or even whether the child has received healthcare services. An IIS also provides many services not readily provided by an HIE, such as vaccine inventory, immunization coverage report by individual provider or practice, and reminder-recall capabilities. The disadvantage of this model is that not all providers in the IIS jurisdiction may be participating in an IIS, so data on many individuals may not be included or be complete in the IIS.

   b. ***HIE-preferred***—The second potential model leverages the HIE as the preferred source of immunization data. EHRs and the IIS transmit immunization data to the HIE with the expectation that the HIE will, in turn, provide reliable, authoritative and comprehensive data. In this case providers can receive all relevant clinical information on a patient from a unified source. An HIE-preferred model primarily refers to the mechanism through which providers receive up-to-date immunization information. Ultimately, the IIS still must hold – or at a minimum have access to – all known immunization data for purposes of periodic immunization coverage assessment across populations and geographies.

   c. ***Synchronize all sources***—The third model aims to synchronize immunization data between the HIE, IIS, and EHRs. This approach recognizes the current status quo: immunization data are distributed among separate systems and no single source may be authoritative for any given patient. It is important to note that the data synchronization/update process as discussed in this document only occurs for a specific EHR system when triggered by that EHR's query to the HIE on a specific patient; immunization information is not "pushed" to multiple EHR systems every time a new immunization is given to that patient by another clinic.

3. ***Evaluating different architectural approaches.***
Because these architectures address different challenges, the three approaches can be evaluated according to relative advantages and disadvantages along various dimensions. One potential dimension addresses the degree to which a given architecture addresses current information-sharing challenges. Another dimension explores the policy challenges (e.g., revisions to privacy and security policies) posed by a given data-sharing architecture. A third dimension relates to the relative feasibility of each technical approach; for example, from a technical perspective, relying on a single source (either IIS or HIE) and eliminating at least one of the synchronization steps may improve technical feasibility. A fourth dimension relates to the issue (cited in #2, above) of whether either the IIS or the HIE has higher provider participation rates, and so presumably a greater amount of immunization information.

4. ***As systems mature, synchronization complexity eases.***
A chief function of the process flow described in this document is to synchronize immunization histories among the data sources over time. However, as technology eases the burden of accessing immunization data, as clinical and public health stakeholders develop stronger trust relationships and data sharing partnerships, and as legal data-sharing precedents are established, immunization data may be primarily maintained within either the HIE or within a state or regional IIS, but not both, because such a situation reflects duplication of effort[5]. While there may not be obvious substantial utility in duplicating immunization data in both an HIE and in an IIS, such replication might be desirable from the perspective of performance (the HIE can respond to queries faster if the immunization data is already stored there) and research (the IIS can better support the surveillance and ad hoc query capabilities necessary for epidemiology if it is not also handling real-time queries.) Until the risks, benefits, advantages, and disadvantages for storing the data in a particular location are more clearly understood, immunization data will likely be stored in the location(s) that provide the most efficient, timely and comprehensive access to the data. To the extent that IISs can adapt to HIE needs, it makes sense for the IIS to serve as the data repository. Conversely, to the extent that the HIE can adapt to the needs of the IIS stakeholders (who are largely the same stakeholders/customers for the HIE), then perhaps HIEs may be a reasonable repository for the data, as well. In both scenarios, it is critical that the relationship of the repository to the provider community be valuable and sustainable.

B. Functionality Necessary for Immunization Data Exchange

A number of specific technical functions must be supported to enable immunization data exchange among HIEs, IISs and EHR systems. These functions include *immunization forecasting*, *end-user application data transformation*, *transport mechanisms*, and *data linkage*. They are discussed in greater detail below.

1. ***Immunization Forecasting: Public Health Decision Support.***
A number of components are necessary to generate and deliver an immunization forecast. The first is a knowledge management component that manages the rules and clinical observations that reflect current immunization guidelines, in order to provide decision support. The INPC infrastructure includes a decision support framework that is used for many use-cases, including public notifiable disease notification, which can accommodate algorithms such as vaccine forecasting as they evolve. HIEs and IISs may benefit from sharing best practices in public health decision support, because both entities are well positioned to provide such services to broad populations. While the forecast ideally provides recommended vaccines based on current immunization information and patient age, those data may be incomplete. When insufficient

[5] It should be noted that not all HIEs actually collect and retain clinical data; some hold only patient identifying information, which is used to point the provider to all sources of data on that patient. As this report documents the approach that would be used by the INPC, a repository of immunization data could be supported.

immunization data are available, the immunization forecast will be inaccurate and therefore of questionable use to the provider. For example, if a patient has no data in the EHR or HIE, should the IIS assume the patient has had no immunizations, and generate a full immunization forecast? Reminder rules must be designed to minimize the false positive alerts for immunizations; experience and research suggests that providers are willing to sacrifice some accurate reminders for the sake of receiving fewer inaccurate reminders.

Second, a format for exchanging immunization forecasts must be established. Where practical and feasible, the format for a forecast transaction would be an HL7 VXU message. In reality, many EHR systems accept other types of messages that can contain forecast information, such as HL7 ORU message and the emerging CCD standard. Consequently, in order to make an informed standards decision, it is crucial for system implementers to monitor the ongoing evolution of standards development nationally and even globally.

If the subsystems supporting *data storage* and *decision support functions* are to be logically separated, then the immunization forecast would optimally be triggered by the arrival registration message (e.g., an ADT^A01 or ADT^A04), because the arrival message occurs immediately prior to the visit, and therefore minimizes the likelihood that new transactions arrive at any of the data sources prior to the patient being seen. If immunization data are updated when a patient is registered for a visit, and not when they arrive (which could be weeks to months later), the immunization data and the forecast may be out of sync. The issue of an out-of-date forecast is particularly sensitive in the first two years of a patient's life, when the sequential doses of the primary series of immunizations are given at relatively close intervals. Doses given too early (that is, before the minimum interval has elapsed since the last dose) have to be repeated, which results in both a financial and time cost for everyone.

Third, business rules and default system behaviors must be established to accommodate different source systems. Business rules must exclude scenarios where data quality is suboptimal. For example, an 18-year-old with no immunization data may have actually received his/her immunizations, or most of them; the data may not have been captured to date by either the provider, the HIE or the IIS. Thus, an immunization forecast that advises all immunizations must be administered may be unhelpful to the clinician, other than as a prompt to ask the patient to bring in their immunization history.

2. ***Linkage and synchronization.***
   There are two categories of linkage challenges that immunization data management systems face; data must accurately link at the person level (identify duplicate patients), as well as at the immunization level (identify duplicate vaccines). While the EHR and HIE systems ideally deliver de-duplicated patient-level immunization data to the IIS, systems that exchange "round-robin" transactions in an effort to synchronize records will invariably transmit duplicate transactions. Robust matching methods and tailored business rules are needed to accommodate the vagaries of the data. In addition to robust matching algorithms and business rules, the INPC uses "data source" to aid in detecting duplicates. The INPC requires that each transaction clearly and consistently identify the sending organization. This is true for all transactions received by the INPC, without exception, and is also true for almost all IISs nationally. This requirement can help track duplicate immunization information across multiple data sources by tagging each immunization transaction with the identity of the sending organization.

C. Existing and Emerging Technical Guidance

In order to be successful, HIEs and IISs must gather, standardize, and aggregate data in a manner that adds value to their stakeholders. Therefore, both must be able to receive data through a variety of mechanisms.

While implementation guides and interoperability specifications exist for immunization data exchange, in their current state they may not fully address the complexities inherent in operational HIEs. HIEs typically implement tightly interwoven use-cases, using highly leveraged technical infrastructure, involving large, varied groups of stakeholders. Consequently, it is unlikely that a single implementation guide addresses all potential variations and constraints present in a real-world HIE.

That issue notwithstanding, several transaction specifications and interoperability resources can help inform the process of implementing immunization data flows among varied stakeholders, including HIEs. These resources include the Office of the National Coordinator for Health IT (ONC) regulations around EHR certification, the Certification Commission for Healthcare IT (CCHIT) guides, the CDC HL7 immunization implementation guide, Health Information Technology Standards Panel (HITSP) immunization interoperability specification (IS10), the Integrating the Healthcare Enterprise (IHE) immunization profile, the National Institute of Standards and Technology's (NIST) test procedures for reporting to immunization registries, local implementation guides and specifications from the various IISs, and best practice guides from the American Immunization Registry Association (AIRA).

1. ***EHR Certification Criteria***
   The U.S. has committed to nationally certifying EHR systems to ensure greater uniformity in standards-based interoperability. This began in 2006 with the CCHIT, and was given added impetus through the HITECH Act of 2009. CCHIT criteria for EHR systems in both ambulatory and in-patient settings includes being able to send data to immunization registries

2. ***CDC HL7 Implementation Guide for Immunization Transactions***
   The CDC maintains an implementation guide, and recently released a new guide supporting version 2.5.1 of the HL7 specification. The guide addresses HL7 transactions and code sets commonly used for immunization data exchange, and is "intended for use by immunization registries that want to participate in a strictly-defined record exchange agreement that limits the amount of optionality normally expected when using the HL7 standard." The previous implementation guide, supporting HL7 version 2.3.1, was widely disseminated and is in broad use. It is notable that both the 2.3.1 and 2.5.1 immunization implementation guides are specifically named in the Department of Health and Human Service's "meaningful use" final rule, released on July 13, 2010.

   HITSP Immunization Interoperability Specification

   On December 18, 2008 the HITSP population health technical workgroup formally released Version 1.0 of the *Immunizations and Response Management Interoperability Specification* (IS10). IS10 outlines six options for communicating vaccinations:

   - Option 1 –Use only HL7 VXU (HITSP/C72) from the message sender (clinician system or IIS) to the message receiver (IIS).
   - Option 2 –If the HIE offers a HITSP/TP22 PIX manager, the clinician system shall first query the PIX manager using a PIX (HITSP/TP22) or PDQ (HITSP/T23) query transaction, and populate the patient identifier in the HL7 VXU (HITSP/C72) message with the HIE domain identifier.
   - Option 3 –From the PHR, a HITSP/C78 Immunization Document can be communicated to a document repository as a shared document, or can be sent to the IIS, using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33).
   - Option 4 –The HITSP/C78 document can be communicated to a document repository as a shared document (HITSP/TP13), or sent to another provider using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33).
   - Option 5 –An IIS may optionally support a document repository and receive vaccination data using document reliable interchange (HITSP/T31) or via media/email (HITSP/T33). The IIS may retrieve an Immunization Document (HITSP/C78) from the document repository or from another jurisdiction document repository for cross-jurisdiction

information sharing, leveraging query and retrieve transactions and the Cross Community Access option in HITSP/TP13. As current immunization registries are not configured with these capabilities, this is a forward-looking option

- Option 6 –An IIS may optionally send an unsolicited notification using HITSP/C72 to a clinical information system to indicate that one of their patients has received an immunization from another source (e.g. Airport, school, another clinician).

IS10 also outlines four options for Immunization Query and Response:

- Option 1 –Use the traditional HL7 VXQ to send a query from the message sender (clinician system) to the message receiver (IIS) and the HL7 VXR to send the result of the query from the message sender (IIS) to the message receiver (clinician system) (HITSP/C70).
- Option 2 –If the HIE offers a PIX manager (HITSP/TP22), the clinician system shall first query the PIX manager (using HITSP/TP22 or HITSP T23) and populate the patient identifier in the HL7 VXQ message with the HIE domain identifier, and in the resulting VXR message (HITSP/C70). NOTE: Policy would need to assert query result policies in PDQ as currently specified for VXR.
- Option 3 –Use HITSP/TP21 *Query for Existing Data* to request and receive immunization data. If the HIE offers a PIX manager, the clinician system shall first query the PIX manager and populate the patient identifier in the HITSP/TP21 query.
- Option 4 –Where there are immunization documents available in the HIE Document repository, use HITSP/TP13 *Manage Sharing of Documents* query/retrieve to gather the most up-to-date immunization data available, which may be published as HITSP/C62 *Unstructured Document Component* containing summary or patient-specific immunization alert, HITSP/C78 Immunization Document.

3. ***IHE Immunization Profile***
IHE, in collaboration with the Public Health Data Standards Consortium (PHDSC), has developed an Immunization Domain proposal that is presented in a white paper entitled, *Building a Roadmap for Health Information Systems Interoperability for Public Health*. The document describes a variety of high-level use-case domains, including *Identifying a Patient, Retrieving Additional Data Elements,* and *Aggregation/Reporting*.

4. ***NIST Test Procedure For Submitting To Immunization Registries***
This document describes the proposed test procedure for evaluating conformance of complete EHRs or EHR modules to the certification criteria as published by the Office of the National Coordinator for Health IT. It is based primarily upon the work of CDC in establishing a core data set and the HL7 implementation guide for immunization data exchange.

5. ***Local Implementation Guides***
Local data exchange specifications exist for individual IISs to help standardize flat file and other non-HL7 messages.

6. ***Best Practice Guides***
AIRA has developed best practice guides such as Managing Moved or Gone Elsewhere Status, Vaccine Level Deduplication, Data Quality Assurance, and Reminder/Recall. Such guides inform the business rules used by IISs to maintain high data quality when exchanging and merging large volumes of patient data, and as such contribute to the body of knowledge that can be shared with an HIE and others that face similar challenges.

7. ***Immunization Forecasting***
To our knowledge, there are currently three approaches to convey forecasting information. The HL7 Version 2.3.1 Implementation Guide provides the longest-standing guidance, and multiple IISs have deployed this specification. While the newer version 2.5.1 Implementation Guide is not

yet widely implemented, it specifies expanded approaches for “push” and “pull” modalities. Finally, a third less widely-adopted approach leverages the CCD, which is an HL7 Clinical Document Architecture (CDA) profile.

D. Specific Standards Germane to Immunization Data Exchange

This section includes a brief description of select standards for immunization data capture and exchange. Both transaction format (message type) standards and vocabulary standards are necessary to exchange immunization data. Additional information can be found at the AIRA web site, including the *Immunization Information System Codebook*. Because the world of standards is evolving rapidly, and implementation of standards is still uneven, it is critical to balance current reality with future trends when monitoring, researching and selecting an appropriate standard for EHR-HIE-IIS exchange.

1. ***Transaction format standards supporting exchange of immunization data***

   a. ***VXU***—HL7 VXU (vaccine record) messages can be used for transmitting unsolicited immunization record data. VXU messages may be sent in batch mode or as a single transaction

   b. ***ORU***—Many systems today rely on ORU messages, although they are not optimal for immunization messaging, and no implementation guides exist for their use in that context. Because an HIE must be able to meet providers “where they are,” an HIE must be capable of processing ORU messages in addition to other formats. ORU messages may be sent in batch mode or as a single transaction.

   c. ***QBP***—HL7 QBP (query by parameter) messages can be used for requesting immunization data.

   d. ***ADT***—HL7 ADT (admit, discharge, transfer) messages can be used for transmitting demographic data and also for triggering the delivery of immunization data to the source system registering the patient. ADT messages themselves can also convey immunization information, as well, although no implementation guide exists for their use in that context.

   e. ***IHE PIX/PDQ***—In addition to discrete HL7 ADT messages, transaction profiles and workflows created by IHE are emerging as potential mechanisms for exchanging patient demographics and locating patient records. The Patient Identifier Cross reference manager (PIX) groups collections of unique patient identifiers (e.g., medical record numbers) for the same patient across different systems. Given a unique identifier and the source of that identifier, a PIX system can return a list of all known identifiers and sources for those identifiers. The Patient Demographics Query (PDQ) integration profile groups collections of demographics for the same patient across different systems. Given a sufficiently discriminating set of demographics, a PDQ-compliant system can return a list of known demographics and sources for those identifiers.

   f. ***CCD***—The CCD is an XML-based transaction format that constrains the HL7 CDA standard. In addition to HL7 version 2 messages, the HITSP Interoperability Specification entitled, "Immunizations and Response Management" (IS 10), identifies the CCD as a document-based transaction format that can transmit immunization data in a pre-specified Immunizations section.

2. ***Vocabulary standards for conveying immunization data***
   Standardized vocabularies for exchange of immunization data include CVX, CPT, LOINC and MVX codes.

   a. ***CVX Codes***— The CDC maintains a comprehensive HL7 code set for vaccines administered. Support for these CVX codes is now required for EHR system certification and provider and hospital eligibility for ’meaningful use’ incentive payments. CVX codes may be used in a variety of message formats, including HL7 ADT messages and ORU messages, in conjunction with a LOINC code. CVX codes can be used independently in VXU messages.

b. ***CPT Codes***—The Current Procedural Terminology (CPT) code set describes medical, surgical, and diagnostic services. Vaccination codes are present in the CPT nomenclature; however, these are not preferred terminology, according to the CDC's implementation guide. CPT codes may be used in a variety of message formats, including HL7 ADT and ORU messages, in conjunction with a LOINC code. It can be used independently in VXU messages.

c. ***LOINC® Codes***—Logical Observation Identifiers Names and Codes (LOINC) is a standard set of codes for identifying clinical observations, including laboratory codes, nursing diagnosis, nursing interventions, outcomes classification, and patient care data set. Depending upon the existing capabilities of an HIE, LOINC codes may be common formats for sending a variety of clinical information, including immunizations. LOINC codes are designed for use in conjunction with either CVX or CPT codes in either HL7 ADT or ORU messages. For example, the LOINC code 30956-7 represents "vaccine type," and must have an associated CVX or CPT code to indicate the specific vaccine given. Similar LOINC codes exist for Lot, Site, Route, and Manufacturer.

d. ***MVX codes***—This HL7 external code set is maintained by the CDC, and uses two- to three-letter abbreviations to designate manufacturers of vaccine products. Vaccine manufacturer is part of the core data set established by CDC for reporting to an IIS, largely to support vaccine safety and recall activities.

E. Message Formats for Transmitting Immunization Data

In addition to the transaction format and vocabulary standards discussed above, message format represents another important decision point in EHR-HIE-IIS interchange. It is important to note that, although ADT messages and LOINC codes are valid methods for conveying immunization data, the IIS community largely does not use them in its transactions. That can be a significant issue for HIEs, because ADT messages are a pervasive transaction in information exchange. ADT messages inform HIE systems and processes when a patient interacts with the system, and the additional benefit of these messages is their ability to convey clinical data. In addition to sending the ADT trigger message for the patient's clinic encounter (either the actual visit or registration for the visit), the same message could also convey any existing immunization data, a combination permitted by the HL7 standard. To interact with prevailing immunization standards, the HIE will need to send immunization data in a separate VXU message.

1. ***From EHR to HIE***
   A commonly used trigger message indicating patient arrival is an HL7 ADT^A04 registration message. In the outpatient setting, the ADT^A04 message is pushed to the HIE, and signals that a patient has physically arrived for an appointment. The HL7 specification allows ADT messages to carry clinical data in OBR and OBX messages. Therefore, an ADT trigger message can indicate not only that the patient has arrived for a visit, but can also convey immunization information in OBR/OBX segments, if needed. Such information can also be conveyed using PIX/PDQ profiles, which use HL7 ADT messages. However, current implementations within the immunization registry community almost exclusively use VXU segments to convey immunization data. When an immunization transaction is intended to simply update the HIE and IIS following a vaccines administration during a clinic visit, a registration (ADT) message may not be the most appropriate format; in this case a VXU message may be better suited.

2. ***From HIE to IIS***
   The HIE must deliver immunization data in a format compatible with IIS requirements. This format will likely be an HL7 VXU message, although other methods such as vendor-specific proprietary formats may be considered.

3. ***From IIS to HIE***
   Query format: To deliver immunization data from the IIS to the HIE, a triggering query

transaction from the HIE, such as an HL7 VXQ or QBP message, will likely be required. Alternatively, any data submission from the HIE, such as a VXU or ORU message, could trigger a data response.
Payload format: We anticipate the IIS will deliver a VXR or proprietary format to the HIE.

4. ***From HIE to EHR***
   Query Format: The EHR may receive immunization data either in response to a specific query, such as an HL7 VXQ or QBP message, or by sending an ADT trigger message.
   Payload format: The INPC currently creates a clinical patient summary by aggregating patient-specific data from the HIE to be delivered at the point of care. These summaries are generated either as a single HL7 version 2 ORU message, or as an HL7 version 3 CDA message. While these information exchange standards exist, technical strategies must "meet EHR's where they are" in order to exchange data in the current milieu. Few out-of-the-box EHRs can receive either of these standards-based transactions today, and thus the messages are transformed into a format consumable by more commonly available applications, such as HTML for a web browser or PDF for Adobe Acrobat. Alternatively, the data can be transmitted securely to a printer or fax machine at the point of care. Because vaccinations are commonly one of many issues addressed at a visit, being able to incorporate immunization data into a unified clinical view is a compelling feature requested by many providers. The INPC currently integrates immunization data with other clinical data into a comprehensive patient summary, and anticipates developing analogous methods for incorporating more complete immunization data into these summaries.

SECTION 3: Addressing Barriers to Data Exchange

A. System Variations Pose Barriers to Integration

1. ***Privacy Policies***

   A fundamental issue related to the exchange and synchronization of immunization data is whether the state's immunization laws allow the HIE to function as an intermediary for information exchange. Two types of laws may pertain: (1) an immunization data sharing law; and (2) enabling legislation for the IIS. A state's immunization data sharing law likely specifies whether consent is required, who can disclose the immunization information (especially without consent), and perhaps for what purposes. The HIE may or may not easily fit within the definitions and provisions of law. A law enabling the IIS may authorize data collection only on individuals within a specified age range, such as birth through age 18 years, and may or may not require consent for an individual's information to be in the IIS and/or for the IIS to disclose such information. Whether and how an HIE could serve as an intermediary or repository of immunization information may involve surprisingly nuanced legal discussions and interpretations.

   An operational HIE must comply with all applicable privacy and security regulations; an HIE can't operate otherwise. The same applies to immunization registries: policies must be in place and followed, since the IIS is approved by the legislature, either under specific enabling legislation or under general public health authority. However, regulations applying to the IIS and the HIE may vary, and stakeholders must understand any subtle or substantive impedance mismatches between the privacy and security policies of the different data sources. If such differences effectively prevent entities from interacting, then stakeholders must develop strategies to overcome and reconcile those issues.

2. ***Workflow and Data Characteristics***

   Not only do HIEs/IISs face differences in privacy policy requirements, but there can be differences related to data characteristics, quality, and workflow. Clinicians rarely capture inventory data, whether for vaccines or supplies, as part of routine care processes; if necessary, inventory data must be captured through other means. Inventory tracking methods vary from fully electronic in larger systems to paper-based in smaller settings. Few EHRs incorporate inventory tracking as a core, standardized component. Also, the field level data elements routinely captured may vary across care settings, and while successfully capturing new data elements in local clinical applications is ideal, gathering new data in deployed local systems is challenging, because it requires changes to either software or workflow, or both.

   Many IISs provide vaccine inventory functionality but it is typically dependent upon the provider manually entering data on vaccine(s) administered. Use of a standalone application outside of a clinic's EHR or other system does not readily fit into a clinic's workflow.

   New national EHR certification requirements, as well as the natural maturing of the EHR marketplace over time, may improve inventory functionality but this is not likely to occur very rapidly given much larger emphasis nationally on care improvement functionalities.

3. ***Other Business Drivers***

   While the primary purpose of an IIS is to increase the age-appropriate immunization of all children (and increasingly, all individuals across the lifespan) within a state or other geographic area—a purpose perfectly suited to working with and through an HIE—there are other, competing demands on IISs that may point toward working directly with immunization providers, or at a minimum would complicate the task flows documented in this report. Chief among these is the growing call for IISs to serve as a tool for providers in the ordering, inventory management, and accountability of publicly-funded vaccines available through the federal Vaccines for Children

(VFC) program. Since those functionalities are beyond what would typically be the scope of an HIE's business, and since almost all childhood immunization providers give VFC-supplied vaccines, an IIS is left with having to make tough choices about which worthy goal to pursue. Other competing drivers include using IISs for tracking vaccines or anti-virals in emergency, mass dispensing situations, and capturing lot numbers for vaccine safety studies and recalls. On the other hand, collaborating with an HIE can help IISs meet other demands, such as having current patient address information for reminder-recall purposes, and reducing costly provider recruitment, training and ongoing helpdesk support responsibilities. Since providers would be accessing IIS data through the HIE, the burden is potentially lifted from the IIS to recruit, train, and support a clinic as a new user, including taking the time to help the clinic determine how to fit use of the IIS into its workflows.

B. Improving Integration by Extending IIS Functionality to Meet Stakeholder Needs

1. ***IIS Import***
   Real-time bidirectional data interfaces for EHRs are costly to implement and maintain; consequently, it is uncommon for EHRs to have a real-time bidirectional connection to an IIS, although the requirement for such interfaces is increasing across the country. Moving toward real-time data exchange while mitigating the cost of building a unique immunization data interface is a chief reason to leverage the existence of an HIE. Currently, rather than exporting data in real time for individual patients, EHRs that capture immunization data commonly export new immunization data for their entire patient population on a routine basis, e.g., once weekly. To minimize both the volume of data transferred and the data processing requirements, the export is commonly an incremental update that delivers recently administered or recently updated immunization data, rather than complete cumulative data. Thus, IISs tend to receive batch transfers of immunization data from these systems on a routine basis.

2. ***IIS Export***
   Designed primarily using a single user-logon web portal paradigm, immunization data are commonly extracted from IISs by a single user querying for a single patient, rather than a single user querying for multiple patients. In terms of obtaining patient immunization history and forecast, IISs have been designed and optimized, both technically and from a policy perspective, to export data in response to a single-user query. Consequently, as a rule, IIS operators and designers focus on systems that may be optimized to *import* data in batch mode, and *export* data on a patient-by-patient basis in response to individual manual queries. The exceptions to this are summary or line-item reports requested by end users, based on defined parameters (e.g., all patients less than six years of age needing at least one MMR vaccine; HEDIS reports).

3. ***Extending performance and functionality***
   Because HIEs and other clinical applications interact with a broad variety of technical systems, they employ a range of mechanisms to exchange data, including batch-mode and real-time approaches. Depending on the HIE use-case, electronic healthcare transactions may convey a single patient's or multiple patients' data. In order to interoperate with HIEs, IISs must either rely on HIEs to respond to such data requests, or implement architectures that accommodate a broader range of data exchange methods and system response requirements; in fact, an increasing number of IISs can do so. For example, IIS implementers may consider ensuring the system's ability to efficiently receive and respond to high-volume, real-time immunization transactions on a patient-by-patient basis, rather than solely in batch mode. Further, IISs may extend beyond single-patient queries by implementing the ability to promptly accommodate multi-patient (cohort) queries (beyond requesting a summary or line-listing report, as described in #2 above).

4. ***Coordination and communication is needed***
   Extending IIS performance and functionality may require substantial architectural changes to

underlying systems. Although identifying functional and performance requirements for more seamless integration between HIEs and IISs may be a straightforward proposition, developing a successful technical approach to deliver on these requirements is a complex undertaking that requires coordinated communication and planning among all technical-system and end-user stakeholders.

5. ***Synergistic Roles***
   To enhance coordination and communication, the roles that the IIS and the HIE will each serve with respect to information data exchange must be clarified. Specifically, stakeholders must determine whether synchronizing data across many data holders is sustainable. If unsustainable due to the complexity of multi-way synchronization, identifying the primary data holder is important to advancing immunization data exchange. Synergistic relationships may evolve between any given HIE and IIS, based on their respective strengths. Given its current central role in vaccine data management, the IIS may emerge as the primary data holder. Given the HIE's propensity to implement and maintain bidirectional interfaces at large scale (the INPC maintains over 1,400 logical data interfaces from more than 78 hospitals, laboratories, and ambulatory care centers), the IIS may leverage these interfaces at lower cost than if they themselves implement separate, potentially redundant interfaces. Additionally, the sending systems benefit by reducing the total number of required outbound interfaces.

C. Improved Integration with Modular, Transparent Architecture

1. ***More flexible technical architecture***
   Many in the IIS community are considering moving toward a modular web services architecture that transparently exposes data access features, making it easier to integrate these features into existing clinical software applications. By providing more flexible and transparent access, web services diminish the need for users to access an IIS in a standalone fashion, and have the potential to expand IIS use to a broader set of stakeholders (within the limits of law). HIEs would be a potential beneficiary of a web services approach, but the extent to which stakeholders are able to leverage a more transparent, modular approach will need to be determined. It is potentially feasible for the HIE to provide an efficient medium through which the web service is accessible to the provider.

2. ***Architecture does not replace clear scope and system requirements***
   While aspects of being a standalone application can be mitigated using a transparent, modular web services approach, the IIS, HIE, and EHR stakeholders must reach agreement on how to scope and refine groups of functions. These groups may include inventory management, forecasting (decision support), emergency response/mass dispensing data capture, and history functions, as potential use-cases. Meaningful dialogue between policy bodies such as the CDC and the potential consumers of these services is needed to ensure that all stakeholders understand (and, ideally, agree on) the scope of functionality.

SECTION 4: Recommendations

While substantial effort has been devoted to technical healthcare interoperability standards, both technical and non-technical issues remain. This section describes high-level recommendations for improving data exchange among HIEs, EHR systems, and IISs.

A. Openly Collaborate

EHR, IIS and HIE stakeholders share a common need for immunization data. However, the fundamental drivers and requirements for these data vary among the stakeholders. These varying drivers and requirements can have the unintended consequence of causing each stakeholder to pursue immunization data independently. Such duplicated effort ultimately results in an inefficient and potentially unsustainable system. Therefore, it is crucial that stakeholders recognize both their commonality and their differences, and work toward the common goal of seamless exchange of immunization data in the broader context of healthcare and public health system reform. This requires that the various stakeholders find meaningful and effective ways of interacting. It further requires that stakeholders earnestly seek to understand the needs of their data sharing partners. For example, patient-level matching is a crucial core function for patient-level aggregation, in both HIE and public health settings. To date, there has been little interaction and sharing of best practices between HIE and public health regarding patient matching. There are many opportunities for HIEs and IISs to collaborate on specific challenges faced by both entities.

B. Incorporate Flexibility into the Design

Health information technology data standards are simply tools. They exist to facilitate the exchange and management of healthcare data. When data standards fail to meet the needs of the data exchange partners, flexibility is necessary; the tool must be adapted. To remain viable, HIEs, IISs and EHRs must exchange data in a manner that adds value to the community of stakeholders. To do this, flexible processes that adapt to the distinct business practices of different stakeholders, ranging from hospital to small single practitioner clinic to public health department, must be developed. This flexibility often requires a variety of technical approaches, and the community of immunization data stakeholders must recognize the need for flexibility, and incorporate that notion into the process of standards development and selection. Even as the nation moves toward greater adoption of standards and certified health IT, it will be many years before complete, ubiquitous standardization in vocabularies and interoperability will be achieved.

C. Track Rapidly Evolving Standards

There are a number of other independent or loosely-coupled initiatives under way aiming to establish technical means for exchanging immunization data. These initiatives range from creating broad interoperability specifications that address high-level use-cases, to developing detailed message and vocabulary specifications for creating actual transactions. It is incumbent upon all immunization data stakeholders to remain abreast of these evolving initiatives.

D. Leverage CDC Leadership to Convene Stakeholders and Provide Cohesive Vision

The CDC is well-positioned to provide the leadership to help all stakeholders remain focused on increasing the age-appropriate immunization of all children (and increasingly, all individuals) within a state or other geographic area. This can be accomplished in part by convening stakeholders through venues afforded by groups such AIRA, HITSP, IHE, and others. CDC's recent initiative to create a nationwide interoperability specification standard for immunization data exchange, as well as to standardized vaccine forecasting, represent important progress. IIS managers will need continued CDC policy and financial support to ensure effective collaboration and leveraging of HIEs, integration or interoperability with other public health information systems, and evolving methods and standards for data exchange, such as the Nationwide Health Information Network.

E. Acknowledge Internal Priorities; Understand What's Important to Others

With the exception of environmental health data, most public-health related data are generated within the context of clinical care, as is true for immunization information. The data collection systems needed for public health must operate within the constraints inherent in the clinical care setting, where users operating under extreme time pressures already face an information-gathering burden which is in part due to information being sequestered in different applications. Barriers to participation will diminish to the extent that evolving systems can be more flexibly and seamlessly integrated into existing workflows.

F. Explore Additional Interoperability Opportunities

By better understanding how immunization-related data fits into the larger clinical community, immunization registry implementers may find opportunities to exchange data with a broader set of stakeholders. One particular strategy to consider is to explore the utility and feasibility of incorporating HL7 ADT messages and LOINC codes as part of the overall interoperability strategy.

G. Expand and Evolve Functionality

Delivering immunization results to providers is a core function of IISs. Providing additional functionality may encourage use and improve adoption. For example, accurately and seamlessly delivering vaccine forecasting as a decision support service may provide compelling incentives for collaboration, particularly among the clinical community. Childhood immunization guidelines are among the few guidelines for which there is national consensus; still, maintaining multiple decision support systems for immunization forecasting is expensive and complex, because immunization guidelines change frequently. The simple solution of providing a consolidated web service that is centrally maintained and, perhaps, certified by authoritative bodies like the CDC, AIRA and/or the American Academy of Pediatrics, would provide added value. To ensure that they continue to provide a vital public health service, IISs should contemplate offering additional value by providing immunization stakeholders expanded access to core functionality beyond forecasting services. Such services may include vaccine ordering and inventory management services.

Appendix A: Tool Templates

This appendix provides an overview of the two tools used to describe the exchange and synchronization of immunization information between EHR systems, an HIE entity, and an IIS (immunization registry). Section II includes the actual documentation of the information flow among the entities. Many variations of these tools are in use today in the business and healthcare arenas. The versions used here reflect the approach developed by the Public Health Informatics Institute.

Business Process Matrix

The *Business Process Matrix* describes all the interrelated components of a business process, starting with the overall goal(s), ending with how the organization will measure whether the goal was achieved, and including everything in between that contributes to achieving the goal. Definitions are provided below for each of the components contained in a Business Process Matrix—Goal, Objective, Business Rules, Trigger, Task Set, Inputs, Outputs, and Measurable Outcomes.

GOAL(S)	OBJECTIVES	BUSINES RULES	TRIGGER	TASKSET	INPUT	OUTPUTS	MEASURABLE OUTCOMES
The major goal that the process supports. The goal is the end state to be achieved, and should be defined in terms of the benefits to the community.	A concrete statement describing what the business process seeks to achieve. A well-worded objective will be SMART: Specific, Measurable, Attainable/ Achievable, Realistic, and Time-bound.	A set of criteria that defines or constrains some aspect of the business process. Business rules are intended to assert business structure or to control or influence the behavior. Examples in healthcare and public health include laws, standards, and guidelines.	An event, action or state that indicates the first course of action in a business process. In some cases, a trigger is also an input.	The key set of activities that are carried out in a business process.	Information received by the business process from external sources. Inputs are not generated within the process.	Information transferred out of a process. The information may have been the resulting transformation of an input, or it may have been information created within the business process.	The resulting transaction of a business process that indicates the goal(s) and objectives have been met.

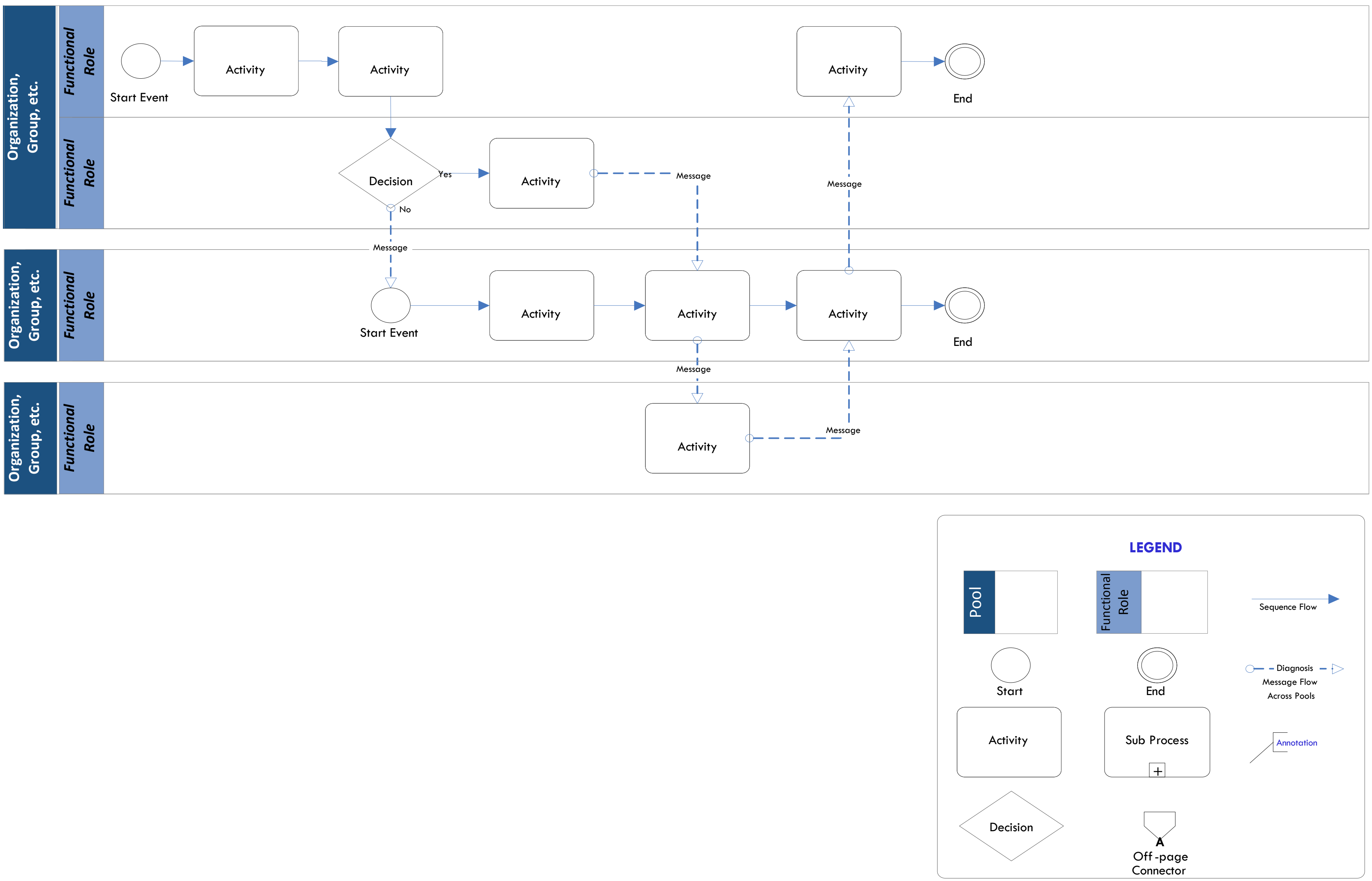
Task Flow

The second tool used in this project is the *Task Flow*, a diagram model that illustrates the activities of a business process, as well as identifying those who perform the activities (known as functional groups). Task Flows provide a "story" for the process being diagramed. They include the following items – *Pools, Swim Lanes (functional roles), Start Event, Activities, Decisions, Sub-Processes, End Events,* and a *Process Narrative*.

1. ***Pools***—A group, department, organization or unit that contains multiple swim lanes (functional groups).
2. ***Swim Lanes***—A functional individual or group. These are entities that perform or are accountable for designated activities in the process.
3. ***Start Event***—A process mapping shape used to define the "start" of the process.
4. ***Activity***—An action performed by the functional individual or group.
5. ***Decision***—A required conclusion needed in the process. These are typically approvals or resolutions.
6. ***Sub-Process***—A shape used as a call out to another process.
7. ***End Event***—A process mapping shape used to define the "end" of the process.
8. ***Activity Details/Narrative***—The supporting information for each process.

An example Task Flow is on the following page.

Business Process Name



Appendix B: The Indiana Network for Patient Care

The perspectives in this document are informed by a specific health information exchange, the Indiana Network for Patient Care (INPC). The INPC is a 15-year-old health information exchange operated in Indiana by the Regenstrief Institute. Regenstrief has made a pioneering commitment to standards, interoperability and the interchange of clinical data for clinical, public health and research purposes. Investigators at the Regenstrief Institute created the INPC in 1995 with the goal of providing clinical information at the point of care for the treatment of patients. The INPC is currently an operational community-wide secure data exchange, with partnership among the major healthcare systems in Indiana that provide care for the 553-square-mile Indianapolis urban metropolitan area, with a population of 1.7 million. Together these healthcare systems operate a total of 35 geographically separate hospitals and more than 100 clinics and day surgery facilities, distributed across Indianapolis and its collar counties. They manage the inpatient, outpatient and emergency room visit care that represents more than 90% of the hospital system care in Indianapolis.

The primary goals of the INPC are: (1) reduction of the costs of care inefficiencies, such as unnecessary repeat testing; (2) increased accuracy of medical diagnoses through common and rapid access to patient information via electronic means; and (3) utilization of the broad-based and ever-growing data collection on the INPC network, for research purposes related to, among other things, studying the efficacy and cost-reducing effects of broad-based access to patient information, public health, and reviewing the information to learn about specific diseases and their treatment.

INPC includes clinical data from a total of over 35 hospitals, the public health departments, local laboratories and imaging centers, and a few large group practices closely tied to hospital systems, with plans underway to expand these efforts. The INPC collects between 350,000 to one million transactions per day. The INPC repository carries more than 3 billion pieces of clinical data, including immunization data from local public health and outpatient clinics (see footnote on previous page).

INPC participants deliver registration records (demographics), laboratory data, ED, inpatient and outpatient encounter data including free-text chief complaint, and coded diagnoses and procedures for hospital admissions and emergency room visits. Some participants also deliver pathology, pharmacy, and vital signs data. The information in the INPC follows the patient, not the physician or a specific health system, so physicians can view a patient's previous care information from all participating institutions as a single virtual record.

The Regenstrief system standardizes all clinical data as it arrives at the INPC vault; laboratory test results are mapped to a set of common test codes (LOINC) with standard units of measure for patient care, public health and research purposes. Each institution has the same file structure in the Regenstrief system and shares the same term dictionary, which contains the codes, names (and other attributes) for tests, drugs, coded answers, etc. INPC allows physicians working in an emergency department and within other hospital settings in any of the participating hospitals to view a patient's previous care information from all participating institutions as a single virtual record. INPC is a centrally managed federated clinical data repository that supports a variety of services.

The INPC is currently one of the longest-tenured HIEs in the U.S. It should not be assumed that other HIE entities could as readily conduct the activities outlined in this document.

INPC users access and interact with clinical data in a variety of ways, using different applications that include paper printout, web portal, and EHR. These applications include the following, briefly described here:

1. ***Clinical Messaging Service (DOCS4DOCS®)***—This service, run by the Indiana Health Information Exchange (IHIE) in conjunction with Regenstrief Institute, delivers a variety of clinical results from participating clinical data sources (e.g., a hospital's lab) to the intended responsible provider. The results can also be transmitted via HL7 directly to a practice's EHR system or via fax. Offices without an EHR can use DOCS4DOCS as an "EHR-lite" to review and manage clinical results

without the overhead of a comprehensive EHR. The system is currently designed to view data "pushed" to the provider, and offers limited data input capabilities. The system can be integrated with healthcare systems' single sign-on (SSO) systems to improve workflow efficiencies by minimizing the number of system log-ins required.

2. ***Community HIE Portal (CareWeb) Service***—This web-based application provides access to the HIE clinical data repository under access rules determined by the HIE stakeholders. Users can query for a patient-specific abstract and receive a comprehensive integrated view that combines data from all HIE stakeholders.

3. ***Automated secure printing***—For situations where the provider lacks an EHR, a patient-specific clinical abstract combining data (including immunization data) from all HIE stakeholders can be securely sent directly to an authorized printer or fax machine. Abstract generation is typically triggered by an electronic patient arrival message, such as an HL7 ADT message.