Public Health Community Platform

Use Case

for

Clinical Decision Support for Immunization (CDSi)

Draft v2.0

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Public Health Informatics Institute

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1. Overview of the Public Health Community Platform Initiative

Public Health and the Healthcare sector have, over the past four decades, developed a wide range of computer-data based systems to help improve the efficiency of and capacity for performing the key tasks required to accomplish the goals of protecting the health of the public, preventing illnesses, and saving lives.

This decade is ushering in a massive influx of new healthcare and public health data as more and more health providers utilize a patient's Electronic Health Record (EHR), which contains a digital documentation of a person's entire health history. As more useful data is arriving, the effective and coordinated use of data analysis systems will be critical for successfully managing this data to result in improved health outcomes.

However, the current state of health information systems remains highly fragmented and insufficient to tackle the complexity and volume of the data that is already flowing. As with most computer-based technology in the past, these data systems and software were originally created on an as-needed basis, usually customized precisely to the needs of a particular program's data analysis methodology with no ability to be easily integrated with the output of the data systems from other programs. This, along with the location of such systems on local infrastructure, ensured that all these systems, which are collecting highly valuable data, remain difficult to integrate.

With a goal of providing a forum for common data exchange and development of new, innovative, and interoperable systems, the Association of State and Territorial Health Officials (ASTHO) is now engaged in the creation of a Centers for Disease Control and Prevention (CDC) initiative, the Public Health Community Platform (PHCP). The PHCP will be a cloud-based exchange where public health and healthcare are able to develop, compare, and exchange interoperable solutions and allow access to common data sets (such as Electronic Health Records (EHRs) and public health survey and assessment data) upon which all types of analyses can be performed. This platform will support data from many public health-relevant sources (even non-standard data sources such as internet-based social media and news feeds), provide a suite of shared services (such as data standardization and normalization) and shared applications for analysis, exploration and visualization. It will also be able to serve as a platform for development and maintenance of new and innovative tools.

Through a PHCP, it is hoped that infrastructure and tools will be readily available for the public health enterprise to develop - through wide-ranging development and comparative assessment - a truly universal, customizable, and expandable solution (or suite of solutions) for easy and powerful data analysis that touches every aspect of public health and healthcare. The achievement of this goal will provide huge improvements in timeliness of information, speed of data gathering and analysis, and efficiency assessing the entirety of the public health situation at any given time, resulting in a dramatic boon to the workflow of public health and healthcare and, ultimately, to improved health and the saving of lives.

2. Use Case Overview[1]

Ensuring that patients receive recommended vaccines is an integral aspect of preventive care and an important public health function. However, as the immunization schedule[2] and the number of vaccines continue to grow, it becomes more challenging for providers, public health agencies (PHAs), and other interested stakeholders to monitor and consistently adhere to the frequently changing guidelines. Computer-based clinical decision support (CDS) can be an effective strategy for improving the quality of care. However, many clinical information systems either lack CDS or are slow to keep their CDS in line with the changing guidelines, which may include new vaccine series, addition or elimination of specific vaccines by specific manufacturers, or changes to clinical recommendations with respect to specific vaccines, dose series, or age groups.

The development and routine administration of vaccines is one of the most important public health achievements of the 20th century. Routine vaccination is an integral component of preventive care in the United States and has led to a dramatic reduction in the incidence, morbidity and mortality of a number of diseases. As the field of medicine advanced over the last century, the number of vaccine preventable conditions grew dramatically, as did the number of routinely recommended immunizations. In the 1980s, a 5 year old child would be up-to-date (UTD) with 10 doses of 3 vaccines (DTP, Polio and MMR) protecting against 7 diseases. In 2013, a 5 year old healthy, fully immunized child would need 9 different vaccines, not counting the annual influenza dose. Those 9 routinely recommended vaccines protect against 13 diseases, and need to be administered in 28 different doses, making tracking a very challenging task. [3] Systems that include CDS for immunization (CDSi) capabilities will evaluate recommended Advisory Committee on Immunization Practices (ACIP) changes and update their rules and algorithms as they deem necessary. Just as CDSi capabilities differ between systems, the speed and nature of response to changing ACIP recommendations also differs based on local interpretations of the changes, impact of the changes on the particular jurisdiction (*e.g.,* some jurisdictions do not use certain vaccines), and staff availability.

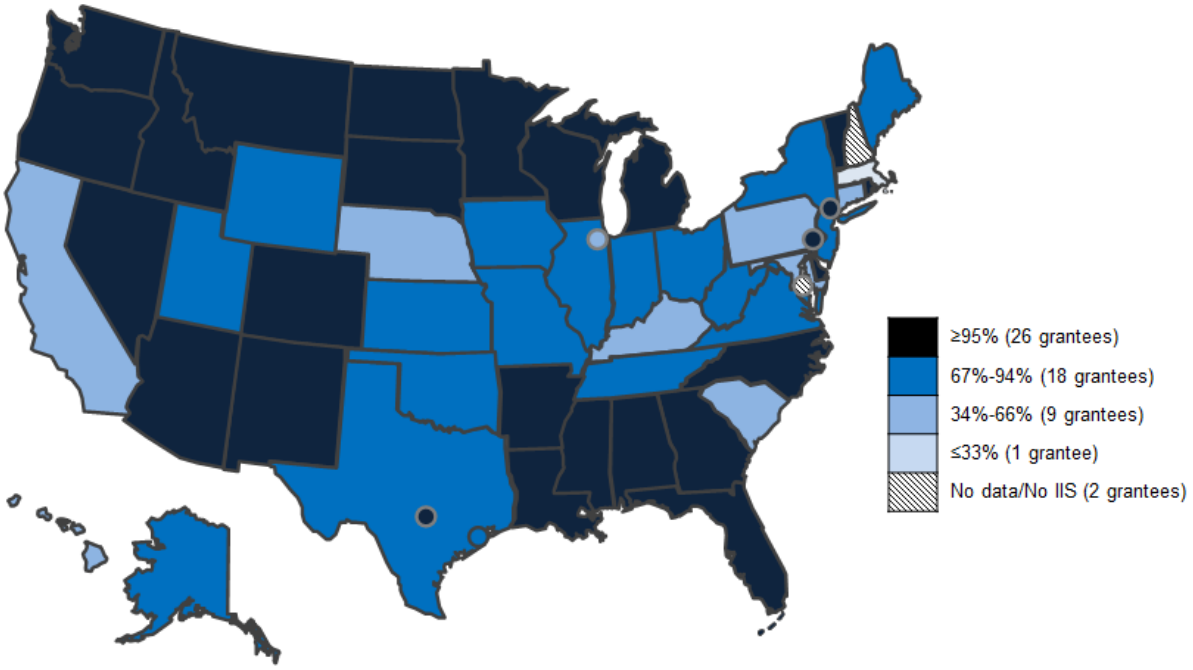
Each of these vaccines is recommended at a specified age, often being invalid if given below a certain minimum age. In addition, these vaccines have to be administered several times to be maximally effective. Each dose has spacing requirements from the previous dose as well as from doses of other vaccines. The ACIP defines and publishes a recommended immunization schedule which constitutes the best practices for immunization, and which it updates and refines several times per year.[4] The routine childhood schedule for 0-18 year olds has 13 separate footnotes, with as many as 13 sub-bullets for some footnotes. The end result is that it is difficult for providers to monitor and consistently adhere to the ACIP guidelines which are lengthy, complicated, and growing.[5] The process of updating a CDSi

[1] Much of the material in this section is based on Michael J. Suralik, et al, *The Immunization Calculation Engine, Open Source Clinical Decision Support for Immunizations,* **Journal of Healthcare Information Management**, 27(3), Summer 2013.
[2] That is, the set of rules that specify the number and timing of all routinely recommended immunizations.
[3] http://www.chop.edu/service/vaccine-education-center/vaccine-schedule/history-of-vaccine-schedule.html
[4] http://www.cdc.gov/vaccines/schedules/index.html
[5] http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-schedule.pdf

algorithm to changing guidelines involves the full system development lifecycle of activities: analysis to determine what the new guidelines mean and how applicable they are; modification of the software code that guides the algorithm; and extensive testing of the new algorithm to make sure the changes have been applied correctly and that existing rules have not been adversely affected or "broken" in the process (see below on testing).

Immunization Information Systems (IIS), known originally as Immunization Registries, are specifically designed to help providers increase immunization coverage rates and were among the first to provide CDSi, sometimes referred to as immunization forecasting. Figure 1 shows the percentage of children less than six years old participating in an IIS in the United States, five major cities, and Washington, DC in 2012.[6] Since it is hard to know exactly which providers perform immunizations, and in many jurisdictions reporting of immunization events to public health is not required by law or regulation, it is difficult to know exactly what proportion of providers currently interact with an IIS. However, in 2013, 39% physicians with computerized capabilities met the Stage 2 Meaningful Use objective for reporting to an IIS under the Centers for Medicare and Medicaid Services (CMS) Electronic Health Records (EHR) Incentive Programs.[7]

Figure 1: Participation of Children in IIS



National Participation: 86% (excluding Territories)
Source: CY2012 IISAR

§ Chicago, IL; Houston, TX; New York City, NY; Philadelphia, PA; San Antonio, TX.

One of the 2013-2017 CDC IIS Functional Standards specifies that, "the IIS has an automated function that determines vaccines due, past due, or coming due ("vaccine forecast") in a manner consistent with

[6] http://www.cdc.gov/vaccines/programs/iis/annual-report-IISAR/downloads/2012-data-adult-map.ppt
[7] http://www.cdc.gov/nchs/data/databriefs/db143.htm

current ACIP recommendations.[8] Any deficiency is visible to the clinical user each time an individual's record is viewed." More specifically, CDC defines CDSi as "an automated process that determines the recommended immunizations needed for a patient and delivers these recommendations to the healthcare provider." Many IIS already meet this standard.

Most common CDSi software in IIS today generate clinically accurate CDSi for groups of vaccines that are routinely administered to children, adolescents, and adults in accordance with the ACIP guidelines. CDSi software includes evaluation of the validity of each immunization in a patient's history as well as a recommendation for each vaccine group (*e.g.*, the date on which the next dose is due, series completed, etc.).

Although CDSi capabilities are functionally adequate in most cases, they have some limitations. As rules, logic, and terminology change due to changes in the underlying schedule, testing procedures require an iterative series of manual steps that are performed by up to three different sets of individuals: the software developers who verify their modifications or additions, the business analysts working with the developers who verify the changes against the agency's specifications, and immunization program personnel who have deep experience with the immunization schedule and do the final acceptance testing to ensure that the changes have been made to their satisfaction. In addition, because of the inherent complexity of the subject matter as well as the complexity of the software implementation, regression testing must also be undertaken to ensure that a change to one rule does not "break" another. A second limitation of common CDSi capabilities is that they often only support a single immunization schedule. This means that many IIS do not have the option of evaluating a record against a second immunization schedule, for example, to determine if students are up-to-date with just the specific immunizations that are required for admission to school.

The IIS community needs to seek greater leverage of existing CDSi implementations to develop a more consistent set of products that can be maintained more easily and more economically. An unpublished CDC study revealed marked inconsistencies in the vaccine forecasts of IIS across the country based on a series of test cases. The results of this study highlight how a well-designed and broadly adopted CDSi service could improve the consistency of vaccine forecasts across the IIS community. Such a well-designed and shared CDSi will allow for the separation of the core software from the underlying rules that will only minimally compromise the shared nature of the approach. The design goals of such an initiative might include:

(1) The ability to support multiple immunization schedules
(2) The ability to simultaneously process multiple requests for CDSi
(3) The implementation of a fully automated testing process
(4) The creation of graphical user interface (GUI) tools that empower clinically-oriented subject matter experts (SMEs) to update and maintain the immunization schedule without any involvement from programmers, and that supports the automated testing
(5) That it be a self-contained module that could be deployed in diverse technical environments and accessed by other systems through a standards-based Web Service interface.

[8] http://www.cdc.gov/vaccines/programs/iis/func-stds.html

Significant work has been done by IIS to develop CDSi capabilities, including services that can be accessed by a variety of systems including IIS, EHR systems (EHR-S) and even Personal Health Record (PHR) systems. Strong CDSi systems are driven by powerful, increasingly complex algorithms that support a number of functions including evaluation of immunization history for validity and forecasting of due, overdue, or future doses. The CMS EHR Incentive Programs ("Meaningful Use") are focusing more attention on CDS generally, including immunizations. One of the core set of measures in both Stage 1 and Stage 2 Meaningful Use involves implementation of CDS to support clinical quality. All indications suggest that Stage 3 will raise the bar even further and expect even more use of CDS.

As CDSi becomes more and more effective for individual patients, it will become more useful in examining populations of patients. Over time, interactive use of CDSi tools within systems will be supplemented by "batch" use of CDS; taking a set of person-specific data for a cohort, cluster, or geographic region and applying CDSi rules to determine if certain characteristics are present in the group. IIS have at their disposal both commercial and Open Source CDSi alternatives which could be made available to healthcare organizations of all sizes, assuming their EHR-S is configured to interact with CDSi Services. Though the underlying rules instantiate the ACIP recommendations and have been recently documented through a collaborative, CDC-led national effort, the devil is still in the details, and individual providers, IIS, and state Departments of Education still define rules that vary for different purposes even within a jurisdiction let alone between them. However, a solid foundation exists for additional progress in this area.

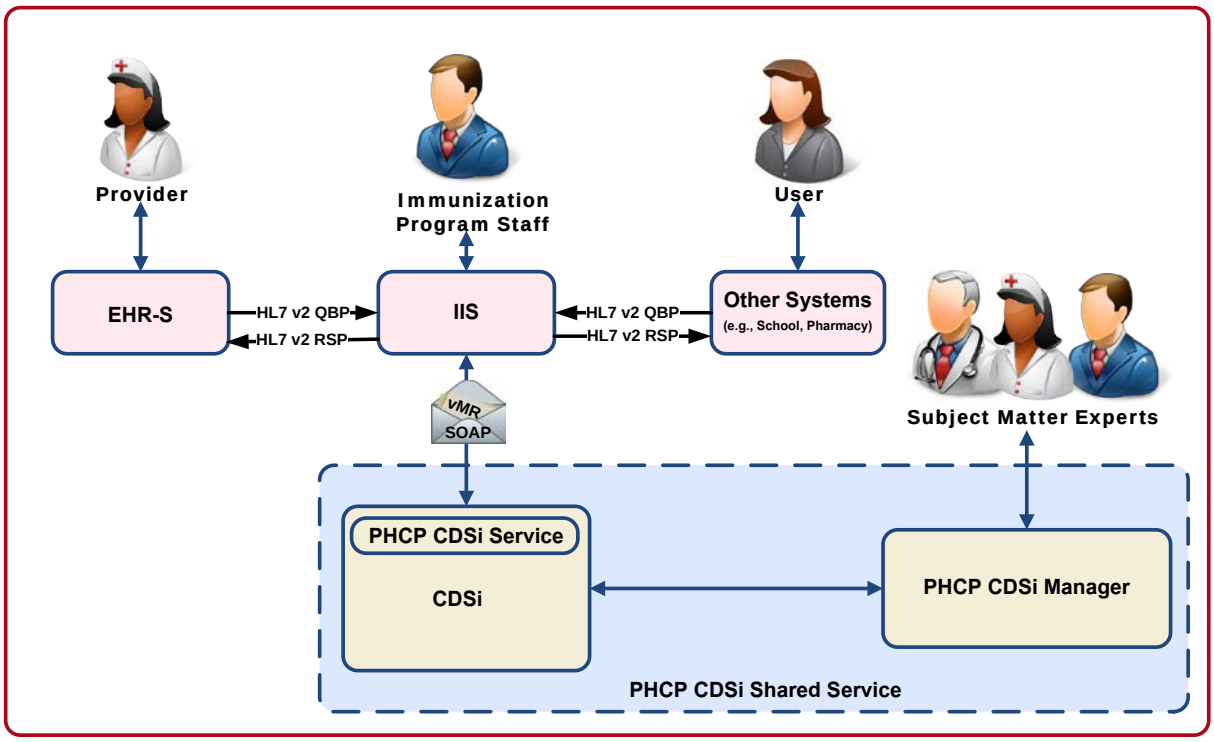
In an effort to harmonize the outcomes of existing CDS tools used by IIS and other systems, CDC funded the Clinical Decision Support for Immunization (CDSi) project to develop new clinical decision aids for each vaccine on the children's immunization schedule to:

- Make it easier to develop and maintain immunization evaluation and forecasting products
- Ensure a patient's immunization status is current, accurate, consistent, and readily available
- Increase the accuracy and consistency of immunization evaluation and forecasting
- Improve the timeliness of accommodating new and changed ACIP recommendations

An expert panel was convened in 2011 to develop recommendations in three areas, including unambiguous logic specifications for the ACIP rules themselves, strategies and examples for testing algorithm behavior, and sustainability, communication, and training around the material developed by the panel. The panel initially produced consensus-driven descriptions of the rules for childhood vaccines, and is working in 2014 on adult vaccine definitions.[9] Generally speaking, the functionality of a CDSi service is displayed in Figure 2.

[9] See http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html

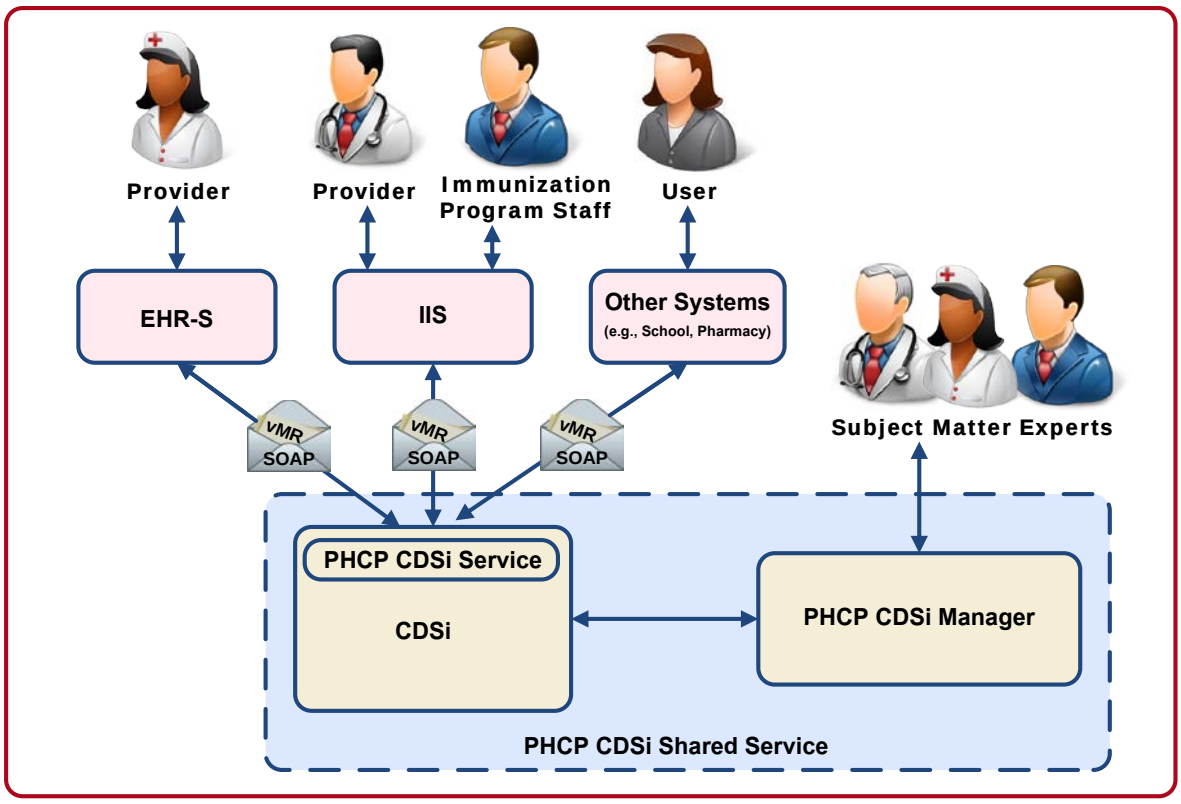
Figure 2: CDSi Architecture Diagram (EHR-S or Other Systems Access the PCHP CDSi Service through an IIS)



EHR-S and other systems initiate a query to the IIS via standard Health Level Seven International (HL7) v2 messages to inquire about the immunization history and forecast for a particular patient. The IIS in turn invokes the CDSi service through a standards-based service call by passing a message structured as a Virtual Medical Record (vMR) to its standard CDSi Web Service. The Web Service utilizes its immunization rules and the data in the vMR, including the patient's date of birth, gender, immunization history, and disease indicators, to evaluate and return the validity of each immunization in the patient's history along with one or more reasons an immunization is invalid, if it is. It also returns a recommendation for each vaccine group (*e.g.*, the date on which the next dose is due, the earliest date a dose could be given, series completed, etc.). The Web Service architecture should scale to support simultaneous real-time processing of many patients submitted by one or more systems. It should also scale to service requests for multiple immunization schedules (*e.g.,* schedules for different jurisdictions, or different uses within a jurisdiction like clinical use and school admission use). A web-based tool with a GUI should sit alongside the CDSi Web Service and enable SMEs to configure and manage the service without the intervention of software developers. Through this tool, SMEs may manage the concepts, series, and rules that are utilized by the service, as well as manage and run automated tests of the service.

An alternate scenario, depicted in Figure 3, allows EHR-S and other systems to invoke the CDSi service *directly* without the IIS intermediating in this transaction. In this case, the functioning of the CDSi service is the same as in the primary scenario as the service does not care how many systems submit service calls so long as they are authorized to do so.

Figure 3: CDSi Architecture Diagram (Systems Directly Access the PHCP CDSi Service)



3. Use Case Scope

- While the CDSi Service described below can be invoked by any of the Requestor's of the PHCP CDSi Service (either people or systems) as listed in Table 8-1 and Table 8-2 (section 8 below), respectively, the Main Success Scenario and Extensions of this use case are limited to describing the PHCP CDSi Service invoked by an:
  - IIS on behalf of an EHR-S
  - EHR-S directly
  - IIS client application
- While the CDSi Service can provide its services to any of the Requestor's of the PHCP CDSi Service (either people or systems) as listed in Table 8-1 and Table 8-2 (section 8 below), respectively, the Main Success Scenario and Extensions of this use case are limited to:
  - Providing CDSi to an IIS who may subsequently relay that information to an EHR-S via an HL7 v2 RSP (Query Response) message, or
  - Directly to an EHR-S.

4. Value Statement/Success Guarantee

Development and maintenance of CDSi requires a multidisciplinary team with fairly sophisticated background and training: medical/nursing staff to understand and interpret the clinical guidelines; analytical staff to translate the medical rules into computer-accessible instructions; programming staff to code the rules and related interfaces in a programming language; testers to develop test cases and test the algorithm as it is developed; and project managers to make sure all the participants work productively together on schedule and within budget.

The reality of constrained budgets, staff reductions, and the flight of technical talent from the public to the private sector will become increasingly challenging. A combination of market, financial and technology forces are driving the IIS community toward increased development and use of "shared services" and the necessary standards, oversight and best practices. CDSi has broad applicability for both public health and clinical systems making it a good candidate for shared development and operations.

A CDSi service offered on a shared platform like PHCP can function in a number of capacities, and even support multiple capacities simultaneously:

(1) **As a shared service:** A CDSi service can be operated on a common platform (like PHCP) and made available to multiple sets of users. If designed properly, the service can support multiple schedules for the multiple communities using the service who will have no knowledge that other communities are sharing the service. Even management of the configuration of the service can be distributed among individuals from the communities who use it. Because invoking such a service happens irregularly during the course of the day by different systems in different time zones, sharing a platform would allow for more efficient use of aggregate services (though peak load times may be more severe). Centralized administration of at least some aspects of the service would also provide more efficiencies in staffing and require fewer individuals with deep knowledge of the services.

(2) **As shared data:** The maintenance of CDSi rules is in and of itself a somewhat detailed and often onerous activity. The "data" of a CDSi service is not the patient data (which does not persist beyond a particular transaction) but the *rules* and terminology. A set of communities could agree to *share* a common set of rules in order to reduce the support burden on them and to increase the conformity to a particular interpretation of the ACIP rules. Historical versions of rules should be retained for research/analytical purposes including retrospective evaluations of immunization histories at moments in the past. A good CDSi service could be configured to support a mixed model where some communities share the rules and some define their own. PHCP could be an important element in providing a common space for this sharing to take place with appropriate security and audit trail.

(3) **Shared application:** Some communities may choose to operate and run a CDSi service on their own infrastructure for a variety of reasons, including performance or policy requirements. Even in this case, the use of a CDSi product that is in use elsewhere in the country, though in this case deployed locally by a project, represents good leverage of joint development and support activities. A good CDSi product allows for the *rules* and configuration to be exported and shared independent of the software to accommodate local implementations. PHCP can be instrumental in facilitating the distribution and support (within intellectual property constraints) of software products in the public health (and even potentially the larger) community.

An optimal CDSi offering from the PHCP may require a variety of services beyond hosting the run-time service, shared data and/or a shared application, including:

- **Technical Support**
  - Provide web conference/telephone/email support to an organization's IT staff
  - Work with an organization's IT staff to integrate the services with their healthcare systems
  - Enhance or customize the software features to meet the custom needs or workflow of an organization
- **User Support**
  - Provide web conference/telephone/email support to local managers of the service's schedule, rules, and tests
  - Train subject matter experts to create and manage the concepts, series, and rules that are utilized by the service
- **Configuration Services**
  - Customize and/or maintain an immunization schedule on behalf of organizations

The need for these types of services comes from a variety of potential user organizations, including:

Table 4-1: Potential User Organizations

	Self-supported	Assisted	Hosted
IIS Immunization evaluation and forecast is a CDC Core Functional Standard.	Most IIS have the expertise and interest in at least defining their own rules if not managing them.	This might involve an IIS deploying its own Web Service but relying on PHCP to configure it and manage the rules, or offer other *ad hoc* assistance.	Some IIS are looking for a turnkey solution that involves little effort or expertise on their part.
Other Public Health Agency PHAs might want to use CDSi for data analytics including up-to-date calculations for individual patients and whole populations.	Local/state PHA with strong informatics capability may want to manage a software service and its rules on their own, but these are likely the exception rather than the rule.	This might involve a PHA deploying its own Web Service but relying on PHCP to configure it and manage the rules, or offer other *ad hoc* assistance.	Most local PHAs likely want a turnkey solution as they do not have the informatics expertise to deploy or maintain a web service.
EHR-S Vendor CDS is a major area of functionality and most general-purpose EHR-S do not do this well, especially when it comes to pediatric functions.	Most EHR-S vendors would likely want to run and maintain their own Web Service.	Some EHR-S vendors may want some level of assistance if they are less confident especially of their medical expertise in this area.	PHCP could offer a fully-hosted service for an EHR-S vendor, but would need to make sure it has the support and technical capacity to maintain it.

	Self-supported	Assisted	Hosted
Academic Medical Center Many have developed and deployed home-grown EHR-S.	Those with strong informatics programs may just want to do it themselves. They also tend to be familiar with the open source model.	Those with less capable informatics programs may want some level of assistance all the way up to a turnkey service.	
Accountable Care Organizations (ACO)/ Patient Centered Medical home (PCMH) ACOs have high expectations placed on them especially for analytics and often little infrastructure to produce results quickly.	Uncertain of how sophisticated *any* ACOs might be.	ACOs are more likely to need *more* services rather than fewer.	

5. Use Case Assumptions

The following are assumptions for this use case:

- The PHCP CDSi Service is installed and configured on PHCP (the exact nature of this platform is not yet determined).
- The PHCP CDSi Manager is installed and configured on the PHCP.
    - The PHCP CDSi Manager is used to specify and maintain the detailed concepts, vaccine series, and rules that drive the PHCP CDSi Service's algorithm.
    - At minimum, the rules defined by the ACIP immunization schedule should be configured. However, multiple immunization schedules are supported.
- The PHCP CDSi Service is available and operating properly.
- The system invoking the CDSi service is authorized to do so, and authenticated for the purposes of maintaining an audit trail of service calls within the CDSi service.
- Patient's immunization record is located in the IIS or EHR-S.
- Neither the IIS nor the EHR-S immunization record may be complete since the patient may have received immunizations that are not yet recorded in either system.
- Only one patient record results from an IIS search.
- System which will invoke the PHCP CDSi Service is capable of structuring a proper message to invoke the service.
- System which will invoke the PHCP CDSi Service can consume the results.

6. Pre-Conditions

The following are the items which must be true *before* this use case runs:

- PHCP must be accessible to users.
- The PHCP CDSi Service must be available.
- Concepts, vaccine series, and rules for the immunization schedule(s) used by the PHCP CDSi Service must be configured.
- Required input parameters for the PHCP CDSi Service must be available and provided by the system calling the service.

7. Post-Conditions

The following are the items which must be true *after* this use case runs:

- Requestor of the PHCP CDSi Service receives the validity of each immunization in the patient's history (*i.e.*, whether each immunization is valid or invalid), and for invalid immunizations, one or more reasons why the immunization is invalid.
- Requestor of the PHCP CDSi Service receives for each vaccine group, a recommendation (*e.g.*, the date on which the next dose is due, patient's age on the recommended date, recommendation reason, the *earliest* date a vaccine could be given and still be valid, etc.).

8. Actors, Goals, and Roles

Table 8-1: Actors (People), Goals, and Roles

Actor	Goal(s)	Role
Provider	• Obtain immunization evaluations and recommendations for clinical decision support.	• Requestor of the PHCP CDSi Service (directly or through an IIS). • Primary Actor of this use case.
Immunization Program Staff	• Obtain immunization evaluations and recommendations to facilitate reporting, data analysis, and other Immunization Program functions (*e.g.*, generating coverage reports, generating reminder/recall reports, supplying data or reports to the CDC, etc.).	• Requestor of the PHCP CDSi Service.
School Nurse	• Obtain immunization evaluations and recommendations for clinical decision support.	• Requestor of the PHCP CDSi Service (directly or through an IIS).

Actor	Goal(s)	Role
Pharmacist	• Obtain immunization evaluations and recommendations for clinical decision support.	• Requestor of the PHCP CDSi Service (directly or through an IIS).
Other Third Party Clinical Information System User	• Obtain immunization evaluations and recommendations for clinical decision support.	• Requestor of the PHCP CDSi Service (directly or through an IIS).
Requestor of the PHCP CDSi Service	• Utilize the PHCP CDSi Service directly or through an IIS to obtain immunization evaluations and recommendations for clinical decision support.	• Any of the above listed actors is a Requestor of the PHCP CDSi Service. • Table 8-2 notes Actors (Systems) which are Requestors of the PHCP CDSi Service.
Subject Matter Expert (SME)	• Specify, configure, and maintain the detailed concepts, vaccine series, and rules that drive the PHCP CDSi Service.	• User of the PHCP CDSi Manager.
User of the PHCP CDSi Manager	• Specify, configure, and maintain the detailed concepts, vaccine series, and rules that drive the PHCP CDSi Service.	• SME is a User of the PHCP CDSi Manager.
IT Staff	• Provide PHCP technical support including but not limited to maintaining the PHCP CDSi Service and the PHCP CDSi Manager.	• Technical Support

Table 8-2: Actors (Systems), Goals, and Roles

Actor	Goal(s)	Role
IIS	• Invoke the PHCP CDSi Service to obtain immunization evaluations and recommendations. • Provide immunization evaluations and recommendations to the EHR-S if it invoked the PHCP CDSi Service on behalf of the EHR-S.	• Requestor of the PHCP CDSi Service. • Supplier of the PHCP CDSi Service results to an EHR-S, if services invoked on behalf of the EHR-S.
EHR-S	• Invoke the PHCP CDSi Service to obtain immunization evaluations and recommendations. • Queries IIS for immunization history and forecast.	• Requestor of the PHCP CDSi Service (directly or through an IIS).
School Health System	• Invoke the PHCP CDSi Service to obtain immunization evaluations and recommendations. • Queries IIS for immunization history and forecast.	• Requestor of the PHCP CDSi Service (directly or through an IIS).

Actor	Goal(s)	Role
Pharmacy Information System	• Invoke the PHCP CDSi Service to obtain immunization evaluations and recommendations. • Queries IIS for immunization history and forecast.	• Requestor of the PHCP CDSi Service (directly or through an IIS).
Other Third Party Clinical Information System	• Utilize the PHCP CDSi Service directly or through an IIS to obtain immunization evaluations and recommendations for clinical decision support.	• Any third party clinical information system able to integrate with the PHCP CDSi Service.
PHCP	• Provide shared services (*e.g.*, the PHCP CDSi Service and the PHCP CDSi Manager), shared applications for analysis, and access to common data sets.	• Platform for shared services, shared applications, and shared data.
PHCP CDSi Service	• Provide immunizations evaluations and recommendations.	• Shared service of the PHCP.
PHCP CDSi Manager	• Provide mechanism to specify and maintain the detailed concepts, vaccine series, and rules that drive the PHCP CDSi Service.	• Shared service of the PHCP.

8.1 Other Stakeholders and Their Interests

Table 8.1-1: Other Stakeholders and Their Interests

Stakeholder	Interests
State or Local Immunization Program	• Reducing the incidence, morbidity, and mortality of vaccine-preventable diseases via preventive care such as routine vaccination. • Performing important public health function of providing preventive care to patients, by ensuring patients are up-to-date on their vaccines and receive their recommended vaccines. • Monitoring and consistently adhering to the frequently changing and complex immunization guidelines. • Providing accessibility of the PHCP CDSi Service to multiple clinical information systems, all of which would receive the same, high-quality decision support. • Easily and economically maintaining the PHCP CDSi Service and the CDSi algorithm used by the PHCP CDSi Service, by sharing the responsibility between public health and the clinical community. • Providing access to de-centralized CDSi rules administration. • Maintaining and updating forecasting rules without the assistance of programmers which can be expensive. • Providing automated testing of the PHCP CDSi Service to facilitate rapid and less labor intensive testing in response to additions to and/or changes in the CDSi algorithm. • Delivering consistent and accurate evaluation and forecasting results to requestors. • Minimizing under-immunization or over-immunization of patients. • Providing richer opportunities for PHAs to leverage both increasingly-digitized medical knowledge and CDS capabilities that will become more dominant features in clinical systems. • Providing highly configurable and scalable services to support and service requests for multiple immunization schedules. • Simultaneously processing multiple requests for CDSi for speedier response as the volume of requests increases.

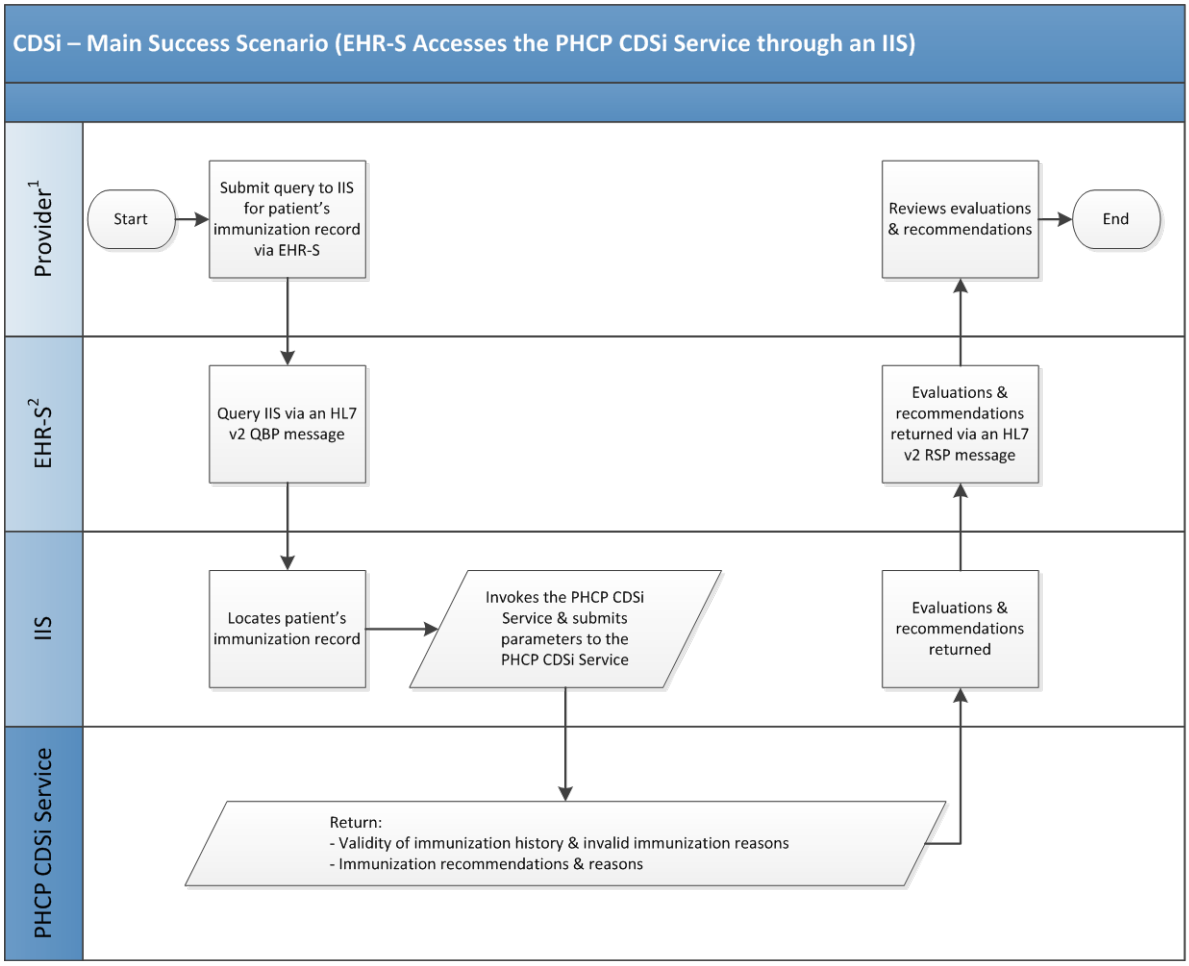
Stakeholder	Interests
Provider Organization	• Improving quality of patient care. • Improving immunization practice and coverage levels by incorporating shared services into clinical workflows. • Utilizing CDSi at the point of care as a strategy to improve quality of patient care and meeting quality reporting requirements. • Receiving high-quality decision support from the PHCP CDSi Service. • Mitigating the risk of losing access to specialized functions offered by the IIS which the provider relies upon for patient treatment and decision support such as CDSi, typically not found or is inadequate in external systems, as providers with access to IIS face pressure to stay within their EHR-S and to not access applications elsewhere. • Ensuring patients receive age-appropriate vaccinations. • Ensuring patients are up-to-date on their recommended immunizations despite the complicated and frequently changing immunization schedule, which will only continue to grow as new vaccines are developed. • Satisfy implementation of CDS to support clinical quality, which is one of the core set of measures in both Stage 1 and Stage 2 Meaningful Use of the Center's for Medicare and Medicaid Services EHR Incentive Programs. • Supports broader health reform/Triple Aim goals.
Public Immunization Clinic	• Improving quality of patient care. • Improving immunization practice and coverage levels by incorporating shared services into clinical workflows. • Utilizing CDSi at the point of care as a strategy to improve quality of patient care. • Receiving high-quality decision support from the PHCP CDSi Service. • Ensuring patients receive age-appropriate vaccinations. • Ensuring patients are up-to-date on their recommended immunizations despite the complicated and frequently changing immunization schedule, which will only continue to grow as new vaccines are developed.
State or Local Health Department	• Reducing costs by sharing services, applications, and data with other stakeholders. • Minimizing replication of efforts across agencies and its associated cost. • Leveraging other community and shared activities in order to mitigate challenges public health programs and agencies face with new systems and systems enhancements given constrained budgets, staff reductions, and staff turnover. • Exploring additional uses of CDSi, *e.g.*, in examining populations of patients.

Stakeholder	Interests
CDC	• Reducing costs by sharing services, applications, and data with other stakeholders, increasing the value of federal investments in IIS programs • Minimizing replication of efforts across agencies and its associated cost. • More accurate and consistent vaccine forecasts provided by IIS programs across the country. • Reducing the incidence, morbidity, and mortality of vaccine-preventable diseases via preventive care such as routine vaccination. • Communicating the frequently changing and complex immunization guidelines. • Minimizing under-immunization or over-immunization of patients. • Leveraging PHCP across program areas for greater efficiency.
Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)	• Reducing the incidence, morbidity, and mortality of vaccine-preventable diseases via preventive care such as routine vaccination. • Performing important public health function of providing preventive care to patients, by ensuring patients are up-to-date on their vaccines and receive their recommended vaccines. • Minimizing under-immunization or over-immunization of patients. • Ensuring patients receive age-appropriate vaccinations. • Ensuring patients are up-to-date on their recommended immunizations despite the complicated and frequently changing immunization schedule, which will only continue to grow as new vaccines are developed. • Reducing costs by sharing services, applications, and data with other stakeholders. • Minimizing replication of efforts across agencies and its associated cost. • Leveraging other community and shared activities in order to mitigate challenges public health programs and agencies face with new systems and systems enhancements given constrained budgets, staff reductions, and staff turnover.
Hospital	• Improving quality of patient care. • Utilizing CDSi at the point of care as a strategy to improve quality of patient care. • Receiving high-quality decision support from the PHCP CDSi Service. • Ensuring patients receive age-appropriate vaccinations. • Satisfy implementation of CDS to support clinical quality, which is one of the core set of measures in both Stage 1 and Stage 2 Meaningful Use of the Center's for Medicare and Medicaid Services EHR Incentive Programs.

9. Diagrams

9.1 Use Case Diagrams

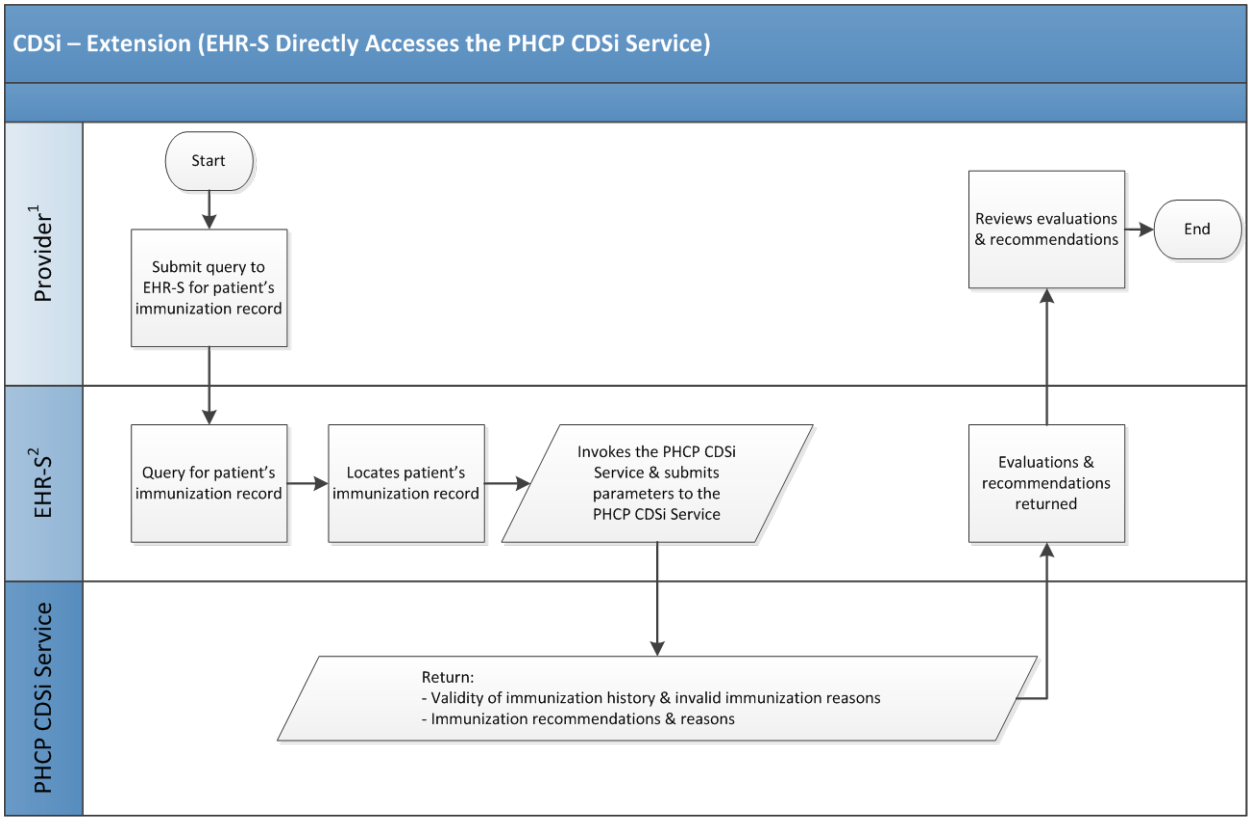
Figure 4: CDSi – Main Success Scenario (EHR-S Accesses the PHCP CDSi Service through an IIS)



[1]Although this diagram indicates a Provider performing this function, "Provider" could be substituted with "School Nurse", "Pharmacist", or "User of Other Third Party Clinical Information System".

[2]Although this diagram indicates an EHR-S performing this function, "EHR-S" could be substituted with "School Health System", "Pharmacy Information System, or "Other Third Party Clinical Information System".

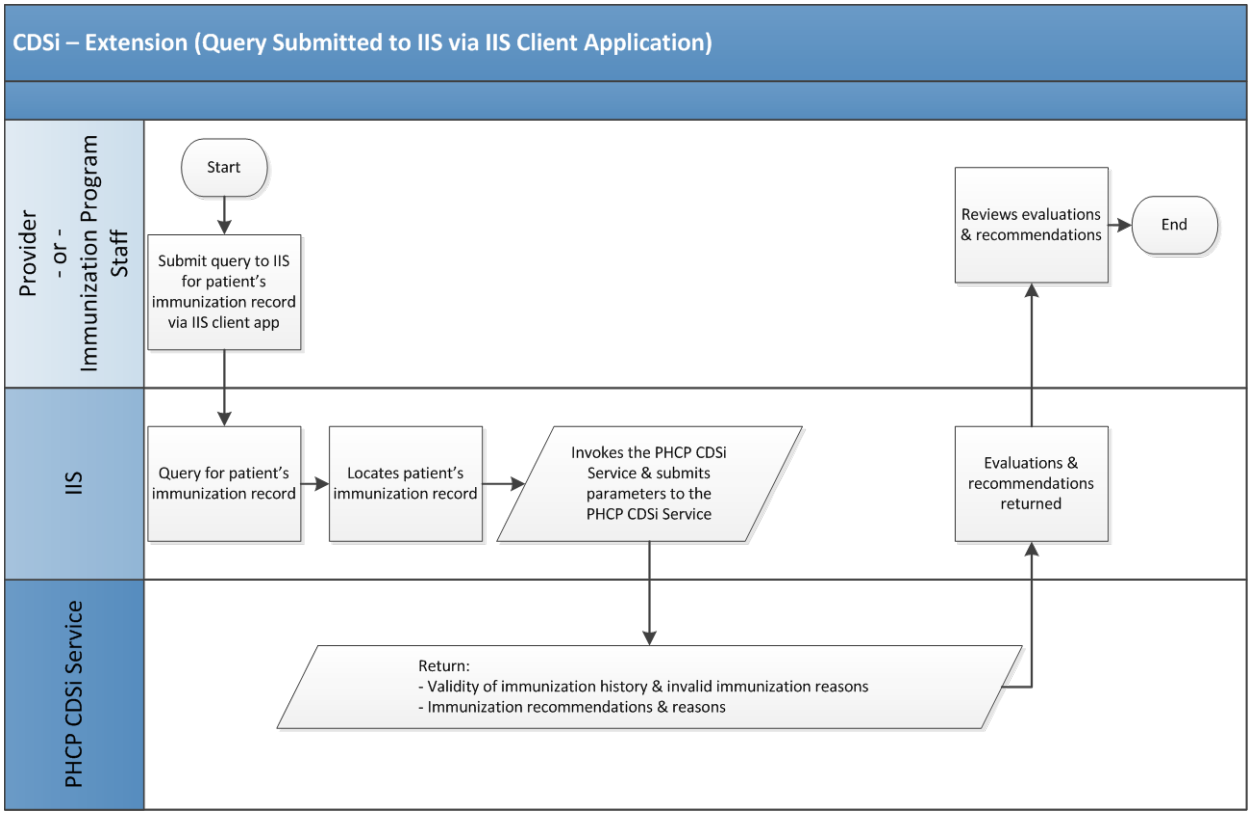
Figure 5: CDSi – Extension (EHR-S Directly Accesses the PHCP CDSi Service)



[1]Although this diagram indicates a Provider performing this function, "Provider" could be substituted with "School Nurse", "Pharmacist", or "User of Other Third Party Clinical Information System".

[2]Although this diagram indicates an EHR-S performing this function, "EHR-S" could be substituted with "School Health System", "Pharmacy Information System, or "Other Third Party Clinical Information System".

Figure 6: CDSi – Extension (Query Submitted to IIS via IIS Client Application)



9.2 Sequence Diagram

Figure 7: CDSi – Main Success Scenario (EHR-S Accesses the PHCP CDSi Service through an IIS)

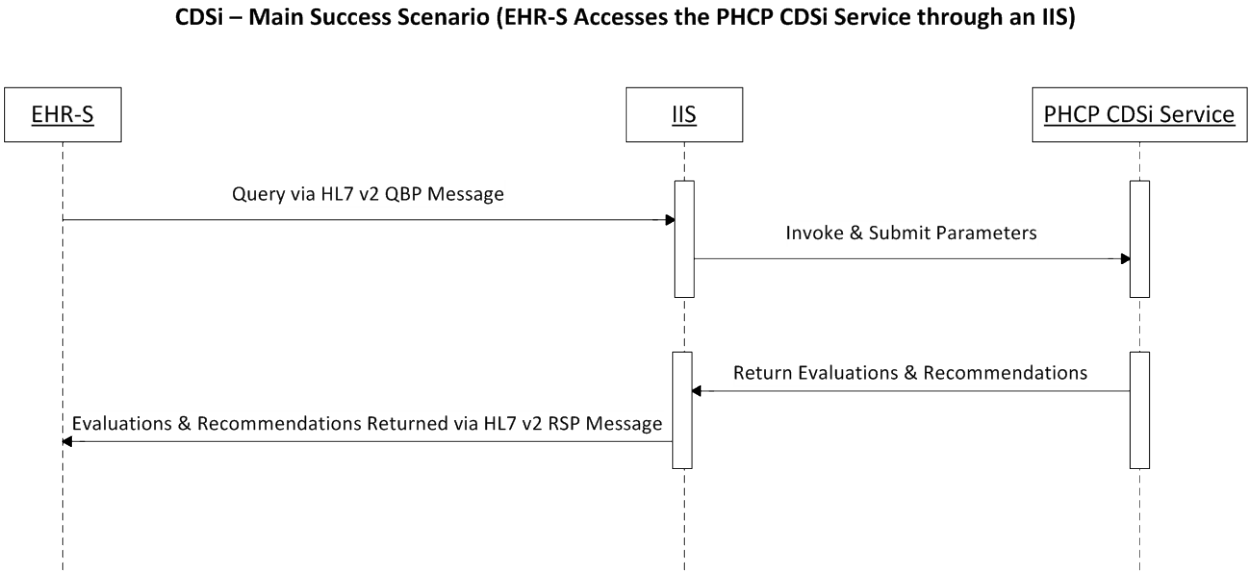


Figure 8: CDSi – Extension (EHR-S Directly Accesses the PHCP CDSi Service)

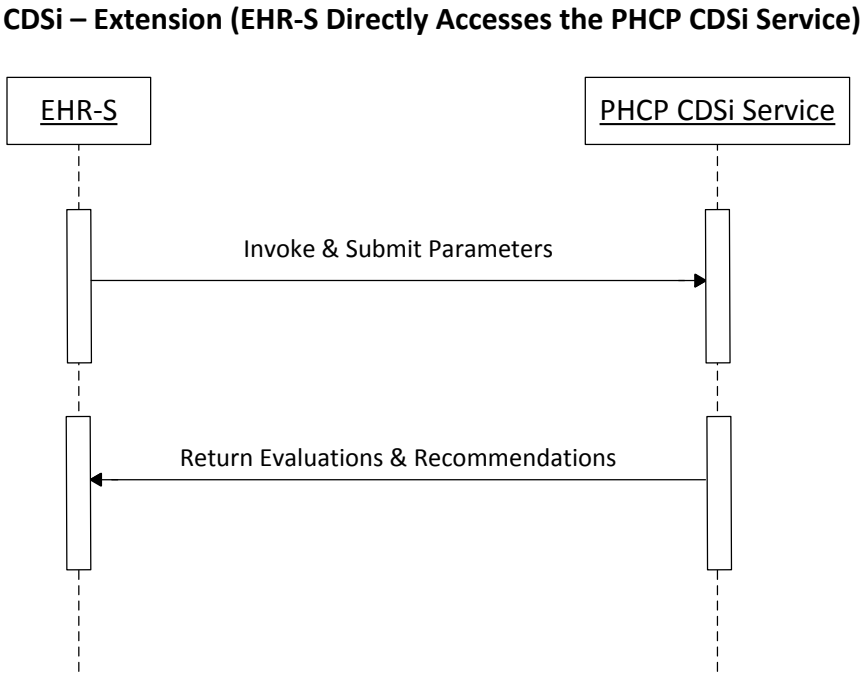
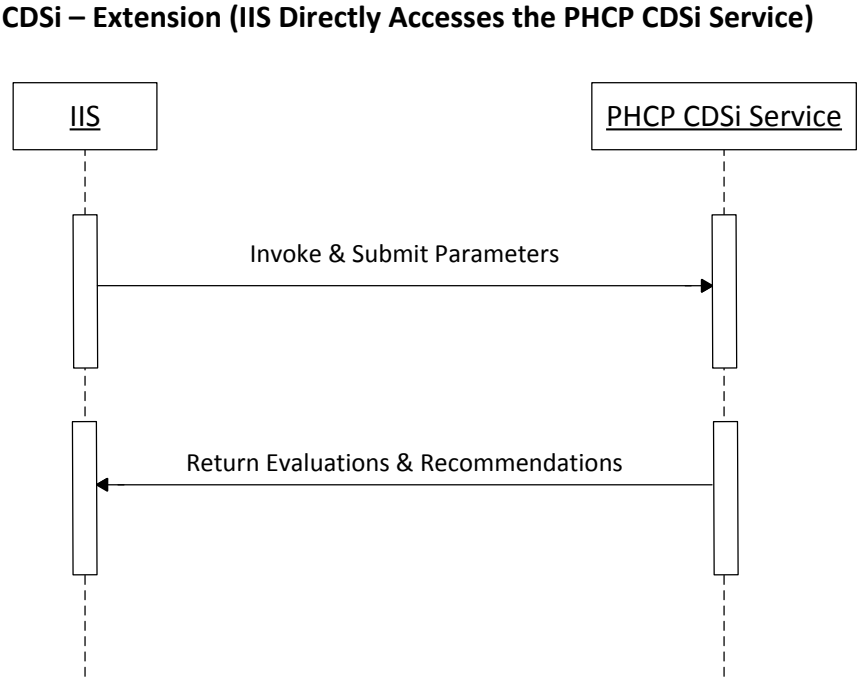


Figure 9: CDSi – Extension (IIS Directly Accesses the PHCP CDSi Service)



10. Usage Narrative

Mary Mommy brings her 5 year old son Jack to Dr. Wellness, his pediatrician, for his annual physical examination. Mary also needs to register Jack for kindergarten for the upcoming school year and brings the school registration forms to the pediatrician's office to fill out. Mary knows that Jack needs to have all the required immunizations before entrance into school.

During Jack's visit, Dr. Wellness uses the office's EHR-S to issue an HL7 v2 QBP (Query by Parameter) message to query for Jack's immunization record in the State's web-based IIS. After the IIS locates Jack's immunization record, it invokes the PHCP CDSi Service, which evaluates and provides the validity of each immunization in Jack's immunization history as well as provides a recommendation for each vaccine group (*e.g.*, the date on which the next dose is due, series completed, etc.). The IIS returns this information to the office's EHR-S via an HL7 v2 RSP message. Based on the evaluations and recommendations provided by the PHCP CDSi Service which are now displayed in the EHR-S, Dr. Wellness sees that Jack is up-to-date on all his immunizations with the exception of MMR, for which he is due. Jack's first dose of MMR was administered when he was 1 year old.

Dr. Wellness administers the MMR vaccine to Jack and records the vaccine given, the administration date, and lot number in the EHR-S which subsequently submits that immunization to the IIS via an HL7 v2 VXU (Unsolicited Vaccination Update) message. Jack's immunization record is refreshed in the EHR-S through another HL7 v2 QBP message to query for Jack's immunization record. Again, the IIS locates Jack's immunization record, invokes the PHCP CDSi Service, and re-evaluates and provides the validity of the immunizations in Jack's immunization history, including the immunization that was just reported, and provides a recommendation for each vaccine group. The IIS returns this information to the office's EHR-S via an HL7 v2 RSP message. Dr. Wellness now sees in the EHR-S that Jack is up-to-date on all his immunizations and has completed the MMR vaccine series.

Dr. Wellness fills out Jack's school registration forms, uses the EHR-S to print out a copy of Jack's immunization history report, which is now populated with the most recent immunization history, and provides the completed forms and immunization history report to Mary Mommy. Now that Jack's annual physical examination has completed, Mary leaves the office knowing Jack has received all the required immunizations necessary for entrance into school and that she has all the appropriate registrations forms, including the immunization history report, completed and ready to provide to Jack's school.

11. Trigger

- Trigger for Main Success Scenario: Provider uses an EHR-S to query the IIS for a patient's immunization record.
- Trigger for Extension 1a: Provider uses an EHR-S to query the EHR-S for a patient's immunization record.

- Trigger for Extension 1b: Provider or Immunization Program Staff uses an IIS client application to query the IIS for a patient's immunization record.

12. Main Success Scenario

1. Provider using an EHR-S queries the IIS via an HL7 v2 QBP message for a patient's immunization record.
2. IIS locates the patient's immunization record.
3. IIS invokes the PHCP CDSi Service and passes it the following information:
    - Patient's Date of Birth (DOB)
    - Patient's gender
    - Immunization history
    - Immunization schedule identifier
    - Information to support contraindications which may be one or more of the following:
        - Proof of Immunity/Documented Disease
        - Indication[10] that patient has a current illness that would prohibit vaccination
        - History of adverse reaction, vaccine group, and reaction specified
        - List of coded allergies
        - Indication[10] of pregnancy
        - Indication[10]of blood transfusion and blood transfusion component specified
        - Indication[10] that patient is immunocompromised
        - Indication[10] of steroid treatment
        - Indication[10] of uncontrolled or evolving neurologic disorder
        - History of paralysis with Guillain-Barré Syndrome (GBS)
    - Patient status is high risk for a specific disease
4. The PHCP CDSi Service evaluates and returns, to the IIS, the validity of each immunization in the patient's immunization history (*i.e.*, whether each immunization is valid or invalid), and for invalid immunizations, one or more reasons why the immunization is invalid.
5. The PHCP CDSi Service returns, to the IIS, a recommendation (subject to contraindication) for each vaccine group (*e.g.*, the date on which the next dose is due, patient's age on the recommended date, recommendation reason, etc.)
6. IIS returns evaluations and recommendations to the EHR-S via an HL7 v2 RSP message.
7. Provider reconciles the data received from the IIS with the records already stored locally in the EHR-S and reviews the evaluations and recommendations rendered in the EHR-S to facilitate clinical decision making.

[10] Indication may be via clinical statement, diagnosis, lab result, procedure, and/or medication(s), etc., as applicable.

12.1 Extensions

1a. EHR-S queried for a patient's immunization record:
  1a1. Provider queries their EHR-S for the patient's immunization record.

1b. Query submitted to the IIS via an IIS client application:
  1b1. Provider or Immunization Program Staff using an IIS client application queries the IIS for a patient's immunization record.

2a. EHR-S queried for patient's immunization record:
  2a1. EHR-S locates the patient's immunization record.

3a. EHR-S directly invokes the PHCP CDSi Service:
  3a1. EHR-S directly invokes the PHCP CDSi Service by passing it the necessary parameters (*i.e.*, the patient's DOB, gender, immunization history, proof of immunity/documented disease, and immunization schedule identifier).

4a. EHR-S directly invoked the PHCP CDSi Service:
  4a1. The PHCP CDSi Service returns evaluations directly to the EHR-S.

4b. Invalid data including but not limited to: invalid coded element, invalid date element (*e.g.*, not parsable/wrong data format), invalid unit of measure element (*e.g.*, measurement for a dose or a test), passed to the PHCP CDSi Service:
  4b1. The PHCP CDSi Service throws a fatal exception and an error message is reported back to the invoker.

4c. Non-existent immunization schedule identifier passed to the PHCP CDSi Service:
  4c1. The PHCP CDSi Service throws a fatal exception and an error message is reported back to the invoker.

4d. Non-fatal error situation (*e.g.*, immunization administration date prior to the patient's DOB):
  4d1. The PHCP CDSi Service returns an evaluation result which explains the issue (*e.g.*, prior to the date of birth).

5a. EHR-S directly invoked the PHCP CDSi Service:
  5a1. The PHCP CDSi Service returns recommendations directly to the EHR-S.

6a. EHR-S directly invoked the PHCP CDSi Service:
  6a1. The PHCP CDSi Service returns evaluations and recommendations directly to the EHR-S.

7a. Provider queried the IIS for a patient's immunization record using an IIS client application:
  7a1. Provider reviews the evaluations and recommendations rendered in the IIS to facilitate clinical decision making.

7b. Immunization Program Staff queried the IIS for a patient's immunization record using an IIS client application:
  7b1. Immunization Program Staff reviews the evaluations and recommendations rendered in the IIS to facilitate reporting, data analysis, and other Immunization Program functions.

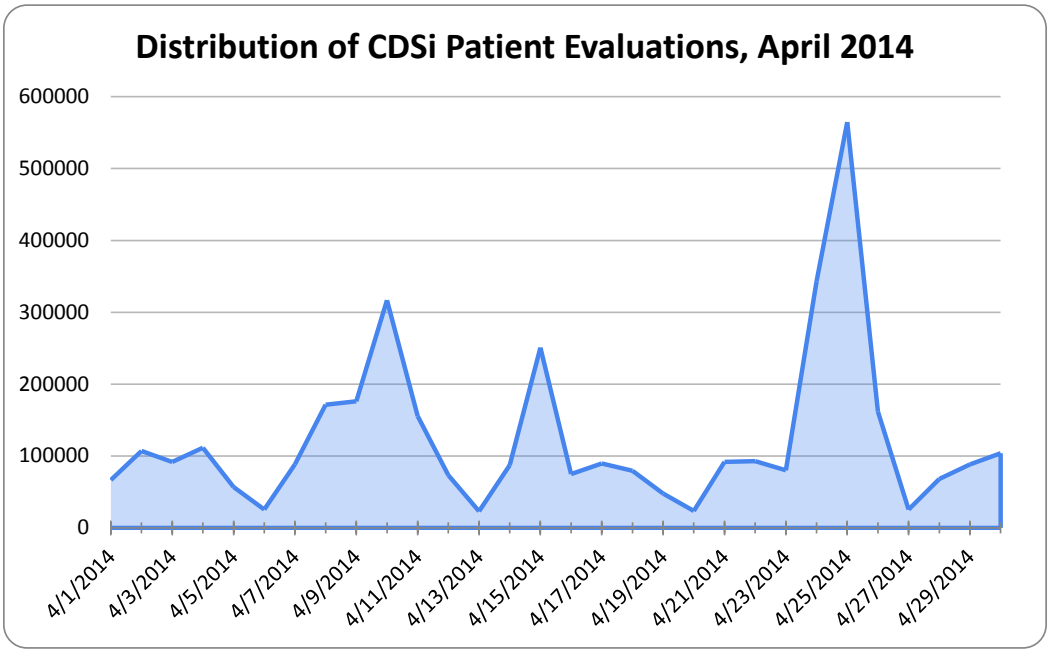
13. Frequency of Occurrence

The frequency of occurrence of this use case can be at any time when immunization evaluations and recommendations are needed for clinical decision support, data analysis, and reporting. This includes evaluation of individual patients as well as evaluation of an entire cohort of patients (*e.g.*, by age group or geography).

CDSi has a unique characteristic in that the forecast for a patient can change simply with the passage of time – no other change in the patient's medical history is necessary (though other factors may also change, such as disease occurrence resulting in an immunity). For this reason, some systems (especially when they contain a small to moderate number of records) may evaluate *all* patients *every* day to ensure that records are automatically up-to-date in their forecast. In other systems, other events may trigger the evaluation of the patient's record. Most commonly, simply accessing a record triggers an evaluation. This type of "on demand" evaluation obviates the need to process the entire database each day (usually overnight), but may introduce some latency as the record is called for display. In addition, some system queries might also be delayed as they would potentially trigger evaluation of a larger proportion of the database (depending on the query). As CDSi solutions become faster and more efficient, their ability to process records more quickly reduces the likelihood that processing delays access to data.

To illustrate frequency of CDSi use, the following data is presented for a large, municipal IIS. In April 2014 there were more than 5.25 million patients and 70.6 million immunizations stored in the system (an average of just over 13 immunizations per patient, though the distribution varies widely). This system is large enough that CDSi evaluation can only be done on demand by the several applications that access data for individual patient display, practice-level assessment, and aggregate reporting. During April 2014 there were nearly 125,000 patients evaluated each day, with the daily totals as low as 23,000 evaluations and as high as nearly 565,000 evaluations (See Figure 10).

Figure 10: CDSi – Distribution of CDSi Patient Evaluations, April 2014



The data for the height of the immunization reporting season – August 2013 just before school begins – saw much higher numbers: An average of more than 250,000 evaluations each day with the daily totals as low as 43,000 evaluations and as high as nearly 870,000 evaluations.[11] This data includes *all* patient evaluations, both those performed routinely by providers when viewing individual patient records as well as those performed by IIS staff in the course of performing surveillance activities and generating reports (this aggregate reporting probably accounts for the large peaks when they occur).

A CDSi service offered by PHCP will therefore vary in its requirements based on the method of delivery, method of access, and the number and profile of systems accessing it.

14. Policy and Regulatory Issues

The use of a CDSi Service by any authorized user would be allowed under existing state immunization data sharing laws, since the patient data used in queries is not actually stored by the CDSi Service or on the PHCP. Using the CDSi Service is, in effect, no different than querying an IIS directly from a data access and disclosure point of view. Since providing immunization services would be part of Treatment-Payment-Operations as defined by HIPAA, no patient consent would be required before a user queries a CDSi Service, nor would the PHCP need to enter into business associate agreements with users.

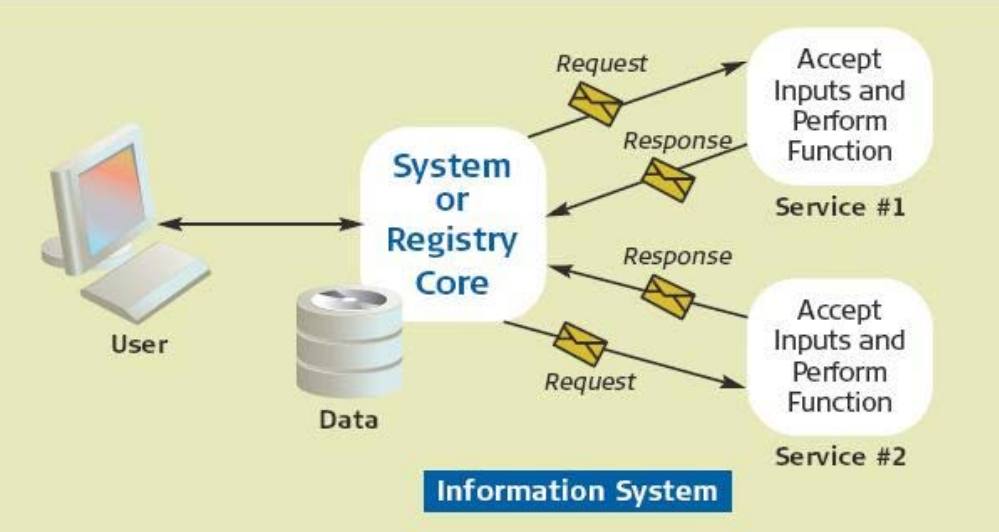
[11] There were clearly fewer patients and immunizations overall back in August 2013 but aggregate data for that moment in the past is not available.

Appendix: Proof of Concept

Most IIS in production today have CDSi algorithms and capabilities deployed within their products. The IIS product market has consolidated somewhat over the past fifteen years with three dominant products remaining, and a variety of single-vendor/public health developed products. Initially, CDSi components were tightly integrated into the products that used them, especially within older products. Software development techniques tended to be less sophisticated in the past, and most CDSi implementations were (and are) difficult to understand, modify, and support. While a good algorithm contains some table-driven configuration elements, the rules for some vaccines are complex and their configuration parameters cannot easily be captured in a table. Regardless, most IIS do have successful algorithm implementations though as time goes on, budget constraints and staff turnover increasingly put the long-term viability of some of the algorithms at risk.

More recently, IIS have turned to CDSi components that are more loosely coupled to the rest of the IIS software. Service-oriented Architecture (SOA) is a building-block approach to system construction which allows complex systems to be broken down into reusable components that can be arranged, re-arranged, and invoked through standard programming interfaces (Figure 11). While originally conceived of as a way to support applications within an organization, SOA has become an architecture upon which system interoperability between organizations can be supported.

Figure 11: Service-oriented Architecture



A CDSi service as described in this use case is making use of SOA strategies. There are several commercial and open source products available that already provide this capability. They fall into several categories:

Table A-1: CDSi Products by Category

Category	Description	Example(s)
Proprietary	Existing IIS vendors and developers have already begun de-coupling their algorithms from the rest of the system as a way to improve performance and maintainability, and/or to begin to position the algorithm potentially as a stand-alone product. These components may or may not use a standards-based way of receiving and responding to service calls.	Software Partners' MatchMerge Decision Support Scientific Technologies Corporation's (STC) ImmuCast™
Public Health Developed	Software developed by public health agencies is generally available to other public health agencies by inter-agency agreement or based on the product's source of funding. There has been some sharing of CDSi software between agencies. These components may or may not use a standards-based way of receiving and responding to service calls.	Web Immunization Service Evaluation and Recommendation (WISER), originally developed as part of California Automated Immunization Registry (CAIR) in CA but provided to RI KIDSNET for use as an SOA component there.
Open Source - limited license[12]	Some products – particularly commercially-developed products – are migrating to the Open Source community, but with restrictions as to how they can be used or who can use them. These components may or may not use a standards-based way of receiving and responding to service calls.	STC's Open ImmuCast™ which is only available to public health entities or programs
Open Source – unlimited license[7]	Some products are being developed and managed in the Open Source community with unrestricted licenses for use and modification. These products may or may not come with support from a vendor or organization.	HLN Consulting, LLC's (HLN) Immunization Calculation Engine (ICE), which is built on OpenCDS and uses Health eDecisions (HeD) standards (no commercial software dependencies). Texas Children's Hospital's Open Immunization Software which is supported by Dandelion Software and Research.

[12] Note that some Open Source products may have commercial product dependencies for them to run properly.