Clinical Decision Support (CDS)

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Clinical Decision Support (CDS)

"[T]he use of information and communications technologies to bring relevant knowledge to bear on the healthcare and well-being of a patient"

Greenes RA. *Definition, scope and challenges*. In Greenes RA, ed. *Clinical Decision Support: The Road to Broad Adoption*. 2nd ed. Waltham, MA: Elsevier; 2014.

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“Five Rights” of CDS

1. The right information
2. To the right person(s)
3. Using the right intervention format
4. In the right channel
5. At the right time during workflow

Campbell RJ. The five rights of clinical decision support: CDS tools helpful for meeting meaningful use. Journal of AHIMA. 2013;84(10): 42–47. Updated February 2016.

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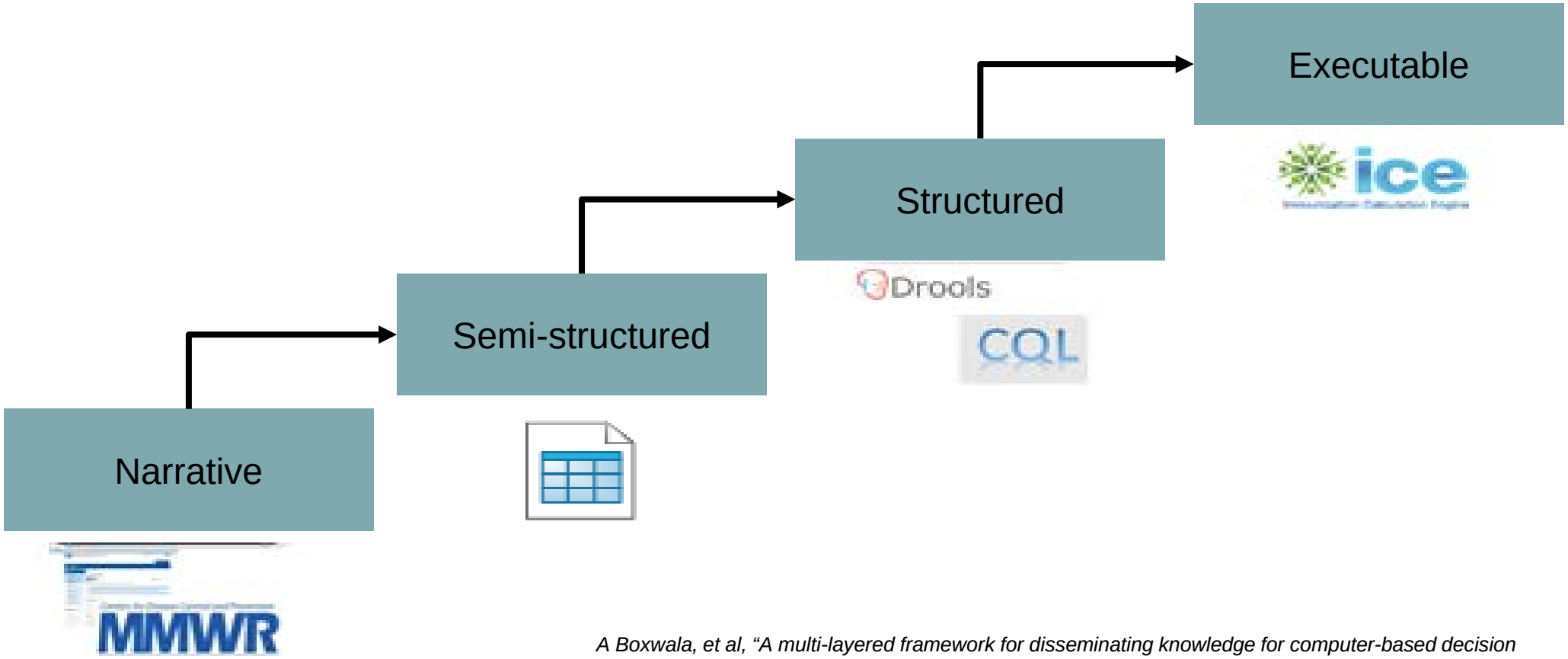
Stages of CDS
Knowledge Development, Part IV



A Boxwala, et al, "A multi-layered framework for disseminating knowledge for computer-based decision systems, J Am Med Inform Assoc 2011;18:i132ei139.

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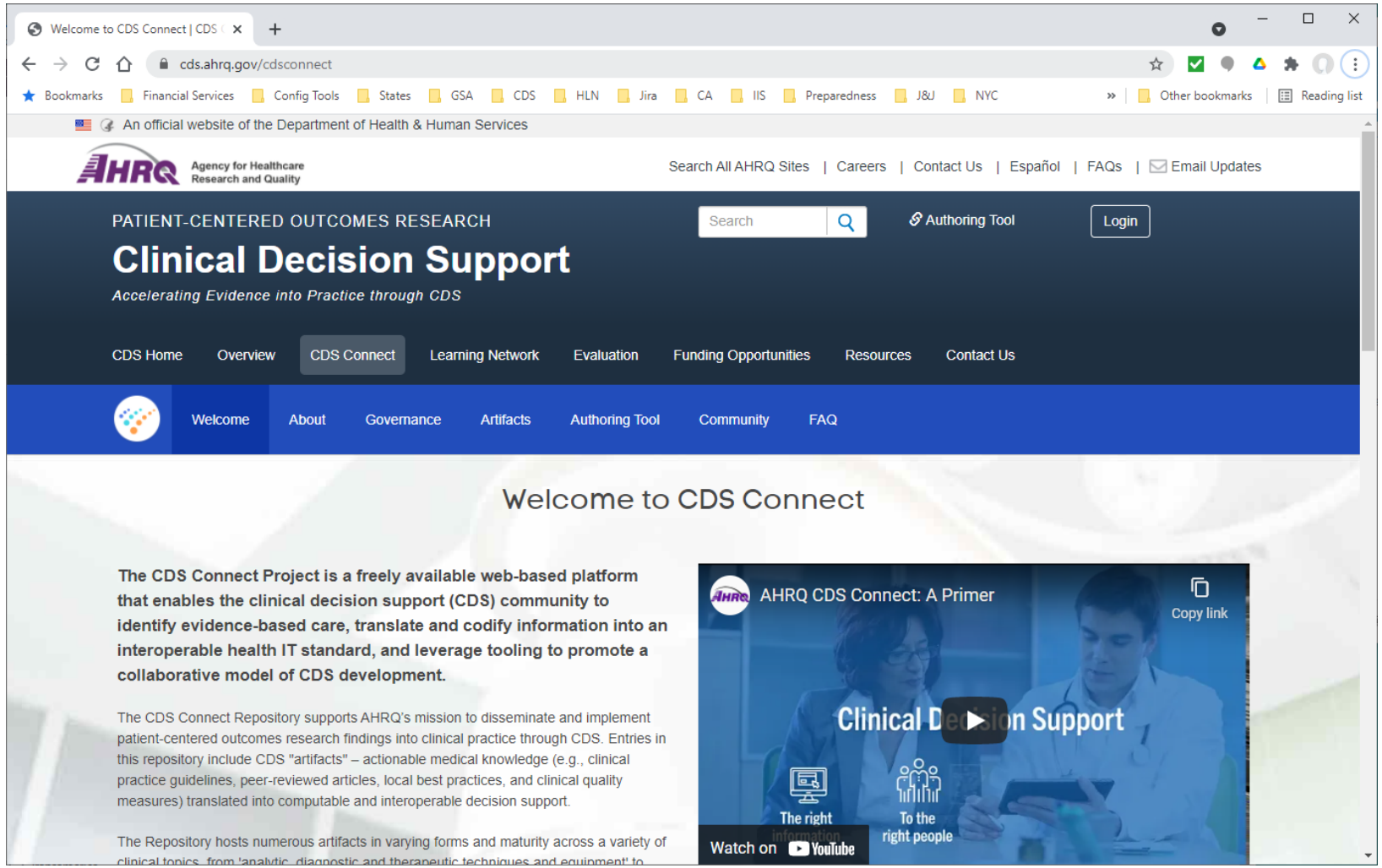
AHRQ: CDSConnect



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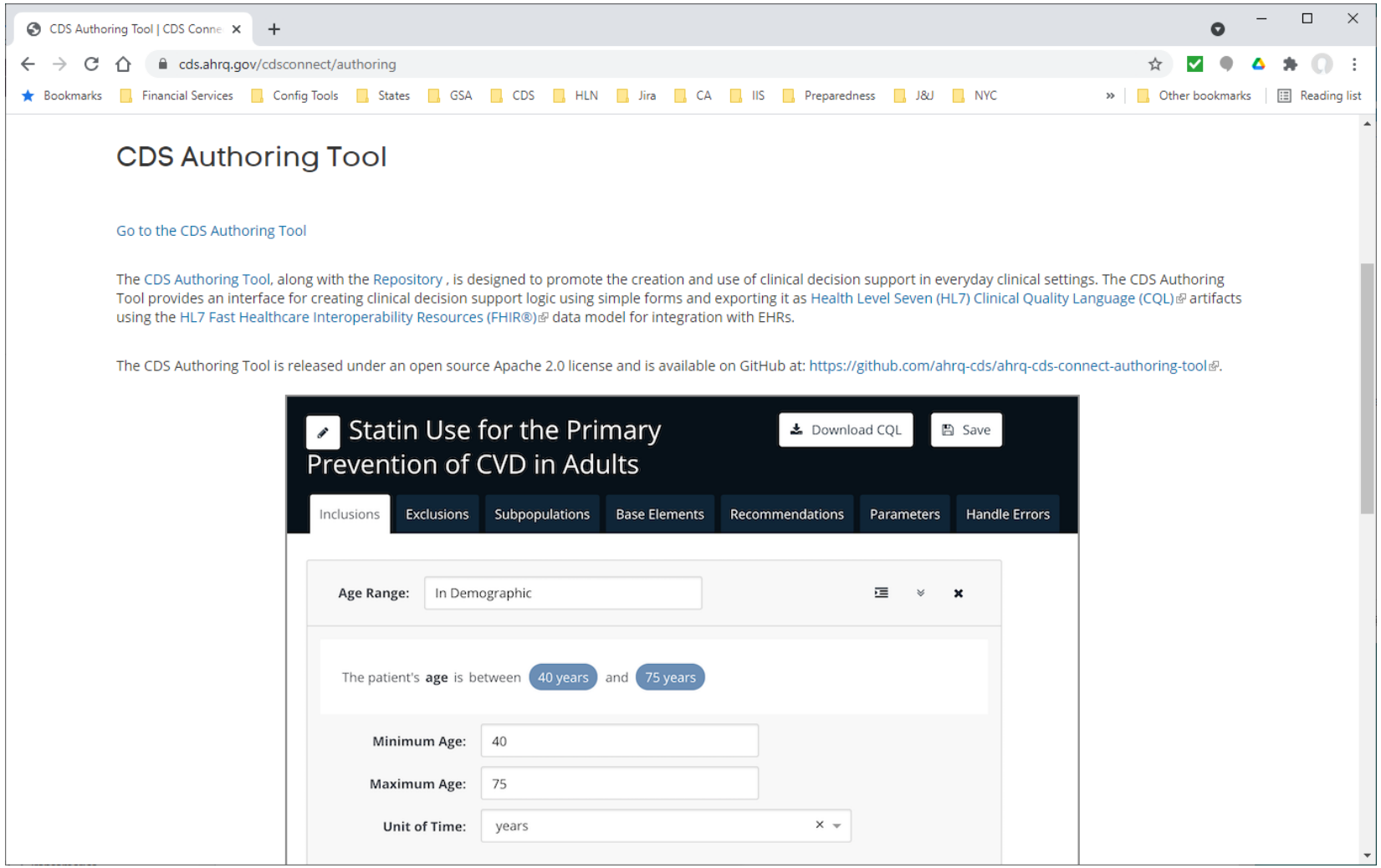
CDS Connect Authoring Tool



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CDS for Immunization

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Examples of Immunization Forecasting

- Evaluations (of immunization history)
  - The polio shot that was administered to the patient on June 1, 2013, was **invalid**.
  - The Td shot that was administered to the patient on March 15, 2014, was **valid**.
- Recommendations
  - The patient's next meningococcal vaccine is **due on September 20, 2015**.
  - The patient has **completed** their MMR immunizations.

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Obstacles to Implementing and Maintaining CDS for Immunizations

- Decisions change simply with the passage of time (patient ages)
- Quantity of immunizations: more than 36 immunizations by age 12
- New vaccines coming to market
- Evolving guidelines from the Advisory Committee on Immunization Practices (ACIP)
- Different protocols followed in different clinical settings
- Often dependence on one or two key staff member to maintain
- Burden of regression testing—test cases age
- Competing priorities, both for EHR/PHRs and public health
- Lack of consistent funding to support ongoing maintenance

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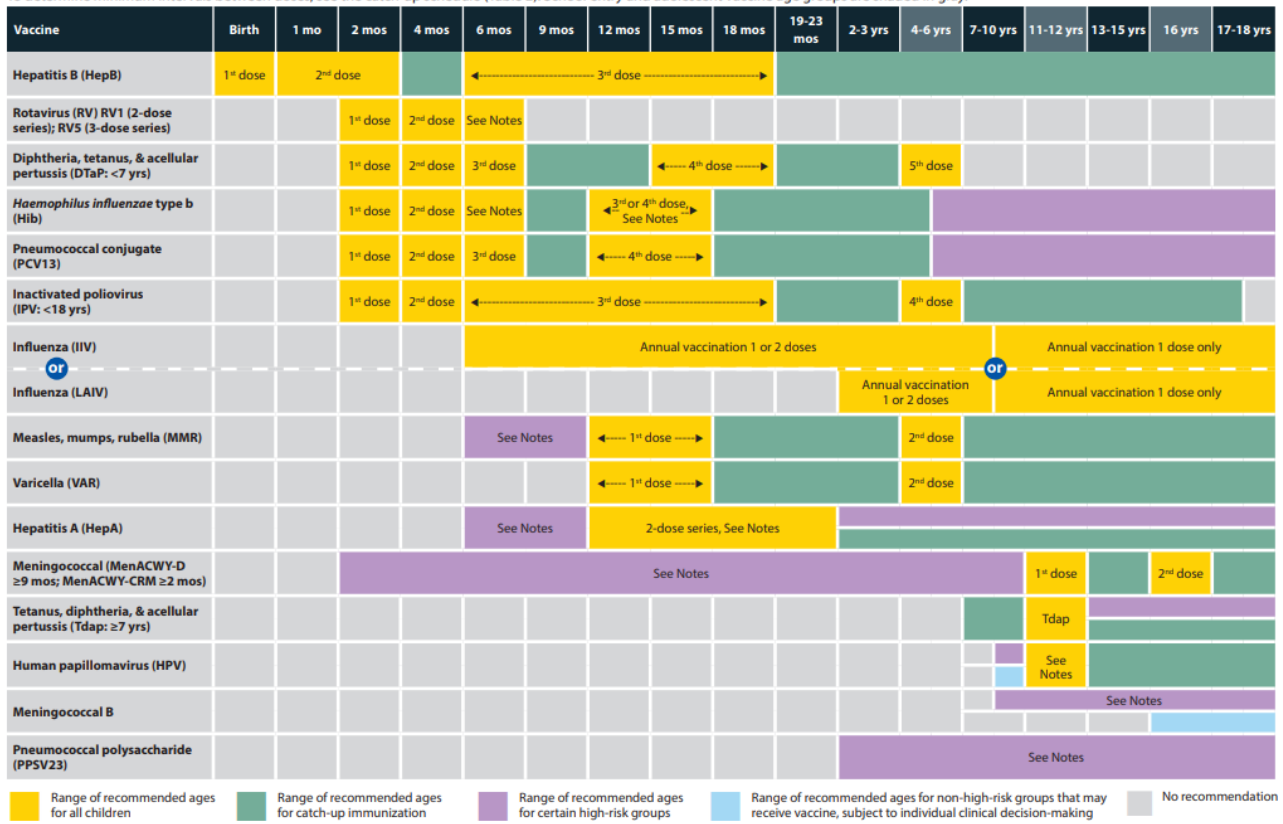
Recommended Immunization Schedule: Birth to 18 Years

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger
United States, 2019

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Table 1. To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.



http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

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Complex! (1 of 4 Pages of Footnotes)

Notes — Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2019

Pneumococcal vaccination
(minimum age: 6 weeks [PCV13], 2 years [PPSV23])

Routine vaccination with PCV13
- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV13
- 1 dose for healthy children age 24–59 months with any incomplete* PCV13 series
- For other catch-up guidance, see Table 2.

Special situations

High-risk conditions below: When both PCV13 and PPSV23 are indicated, administer PCV13 first. PCV13 and PPSV23 should not be administered during same visit.

Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Age 6–18 years
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Cerebrospinal fluid leak, cochlear implant:

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13, 8 weeks after the most recent dose and administered 8 weeks apart
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

Age 6–18 years
- No history of either PCV13 or PPSV23: 1 dose PCV13, 1 dose PPSV23 at least 8 weeks later
- Any PCV13 but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV13
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent dose of PPSV23

Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:

Age 2–5 years
- Any incomplete* series with:
  - 3 PCV13 doses: 1 dose PCV13 (at least 8 weeks after any prior PCV13 dose)
  - Less than 3 PCV13 doses: 2 doses PCV13 (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose) and a 2nd dose of PPSV23 5 years later

Age 6–18 years
- No history of either PCV13 or PPSV23: 1 dose PCV13, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV13 but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV13 and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV13: 1 dose PCV13 at least 8 weeks after the most recent PPSV23 dose and a 2nd dose of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV13

Chronic liver disease, alcoholism:

Age 6–18 years
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after any prior PCV13 dose)

*An incomplete series is defined as not having received all doses in either the recommended series or an age-appropriate catch-up series. See Tables 8, 9, and 11 in the ACIP pneumococcal vaccine recommendations (www.cdc.gov/mmwr/pdf/rr/rr5911.pdf) for complete schedule details.

Rotavirus vaccination
(minimum age: 6 weeks)

Routine vaccination
- **Rotarix:** 2-dose series at 2 and 4 months.
- **RotaTeq:** 3-dose series at 2, 4, and 6 months.

If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

Catch-up vaccination
- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Figure 2.

Tetanus, diphtheria, and pertussis (Tdap) vaccination
(minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination
- **Adolescents age 11–12 years:** 1 dose Tdap
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination
- **Adolescents age 13–18 years who have not received Tdap:** 1 dose Tdap, then Td booster every 10 years
- **Persons age 7–18 years not fully immunized with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td.
- **Children age 7–10 years** who receive Tdap inadvertently or as part of the catch-up series should receive the routine Tdap dose at 11–12 years.
- **DTaP inadvertently given after the 7th birthday:**
  - **Child age 7–10 years**: DTaP may count as part of catch-up series. Routine Tdap dose at 11–12 should be administered.
  - **Adolescent age 11–18 years**: Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.
- For information on use of Tdap or Td as tetanus prophylaxis in wound management, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Varicella vaccination
(minimum age: 12 months)

Routine vaccination
- 2-dose series: 12–15 months, 4–6 years
- Dose 2 may be administered as early as 3 months after dose 1 (a dose administered after a 4-week interval may be counted).

Catch-up vaccination
- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2-dose series:
  - **Ages 7–12 years**: routine interval: 3 months (minimum interval: 4 weeks)
  - **Ages 13 years and older**: routine interval: 4–8 weeks (minimum interval: 4 weeks).
  - The maximum age for use of *MMRV* is 12 years.

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But a Good Candidate for Development!

- Routine, lifelong events
- With all its complexity, knowledge relatively stable with general consensus clinically
- Good results achievable; serves as a good “test case” for CDS overall
- CDC’s Clinical Decision Support for Immunization (CDSi): consensus-driven logic specification

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Clinical Decision Support for Immunizations

- More commonly referred to as vaccine evaluation and forecasting services by the immunization community
- Performed by many different computer systems
  - Electronic health record systems (EHRs)
  - Immunization information systems (IIS)
  - Stand-alone applications: web-based schedulers, smart phone apps, etc.

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CDC CDSi Project

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Bridging the Gap

The CDSi resources bridge the gap between the scientific ACIP recommendations and the IT world of computer systems.

- Designed to work in a wide variety of computer systems
  - Doesn’t require a single tool to be used
  - Needs to be able to support all software tools using ACIP logic
- Promotes consistent interpretation of ACIP recommendations in a wide variety of tools
- Helps ensure that a patient’s immunization status is current, accurate, and consistent, regardless of where the provider is located in the United States

Before the Clinical Decision Support for Immunization (CDSi) Project, Part IV

ACIP recommendations with Communication and Education Branch (CEB) clarifications

System A

System B

System C

Individual interpretation and implementation

System C recommendation

System B recommendation

System A recommendation

With CDSi, Part IV

ACIP recommendations with Communication and Education Branch (CEB) clarifications

=

CDSi resources

Individual implementation

Consistent system recommendations

Project Clarification

The Project Is Not…	The Project Is…
New vaccine recommendations	**A catalog of existing ACIP recommendations in a computer-friendly format**
A software application	**Computable and implementation-neutral logic framework and data that can be used by a variety of different systems and configurations**
A replacement for current computer systems	**Clarification and validation for existing systems or guidelines to improve systems**

CDSi Resources

The complete suite of CDSi resources comprises:

Logic Specification	Supporting Data	Test Cases
– Vocabulary – Business Rules – Decision Tables – Processing Definitions – Domain Model	– Excel Format – XML Format – Release Notes	– Excel Format – XML Format – Test Case Management Tool
Training Materials	– Brochure – Quick Guides	– Practice Exercise – Quiz	– Videos

Immunization Calculation Engine (ICE) Project

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Goal of the ICE Project

Objective	Achievement
Supports routinely administered vaccine groups	• Supports 17 vaccine groups from birth through adulthood (now COVID-19)
Promotes clinical best practices	• Follows ACIP recommendations • Informed by CDC's CDSi project
Adapts to changing requirements	• Tools for self-administration if practical • Automated testing tool • Engineered for high performance and scalability
Easily integrates with IIS and other health systems	• Standards-based architecture and APIs • Variety of deployment options
Software and knowledge base freely available	• Standard, permissive open-source license (LGPL v3) • Downloadable from public website

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Project Principles

- Changes to the open source software should be available to all users.
- A base set of rules developed by consensus should be maintained and be freely available to all users.
- Alternate rule sets may or may not be freely available at the discretion of the organizations that create them or sponsor their creation.
- Resources and activities should be leveraged across participants as much as possible.
- Anyone may create products with “enhanced features” that must comply with the open source license but might not be freely available.

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Original ICE Collaborators

- New York City Citywide Immunization Registry (CIR)
- HLN Consulting, LLC
- Alabama Department of Public Health
- OpenCDS team
  - Software platform and toolkit
  - Open source
  - Standards-based
  - Web service interface
  - Collaborative project:
    Dr. Kensaku Kawamoto at University of Utah

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ICE: “Five Rights”

The right information	The architecture delivers a clear determination, based on the clinical data provided about whether the patient’s past immunizations are valid, and based on that determination, what immunizations may be due now or in the future.
To the right person(s)	The determination of whether the patient requires immunizations is delivered directly to the provider or his/her designee, as well as directly to the patient if desired.
Using the right intervention format	Once the clinical decision support is activated—locally or centrally—EHRs should be able to display immunizations due as alerts, on reports, or through practice-level or population-level reminder/recall processes.
In the right channel	EHRs and registries should be able to display immunizations due within their user interface.
At the right time during workflow	EHRs can decide how and if the clinician is alerted within the workflow. This can be done before a patient is seen or at the point of service.

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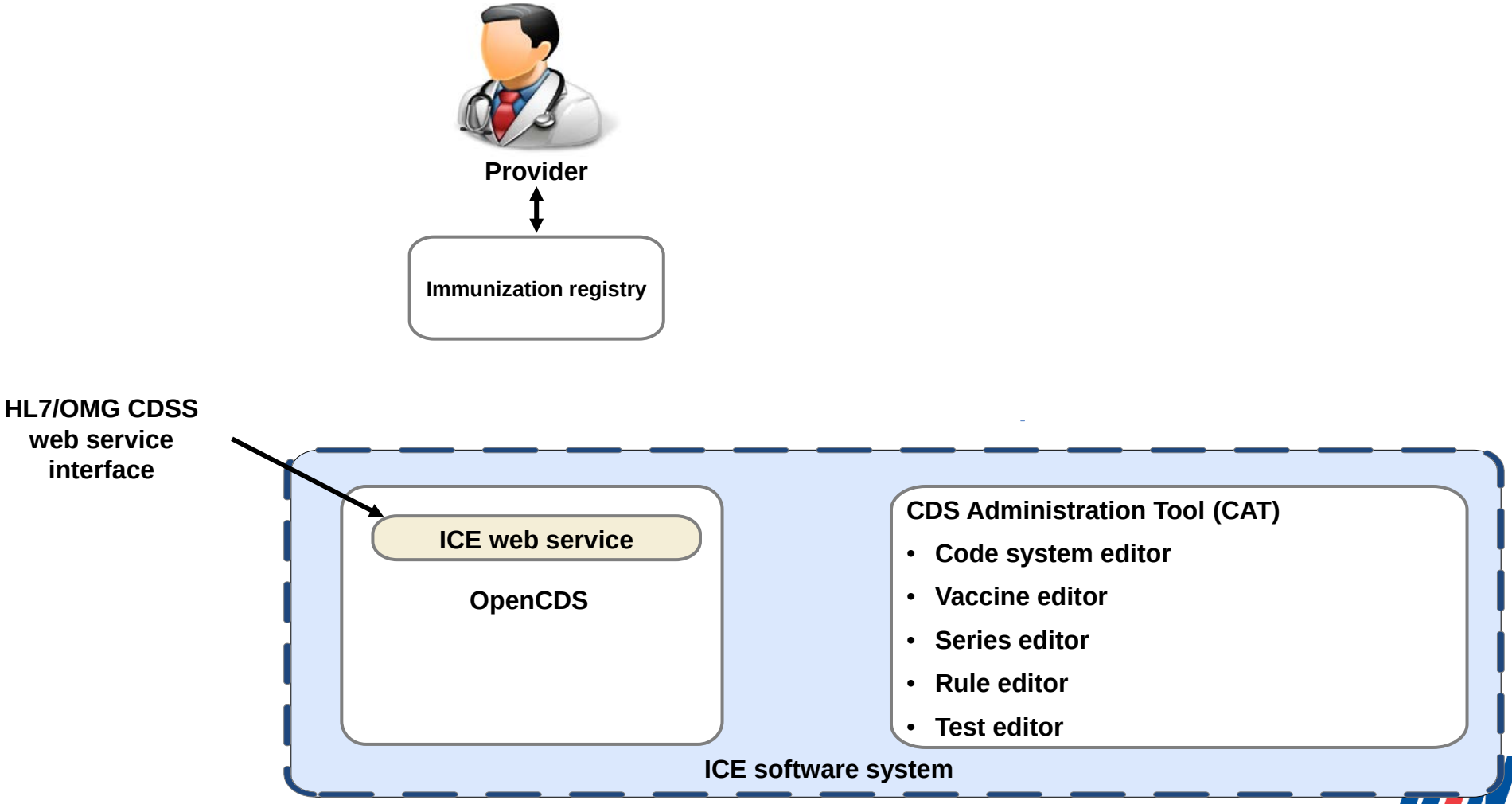
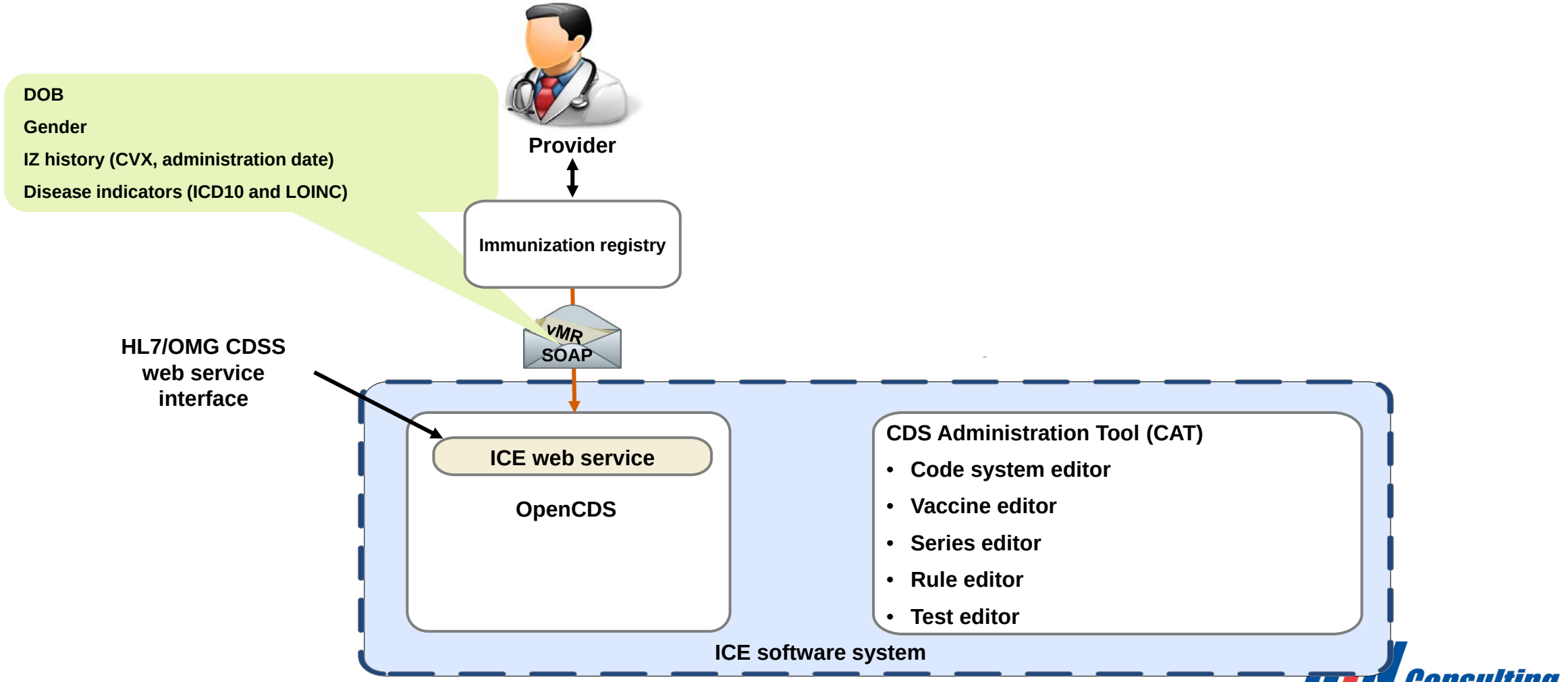
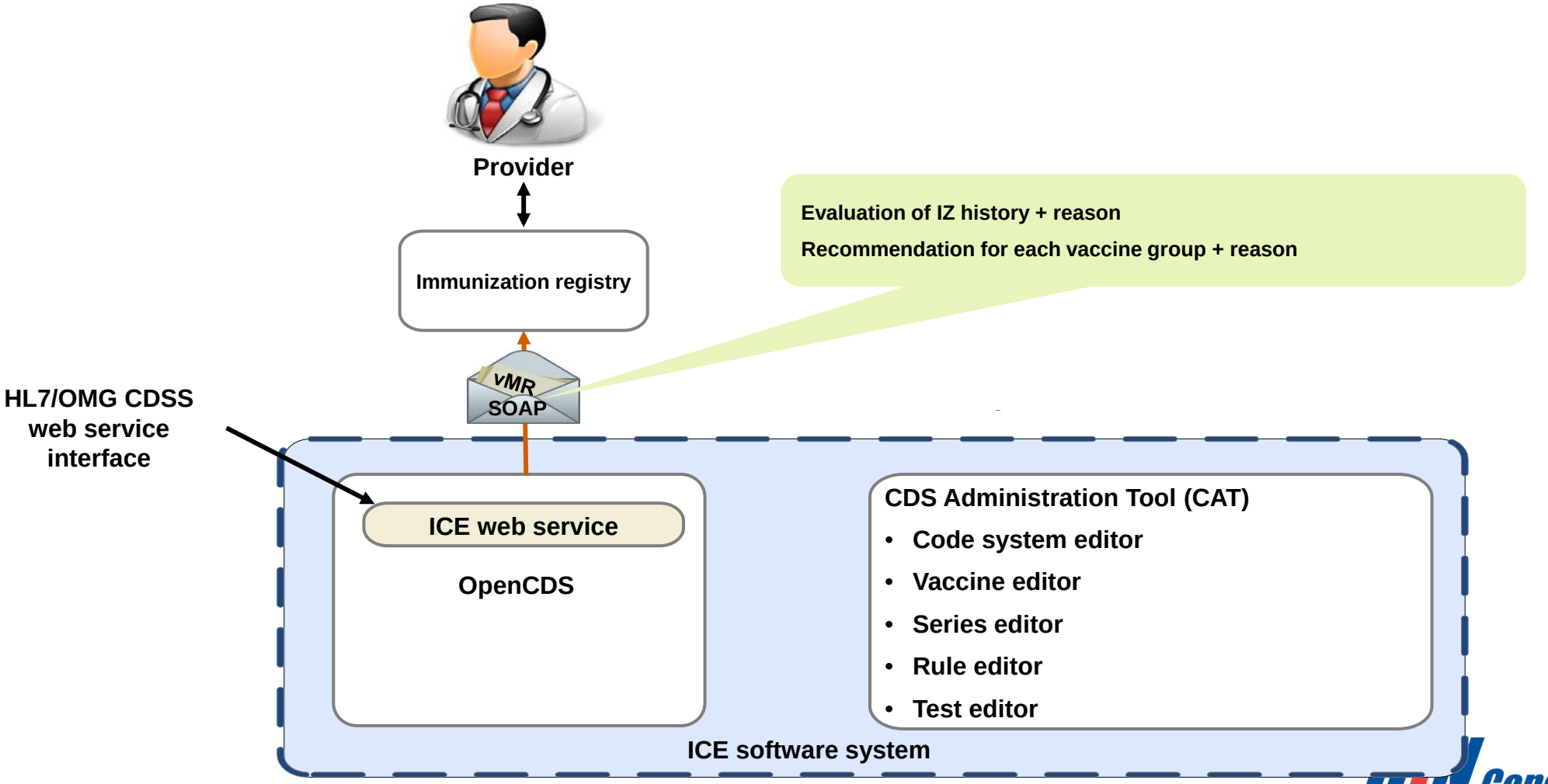
How Does ICE Work? Part I



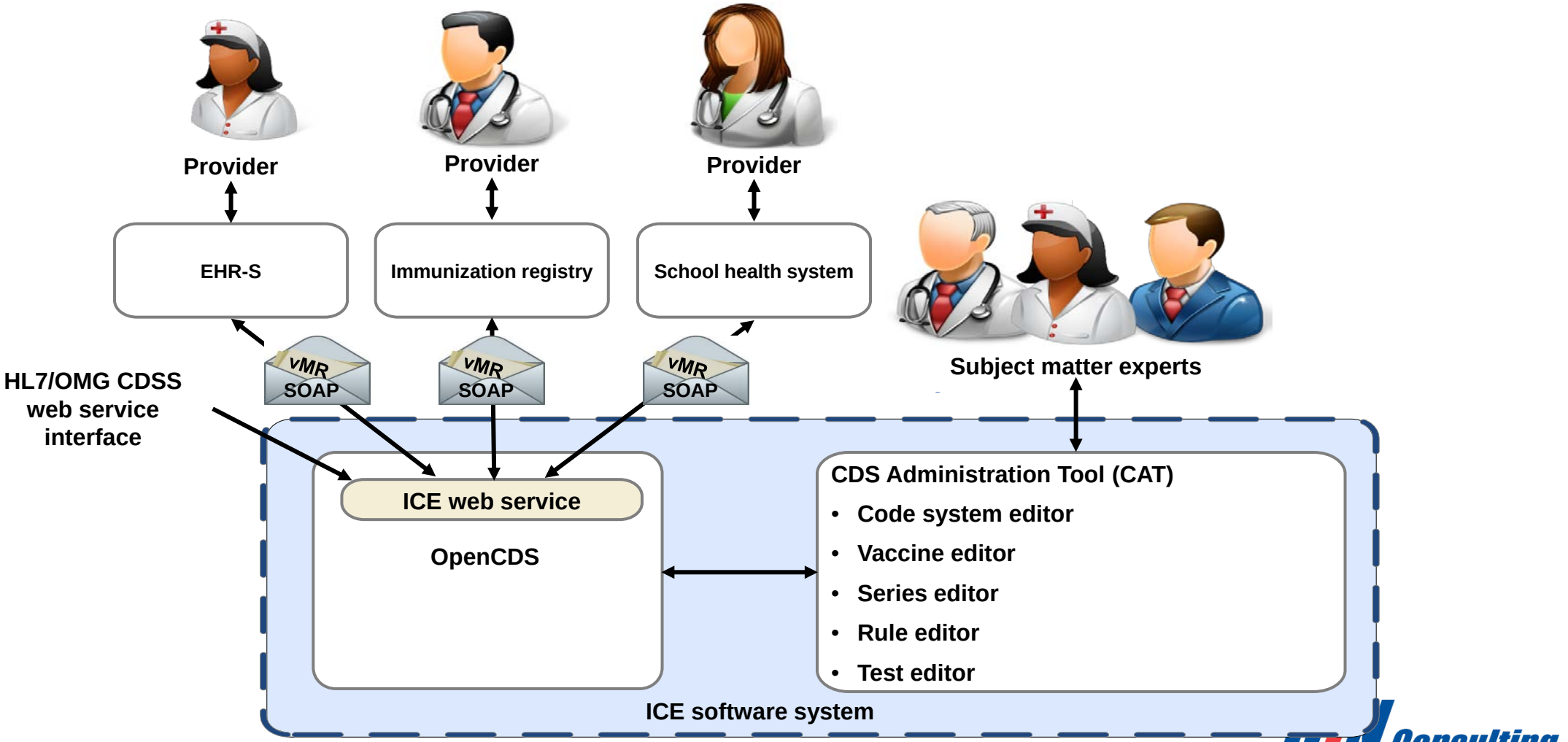
How Does ICE Work? Part II



How Does ICE Work? Part III

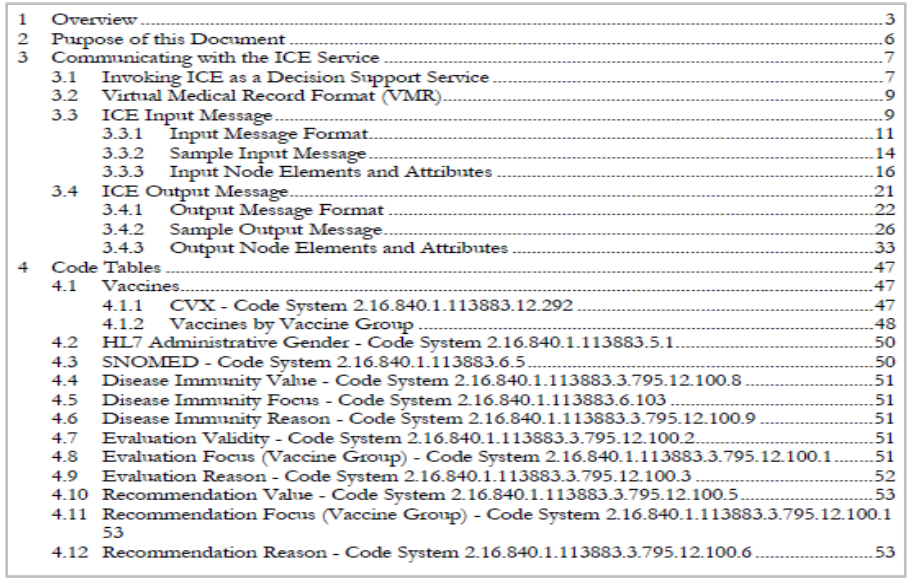


How Does ICE Work? Part V



Easy to Adopt and Integrate (cont.)

- Open source (GNU LGPL v3)
- Java-based system runs on a wide variety of sever platforms
- Can be deployed in a variety of ways
- Standards-based web service interface
- Comprehensive documentation
  - Public wiki: CDS Framework
  - Implementation Guide for Integrating with ICE
  - ICE Default Immunization Schedule
  - Binary releases
  - Source code



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Immunization Information Systems (IIS)

- Previously referred to as “immunization registries”
- Defined as *“confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area”*
- Provide services at the point of care as well as at a population level

https://www.cdc.gov/vaccines/programs/iis/about.html

IIS and CDS for Immunizations

- One of the core components of an IIS is its immunization evaluation and forecasting system
- Used to support CDS at the point of care and also to help public health agencies understand and manage the immunization status of whole populations.
- CDC CDSi project grew out of IIS
- ICE grew out of IIS
- IIS at the forefront of CDS for immunizations

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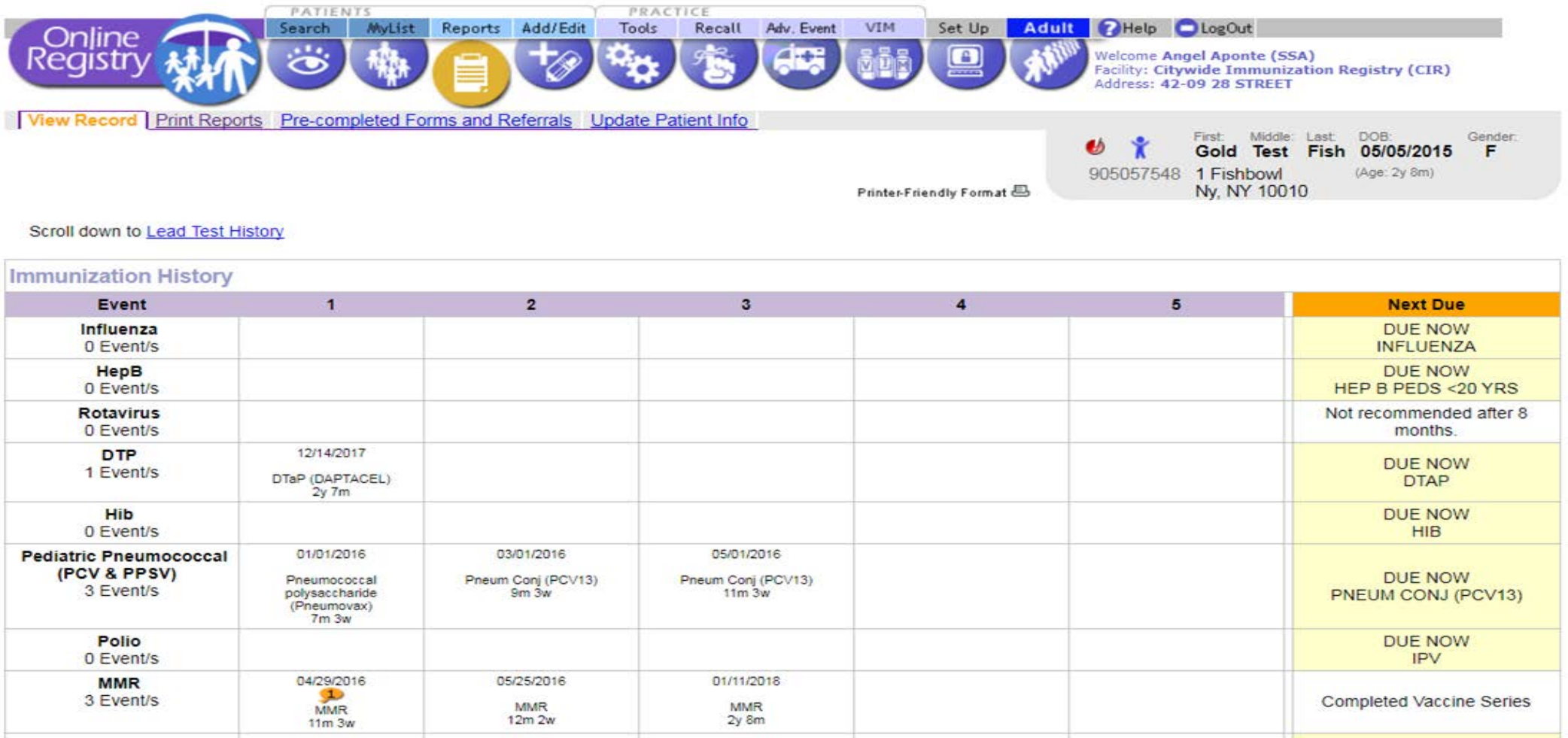
Provider View: NYC CIR, Part I



Immunization History

Event	1	2	3	4	5	Next Due
Influenza 0 Event/s						DUE NOW INFLUENZA
HepB 0 Event/s						DUE NOW HEP B PEDS <20 YRS
Rotavirus 0 Event/s						Not recommended after 8 months.
DTP 1 Event/s	12/14/2017 DTaP (DAPTACEL) 2y 7m					DUE NOW DTAP
Hib 0 Event/s						DUE NOW HIB
Pediatric Pneumococcal (PCV & PPSV) 3 Event/s	01/01/2016 Pneumococcal polysaccharide (Pneumovax) 7m 3w	03/01/2016 Pneum Conj (PCV13) 9m 3w	05/01/2016 Pneum Conj (PCV13) 11m 3w			DUE NOW PNEUM CONJ (PCV13)
Polio 0 Event/s						DUE NOW IPV
MMR 3 Event/s	04/29/2016 MMR 11m 3w	05/25/2016 MMR 12m 2w	01/11/2018 MMR 2y 8m			Completed Vaccine Series

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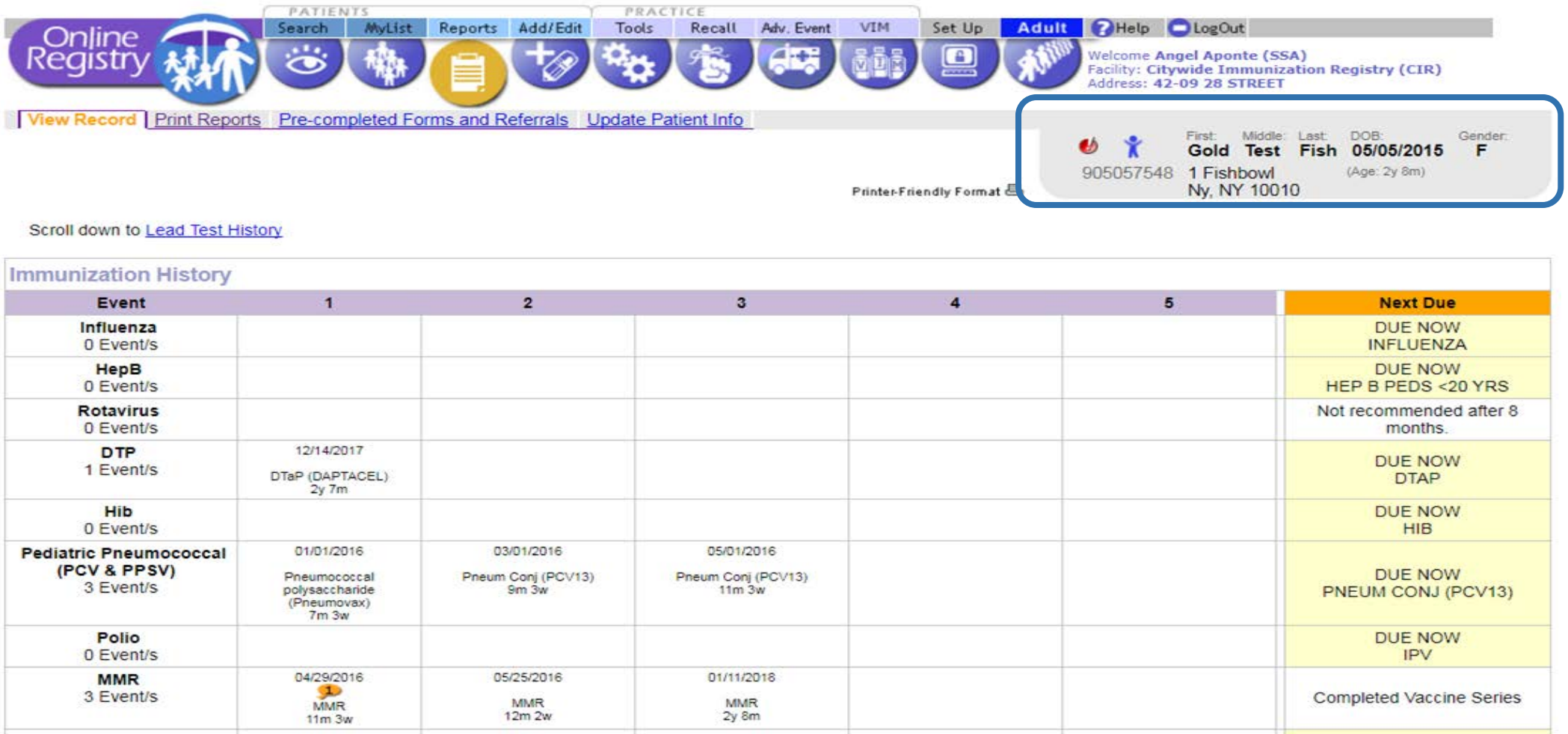
Provider View: NYC CIR, Part II



Immunization History

Event	1	2	3	4	5	Next Due
Influenza 0 Event/s						DUE NOW INFLUENZA
HepB 0 Event/s						DUE NOW HEP B PEDS <20 YRS
Rotavirus 0 Event/s						Not recommended after 8 months.
DTP 1 Event/s	12/14/2017 DTaP (DAPTACEL) 2y 7m					DUE NOW DTAP
Hib 0 Event/s						DUE NOW HIB
Pediatric Pneumococcal (PCV & PPSV) 3 Event/s	01/01/2016 Pneumococcal polysaccharide (Pneumovax) 7m 3w	03/01/2016 Pneum Conj (PCV13) 9m 3w	05/01/2016 Pneum Conj (PCV13) 11m 3w			DUE NOW PNEUM CONJ (PCV13)
Polio 0 Event/s						DUE NOW IPV
MMR 3 Event/s	04/29/2016 MMR 11m 3w	05/25/2016 MMR 12m 2w	01/11/2018 MMR 2y 8m			Completed Vaccine Series

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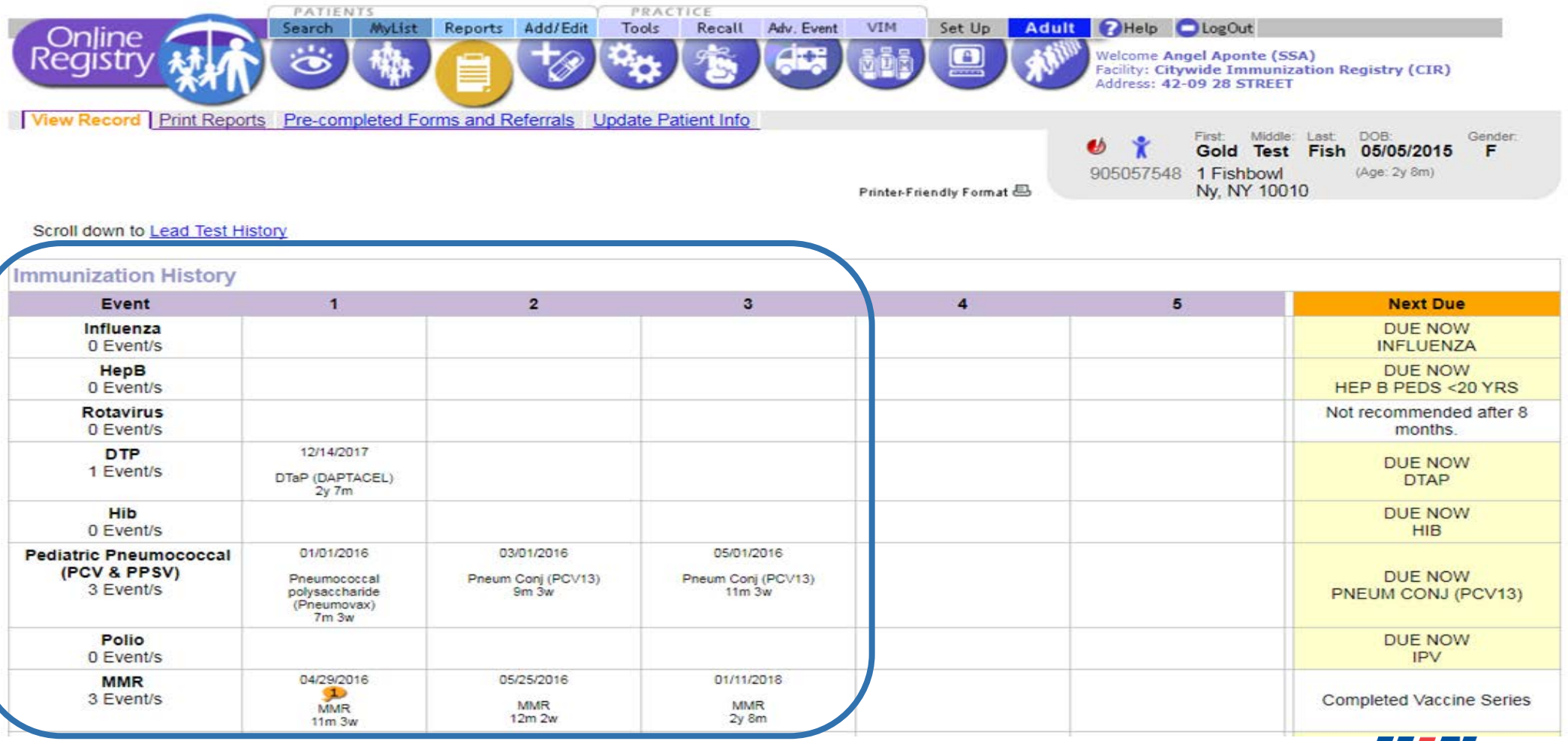
Provider View: NYC CIR, Part III



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Invalid Dose: NYC CIR

(PCV & PPSV) 3 Event/s	Pneumococcal polysaccharide (Pneumovax) 7m 3w	Pneum Conj (PCV13) 9m 3w	Pneum Conj (PCV13) 11m 3w
Polio 0 Event/s			
MMR 3 Event/s	04/29/2016 1 MMR 11m 3w	05/25/2016 MMR 12m 2w	01/11/2018 MMR 2y 8m
Varicella 0 Event/s			
HepA 0 Event/s			
Meningococcal			

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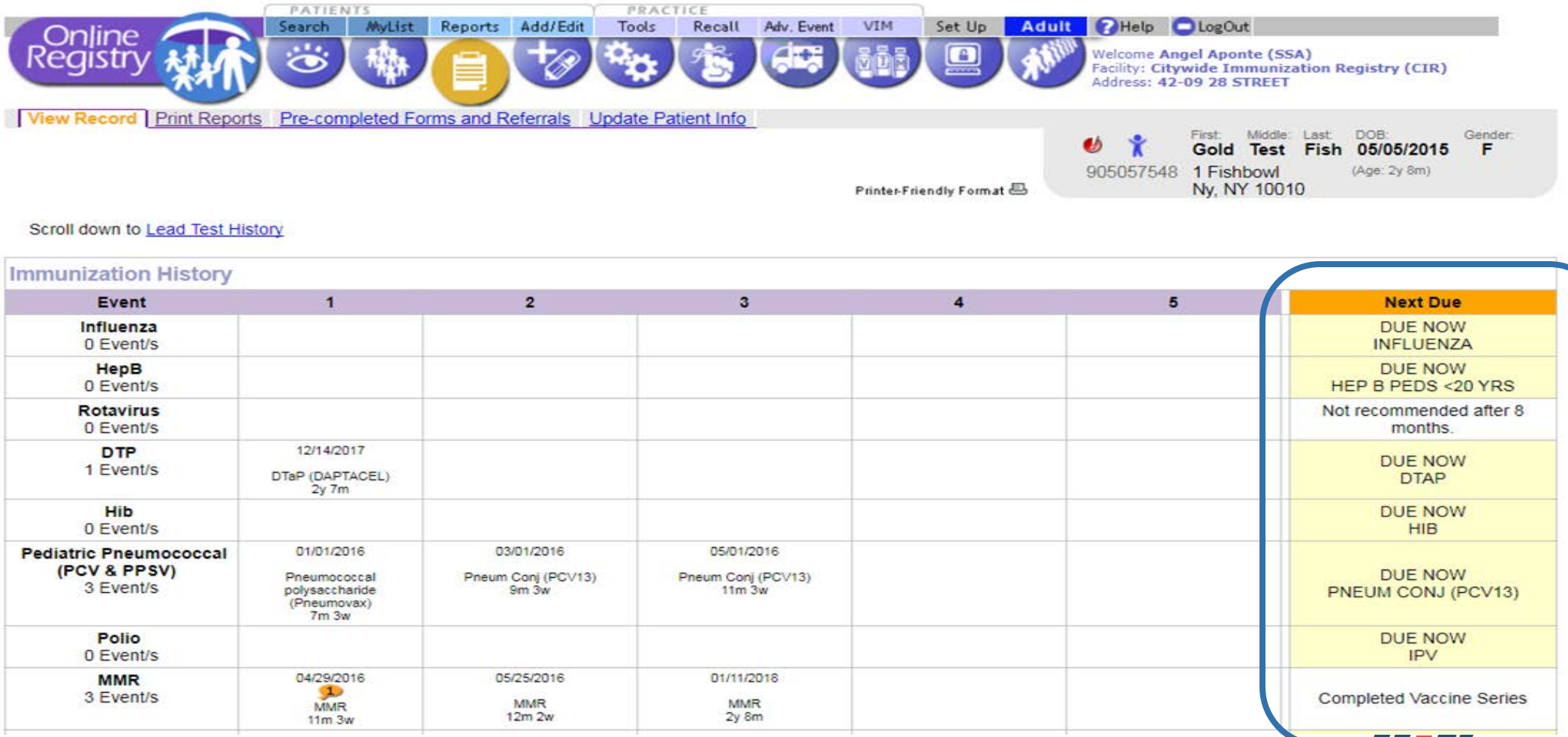
Provider View: NYC CIR



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CDS for Electronic Case Reporting (eCR)

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Business Case for eCR

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Case Reporting Fundamentals

- Public health surveillance: reporting of infectious and certain non-infectious conditions to state, local, territorial, and tribal public health agencies (PHA)
- Allows PHAs to monitor, control, and prevent the occurrence and spread of diseases and conditions within the population
- CDC provides leadership and funding to assist states in collecting this information and request notification of the occurrence of a national set of conditions to CDC
- Once a case is established, PHAs have established protocols for different conditions
  - Contact tracing from the patient to determine if others are affected
  - Prophylaxis such as targeted (or even mass) immunizations or medication administration (e.g., antibiotics)
  - Education to ensure that affected or potentially affected patients are informed about the risks or of the impact of subsequent behavior
- Case reporting is the event that sets these interventions in motion

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Case Reporting Today: Challenges

- Manual process: The quality, timeliness, and completeness of case reports is widely variable.
- There are differing laws about which conditions require a case report and how quickly the reports need to be submitted.
- Some jurisdictions require a case report based on where *the care was given*; some require a case report based on where *the patient lives*, and some require both.
- Clinical guidelines surrounding how one determines that a reportable condition exists can be complicated and varying.
- Some jurisdictions have trouble matching case report data with ELR data.
- In some cases, a report is required when a condition is *suspected,* not necessarily *confirmed,* and this represents a key note of urgency that is not always adequately met by current reporting.

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Electronic Case Reporting (eCR)

Electronic case reporting (eCR) is the automated identification and transmission of reportable health events from the electronic health record (EHR) to state and local public health departments. Because eCR uses a consensus set of trigger events and a standardized format, EHR vendors can incorporate automated case reporting into the medical record systems consistently across the nation, minimizing development time and simplifying disease reporting for providers. Because the EHR is the data source for case reports, eCR will improve the completeness of patient contact, clinical, and epidemiologic information to jump start case investigations.

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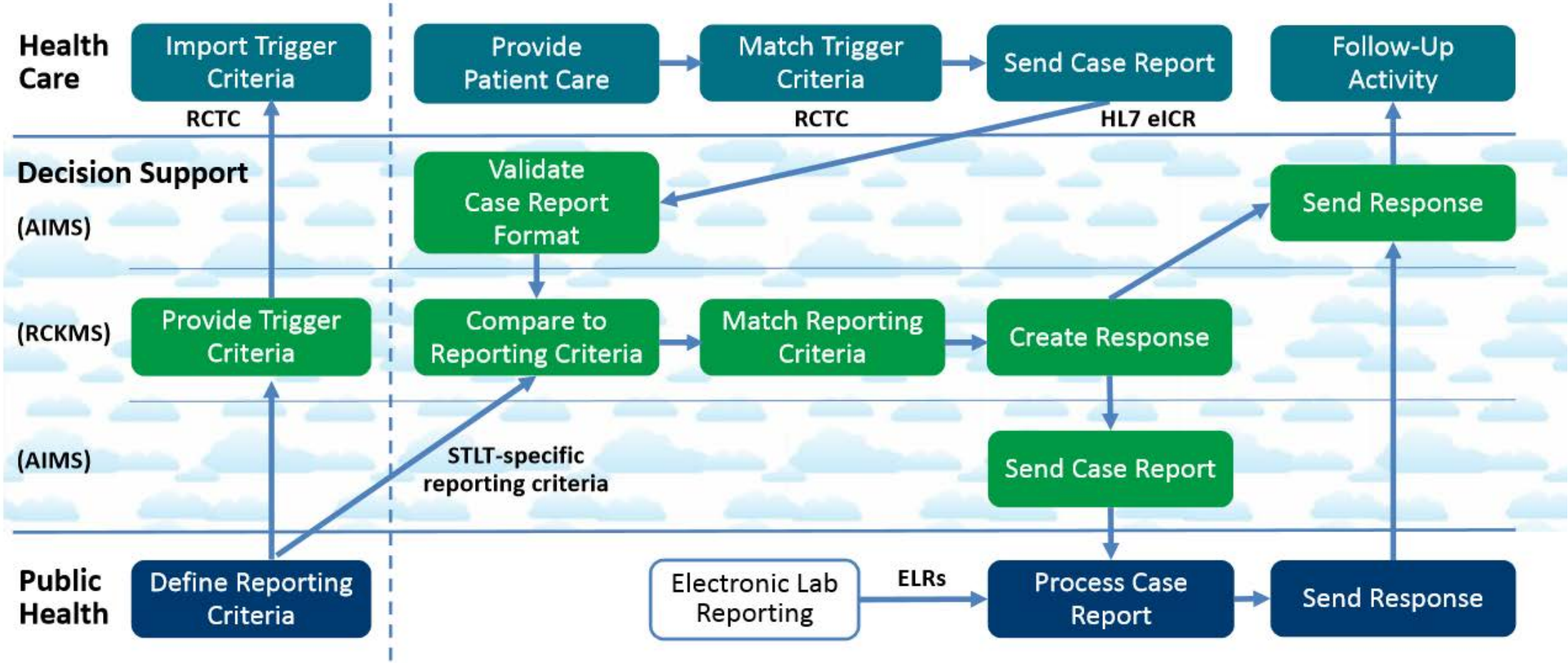
https://wwwn.cdc.gov/nndss/electronic-case-reporting.html

Electronic Case Reporting Process Flow



Source: http://www.digitalbridge.us/db/wp-content/uploads/2017/03/DigitalBridge_eCR_MidLevelDiagram_20170213.pdf

Reportable Conditions Knowledge Management System

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Reportable Conditions Knowledge Management System (RCKMS)

- CDS component of national eCR strategy
- Funded by CDC, developed by the Council of State and Territorial Epidemiologists (CSTE) and their partners
- Allows jurisdictions to author rules in a distributed manner that determine whether a patient's encounter is reportable for certain conditions
- Decision support service (DSS) to which the authored rules are deployed

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RCKMS Purpose

RCKMS answers several key questions.

- Do the clinical data represent an event reportable to one or more public health agencies?
- If so, which condition(s) is reportable?
- To which public health authority(ies) is the condition(s) reportable?

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RCKMS: “Five Rights”

The right information	The architecture delivers a clear determination, based on the clinical data provided about whether the patient represents a reportable event to public health. If the event is reportable, the actions required to report to public health are also provided.
To the right person(s)	The determination of whether the patient is considered reportable is delivered directly to the provider or his/her designee, as well as the appropriate public health agency.
Using the right intervention format	Once the clinical decision support is activated—locally or centrally—EHRs should be able to display case determinations as alerts or simply as an item in the medical record. But more likely, the EHR will trigger the transmission of an electronic report to public health automatically without clinician intervention.
In the right channel	EHRs should be able to display case determinations within their user interface. Public health agencies should be able to receive a report that they may import into their case management systems as needed.
At the right time during workflow	EHRs can decide, based on the determination of reportability, how and if the clinician is alerted within the workflow. Public health will receive reports and process them within their workflow.

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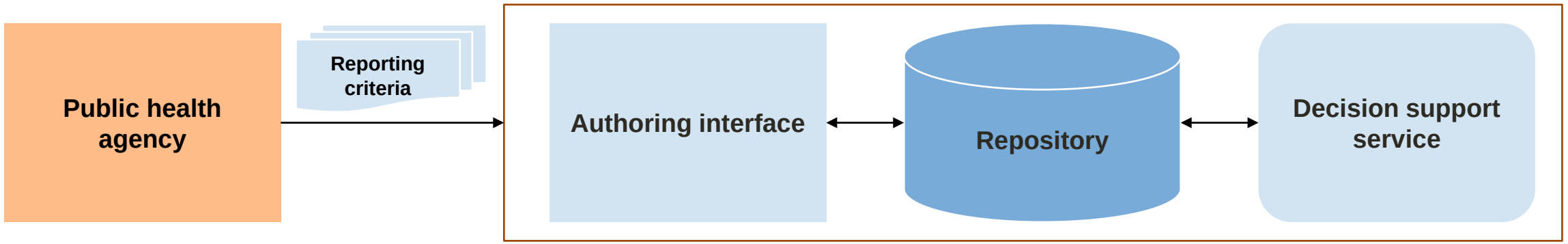
RCKMS Components



1. ***Authoring interface:*** jurisdiction enters reporting specifications into tool that comes prepopulated with *default reporting specifications* that PHAs can choose to use as is or customize to meet their needs
2. ***Repository:*** reporting specifications and criteria stored in a repository
3. ***Decision support service (DSS):*** reporting specifications deployed from the repository to DSS (rules engine)

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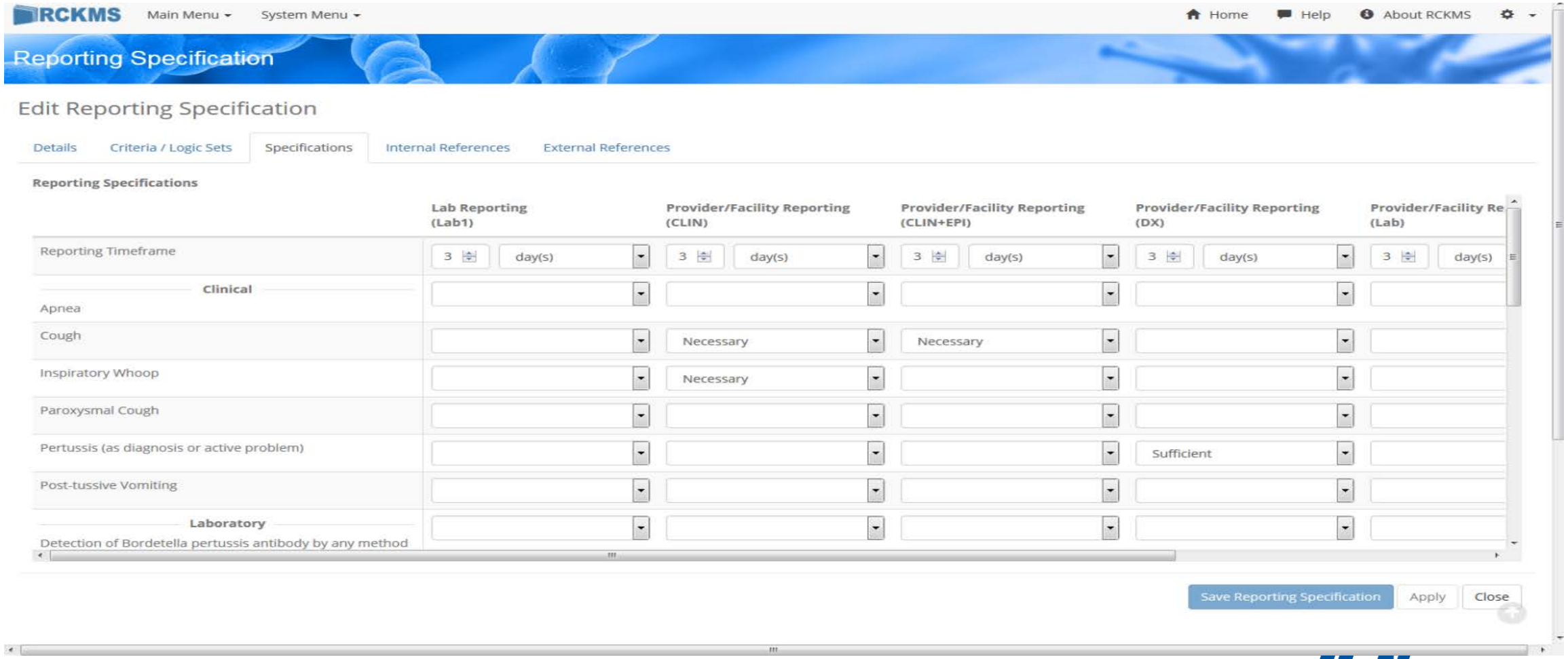
Maintaining RCKMS Rules



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Software Architecture

OpenCDS CDS service

- Java servlet container (Tomcat 7/8/9)
- JBoss Drools rules engine
- HL7/OMG Decision Support Service “DSS” (web service interface)
- HL7 Virtual Medical Record “vMR” (data model)
- Working to support CQL evaluation via CDS hooks interface (as additional rules language and interface option)
- Working to support FHIR compatibility for RCKMS service

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Software Architecture (cont.)

Authoring tool

- Application server (Java EE compliant)
- Responsive UI: based on Bootstrap and React tooling
- Enterprise JavaBeans business logic
- Any JDBC-compliant database (currently PostgreSQL)

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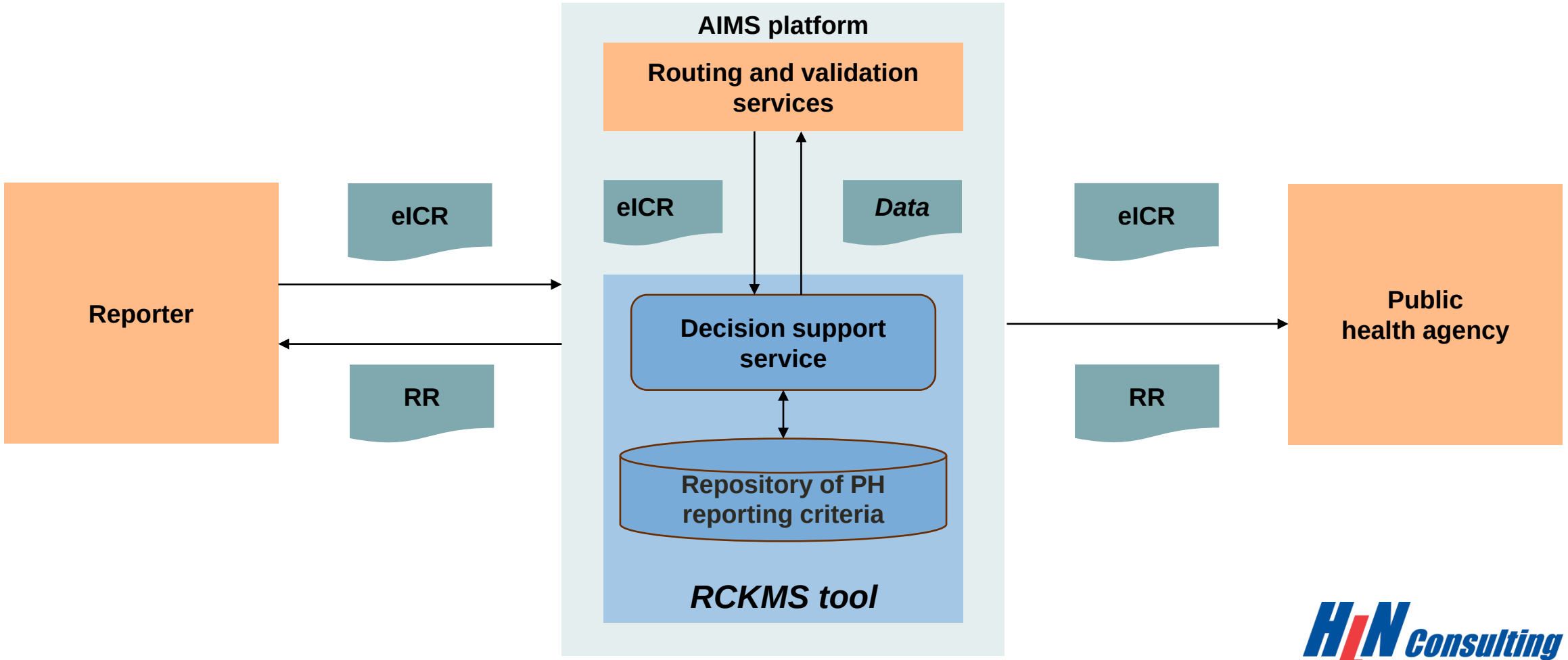
RCKMS: Centralized Approach, Part I



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Benefits of a Centralized Approach

- Ensure a standards-based approach
  - HL7 electronic initial case report (eICR)
  - HL7 reportability response
- Scalable
  - Centralized AIMS platform
  - Established trust framework
- Shared set of rules for all jurisdictions
- Collaborative effort and governance (through Digital Bridge project)

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Summary and Conclusions

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Summary and Conclusions

- CDS is critical to healthcare systems
- Some areas more mature, some less mature
- Standards still evolving to do this work in a consistent way
- Tension between the “mysteries” of artificial intelligence (AI) and discoverable rules in CDS

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CDS: General Resources

Resource Name/Description	URL
IMIA Yearbook 2018 for Decision Support	https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0039-1677929
AHRQ CDS Connect	https://cds.ahrq.gov/cdsconnect
AHRQ Patient-Centered Clinical Decision Support Learning Network	https://pccds-ln.org/
CDC Adapting Clinical Guidelines for the Digital Age	https://www.cdc.gov/ddphss/clinical-guidelines/index.html
HL7 Clinical Quality Language (CQL)	https://cql.hl7.org/
CDS hooks	https://cds-hooks.org/

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CDS: ICE Resources

Resource Name/Description	URL
Basic information	https://www.hln.com/ice/
Main public wiki page	https://cdsframework.atlassian.net/wiki/display/ICE/Home
Rules/philosophy	https://cdsframework.atlassian.net/wiki/display/ICE/Default+Immunization+Schedule
Software and documentation	https://cdsframework.atlassian.net/wiki/display/ICE/Downloads
Journal articles	Suralik MJ et al. The immunization calculation engine, open source clinical decision support for immunizations. *Journal of Healthcare Information Management.* 2013(27):3. Arzt NH. Clinical decision support for Immunizations (CDSi): A comprehensive, collaborative strategy, Biomedical Informatics Insights, Suppl. 2013(2).
Feature article	http://www.openhealthnews.com/articles/2019/anatomy-public-health-open-source-project-hlns-immunization-calculation-engine-ice

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CDS: eCR Resources

Resource Name/Description	URL
Digital Bridge project	https://digitalbridge.us/
CDC eCR home page	https://wwwn.cdc.gov/nndss/electronic-case-reporting.html
CSTE RCKMS home page	https://www.cste.org/group/RCKMS
OpenCDS	http://www.opencds.org/
Feature article: RCKMS	http://www.openhealthnews.com/story/2019-05-23/clinical-decision-support-strategies-electronic-case-reporting-and-its-open-source-

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