Clinical Decision Support for Immunizations as a Community-drive, Standards-based Activity

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Topics

- The Business Case for CDS for Immunizations [Noam]
- Knowledge Development: CDC CDSi [Stuart]
- Open Source Implementation: HLN's ICE [Noam]
- Real-world Implementation: NYC Provider and Patient portals [Angel]

Business Case for 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 Meningococal vaccine is **DUE ON SEPTEMBER 20, 2015**.
- The patient has **COMPLETED** their MMR immunizations.

Obstacles to Implementing and Maintaining CDS for Immunizations

- Decisions change simply with the passage of time (patient ages)
- 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

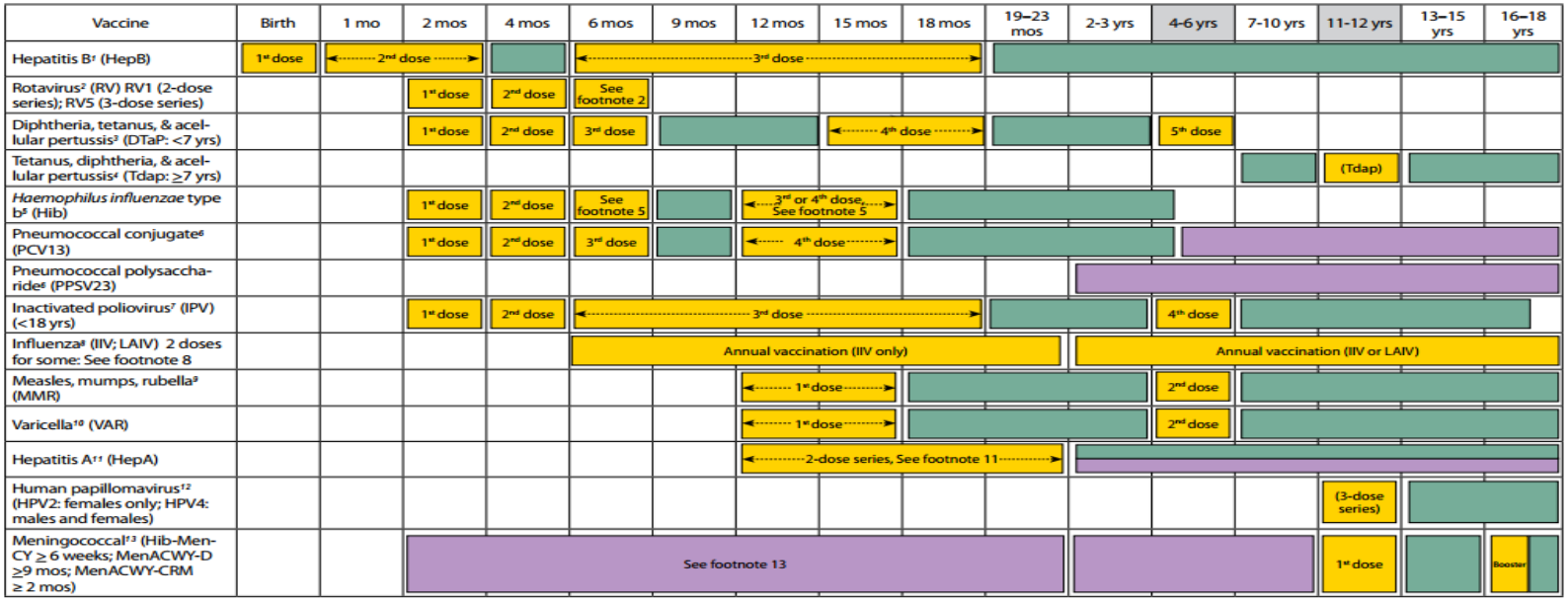
Recommended Immunization Schedule Birth - 18 Years

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

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2014.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes 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 Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.



This schedule includes recommendations in effect as of January 1, 2014. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967).Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http//www.cdc.gov/vaccines/acip), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Complex! – (*e.g.,* Footnote #13: Meningococcal Conjugate Vaccines)

13. **Meningococcal conjugate vaccines. (Minimum age: 6 weeks for Hib-MenCY [MenHibrix], 9 months for MenACWY-D [Menactra], 2 months for MenACWY-CRM [Menveo])**

Routine vaccination:

- Administer a single dose of Menactra or Menveo vaccine at age 11 through 12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of Menactra or Menveo with at least 8 weeks between doses.
- For children aged 2 months through 18 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer Menactra or Menveo vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up guidance, see Figure 2.

Vaccination of persons with high-risk conditions and other persons at increased risk of disease:

- Children with anatomic or functional asplenia (including sickle cell disease):
  1. For children younger than 19 months of age, administer a 4-dose infant series of MenHibrix or Menveo at 2, 4, 6, and 12 through 15 months of age.
  2. For children aged 19 through 23 months who have not completed a series of MenHibrix or Menveo, administer 2 primary doses of Menveo at least 3 months apart.
  3. For children aged 24 months and older who have not received a complete series of MenHibrix or Menveo or Menactra, administer 2 primary doses of either Menactra or Menveo at least 2 months apart. If Menactra is administered to a child with asplenia (including sickle cell disease), do not administer Menactra until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.
- Children with persistent complement component deficiency:
  1. For children younger than 19 months of age, administer a 4-dose infant series of either MenHibrix or Menveo at 2, 4, 6, and 12 through 15 months of age.
  2. For children 7 through 23 months who have not initiated vaccination, two options exist depending on age and vaccine brand:
     a. For children who initiate vaccination with Menveo at 7 months through 23 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
     b. For children who initiate vaccination with Menactra at 9 months through 23 months of age, a 2-dose series of Menactra should be administered at least 3 months apart.
     c. For children aged 24 months and older who have not received a complete series of MenHibrix, Menveo, or Menactra, administer 2 primary doses of either Menactra or Menveo at least 2 months apart.
- For children who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic, including countries in the African meningitis belt or the Hajj, administer an age-appropriate formulation and series of Menactra or Menveo for protection against serogroups A and W meningococcal disease. Prior receipt of MenHibrix is not sufficient for children traveling to the meningitis belt or the Hajj because it does not contain serogroups A or W.
- For children at risk during a community outbreak attributable to a vaccine serogroup, administer or complete an age- and formulation-appropriate series of MenHibrix, Menactra, or Menveo.
- For booster doses among persons with high-risk conditions, refer to *MMWR* 2013; 62(RR02);1-22, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm.

Catch-up recommendations for persons with high-risk conditions:

1. If MenHibrix is administered to achieve protection against meningococcal disease, a complete age-appropriate series of MenHibrix should be administered.
2. If the first dose of MenHibrix is given at or after 12 months of age, a total of 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease.
3. For children who initiate vaccination with Menveo at 7 months through 9 months of age, a 2-dose series should be administered with the second dose after 12 months of age and at least 3 months after the first dose.
4. For other catch-up recommendations for these persons, refer to *MMWR* 2013; 62(RR02);1-22, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm.

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

Clinical Decision Support for Immunizations (CDSi): A Comprehensive, Collaborative Strategy, **Biomedical Informatics Insights,** Suppl. 2, October 2016. <http://www.la-press.com/clinical-decision-support-for-immunizations-cdsi-a-comprehensive-colla-article-a5971-abstract?article_id=5971>

Knowledge Development: CDC CDSi

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Clinical Decision Support

- More commonly referred to as vaccine forecasting and evaluation 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.

Computer Systems and ACIP Integration

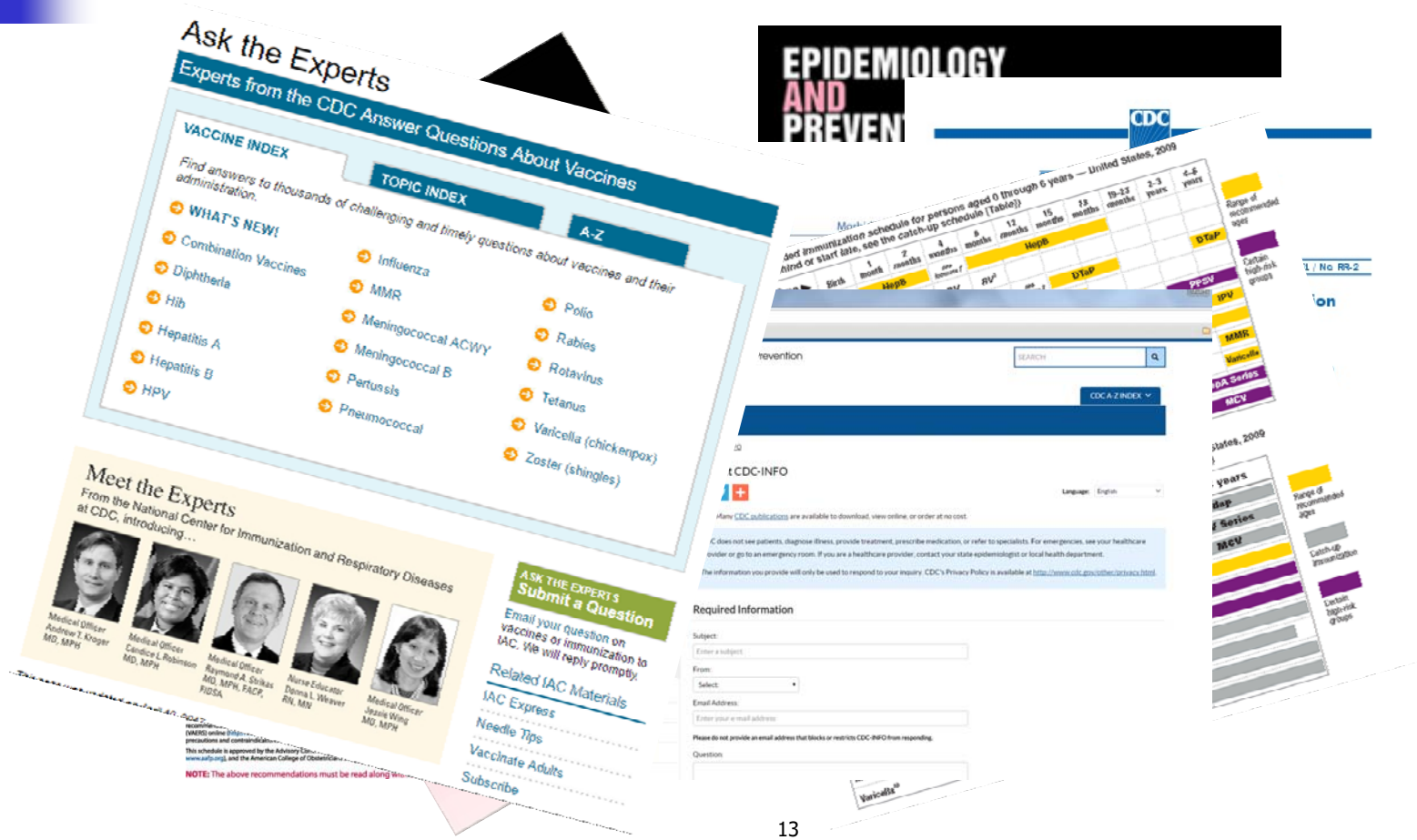
- New ACIP schedule changes are communicated through scientific language.
- Recommendations were interpreted and integrated by technical and clinical subject matter experts (SMEs).
  - Translation into technical logic is time-consuming.
  - The schedule is complex.
  - The schedule changes frequently.
- Computer systems are decentralized and do not share a common technology or logic framework.
  - Integration occurred mostly independently.
  - Implementation was often specific to a given application and implementation setting.

Bridging the Gap

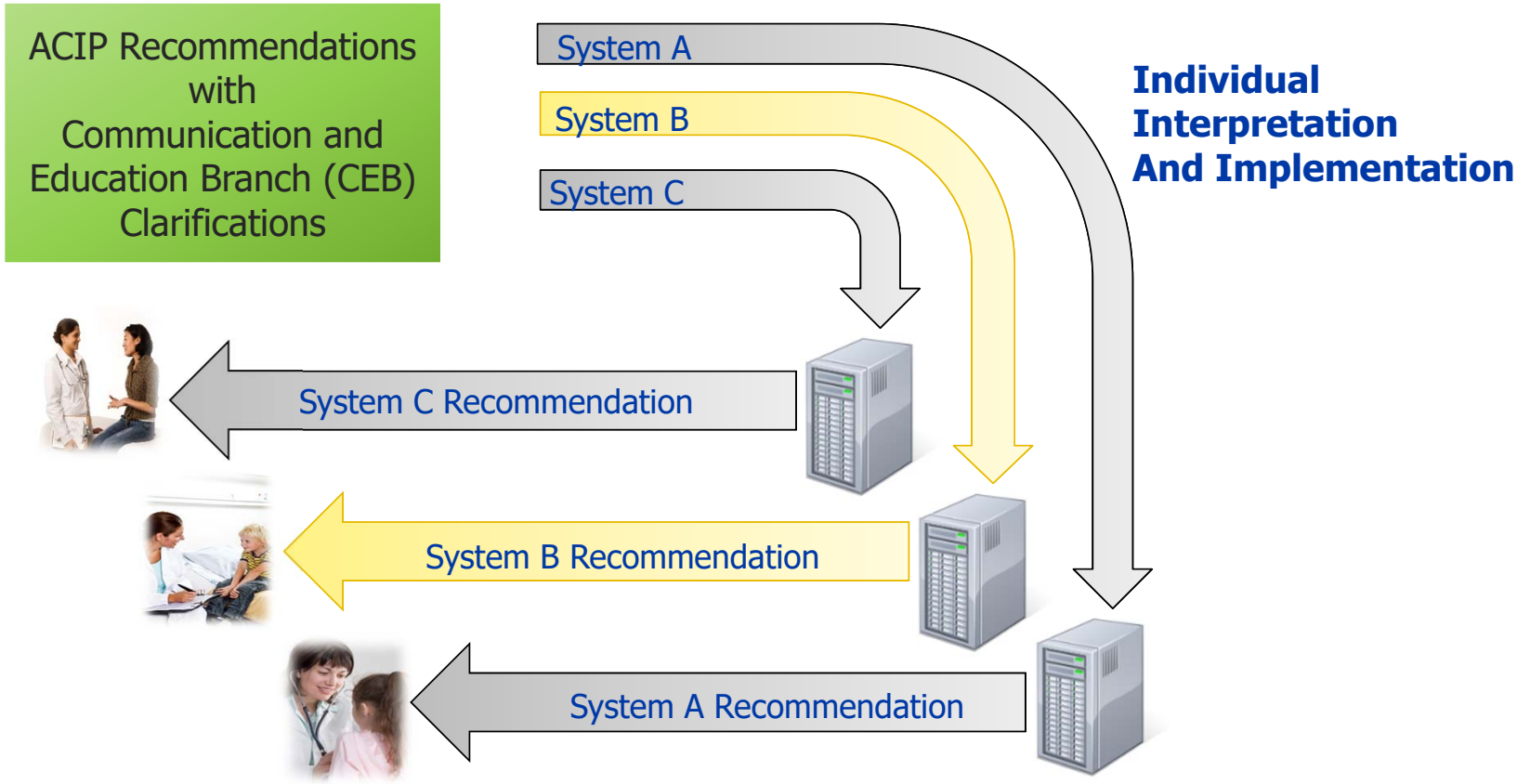
The Clinical Decision Support for Immunization (CDSi) resources bridge the gap between the scientific ACIP recommendations and the IT world of computer systems.

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

Sources of Knowledge



Before the Clinical Decision Support for Immunization (CDSi) Project

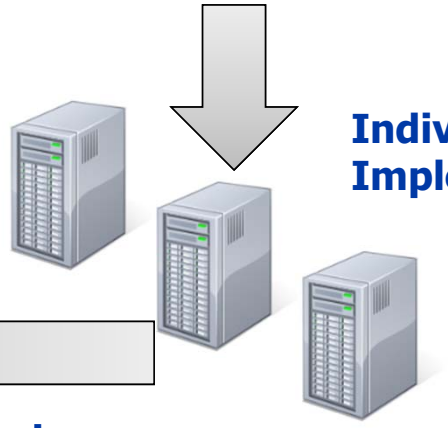


With CDSi

ACIP Recommendations with Communication and Education Branch (CEB) Clarifications

=

CDSi Resources

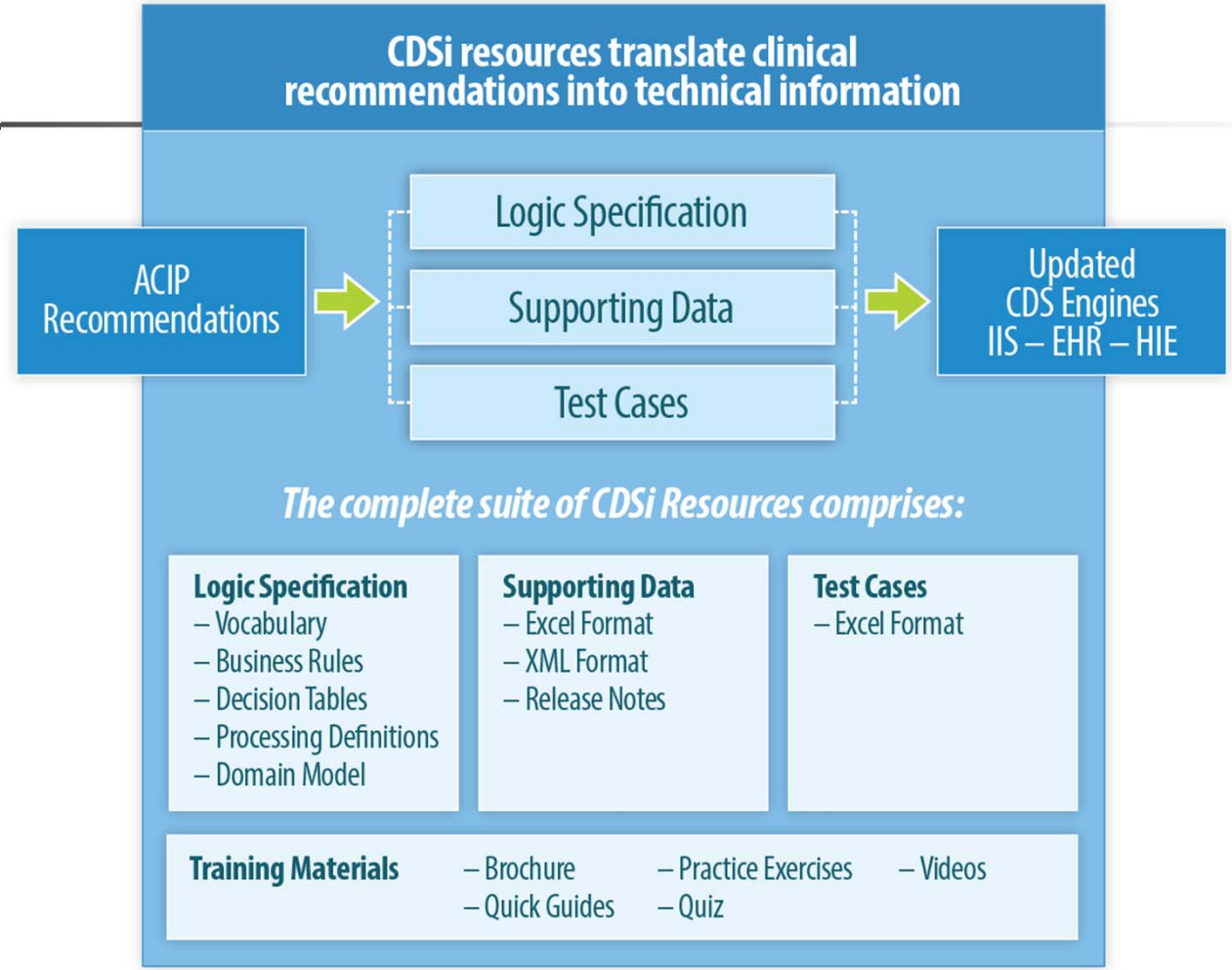


Individual Implementation

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 translate clinical recommendations into technical information
ACIP Recommendations
Logic Specification
Supporting Data
Test Cases
Updated CDS Engines IIS – EHR – HIE
The complete suite of CDSi Resources comprises:
Logic Specification
– Vocabulary
– Business Rules
– Decision Tables
– Processing Definitions
– Domain Model
Supporting Data
– Excel Format
– XML Format
– Release Notes
Test Cases
– Excel Format
Training Materials
– Brochure
– Quick Guides
– Practice Exercises
– Quiz
– Videos

CDSi Project Timeline

v1.0 - 2013

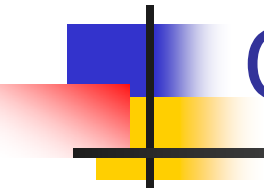
- Birth through 18
- Limited Immunities & Contraindications

v2.0 - 2015

- Birth to Death
- Limited Immunities & Contraindications

v3.0 - 2016

- Birth to Death
- Risk Factors
- Immunities
- Contraindications
- Travel



Open Source Implementation: HLN's ICE

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Goal of the ICE Project

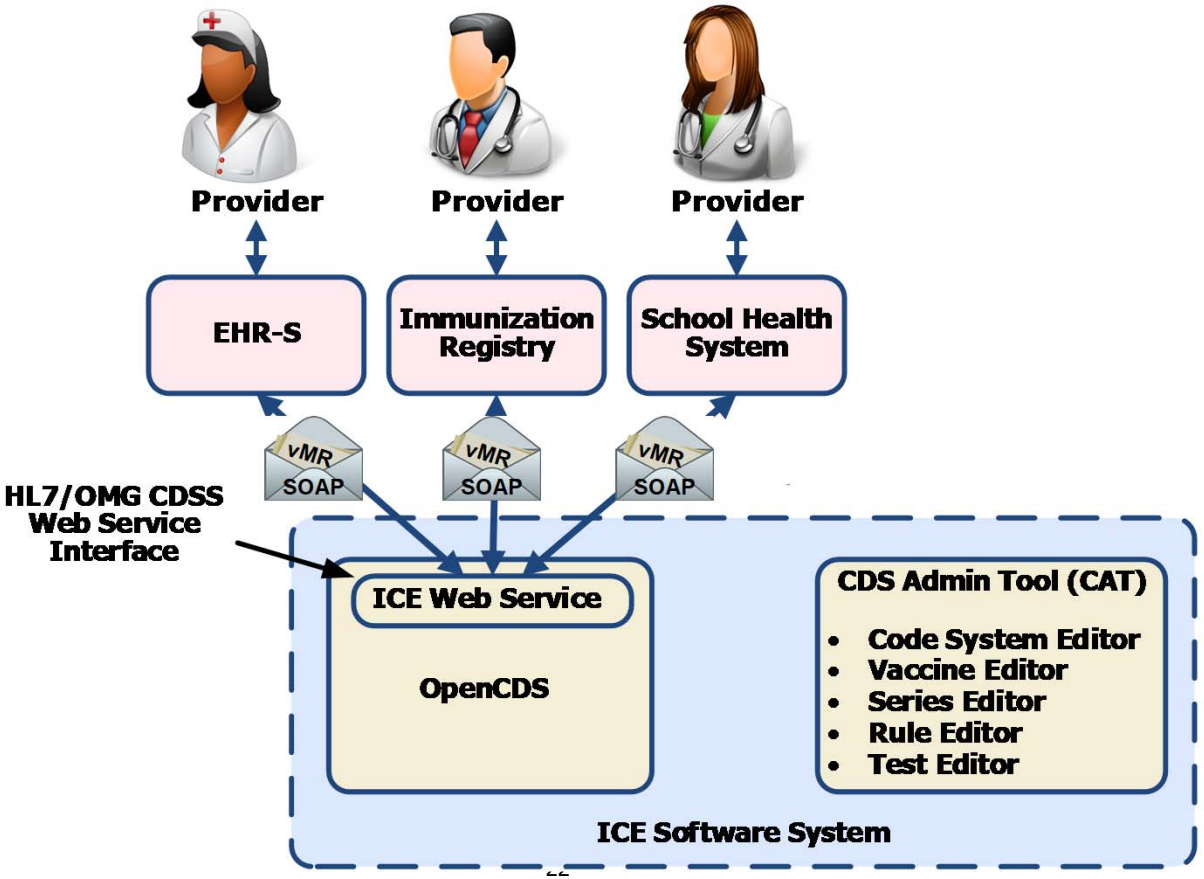
Create an immunization decision support system that:

Objective	Achievement
Supports routinely administered vaccine groups	• Supports 15 vaccine groups from birth through adulthood
Promotes clinical best practices	• Follows ACIP recommendations • Informed by CDC's CDSi project
Adapts to changing requirements	• Tools that allow self-administration where practical • Automated testing tool w/2,700+ test cases • 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

Original ICE Collaborators

- New York City Citywide Immunization Registry
- HLN Consulting, LLC
- Alabama Dept 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

Sample ICE Deployment



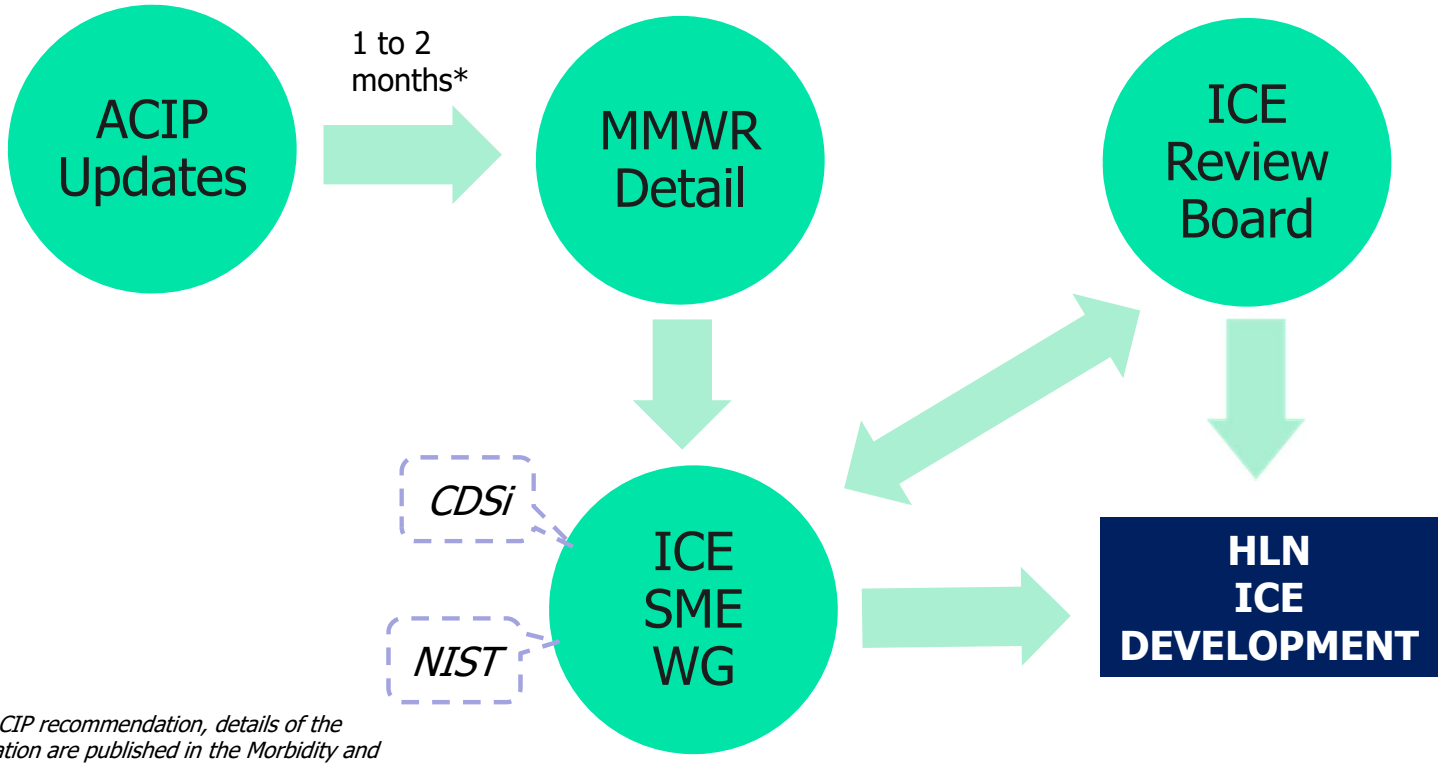
Software Architecture

- ICE/OpenCDS
  - Servlet Container
  - JBoss Drools (rule
  - HL7 Decision Supp
  - HL7 Virtual Medic
- CAT (CDS Adminis
  - Application Server
  - JavaServer Faces
  - Enterprise JavaBe
  - JDBC compliant d

Deployments of ICE

- eClinicalWorks, National EHR (De
- CareDox, National PHR (Novembe
- Denver Public Health (July 2016)
- Selected and Tested by Veteran's
- Major Academic Medical Center (J
- New Jersey IIS (January 2018)
- GE Centricity (through H1Tech, S
- vxVistA (Scheduled for 2018)
- New York City IIS (Scheduled for
- Rhode Island KIDSNET (Schedule
- Other organizations evaluating ICE…

Update Process Flow & Advisory Structure



**After any ACIP recommendation, details of the recommendation are published in the Morbidity and Mortality Weekly Report (MMWR). Publication is typically 1-2 months after ACIP approves a recommendation.*

ICE Resources

- Basic information: https://www.hln.com/ice/
- Main public wiki page: https://cdsframework.atlassian.net/wiki/display/ICE/Home
- Wiki page with documentation of the rules/philosophy: https://cdsframework.atlassian.net/wiki/display/ICE/Default+Immunization+Schedule
- Software download/documentation page: https://cdsframework.atlassian.net/wiki/display/ICE/Downloads
- Product Roadmap: https://cdsframework.atlassian.net/wiki/spaces/ICE/pages/77365249/Roadmap

Real-world Implementation: NYC

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New York Citywide Immunization Registry (CIR)

- NYC's Immunization Information System
- Established in 1996
- Mandatory reporting of immunizations for patients 0-18 years of age
- 6.5 million patient records
- 90 million immunizations
- Population-based
  - Birth certificates loaded twice a week
- Uses legacy ICE version 2 implementation (before Open ICE)
- Migrating to Open ICE in coming months

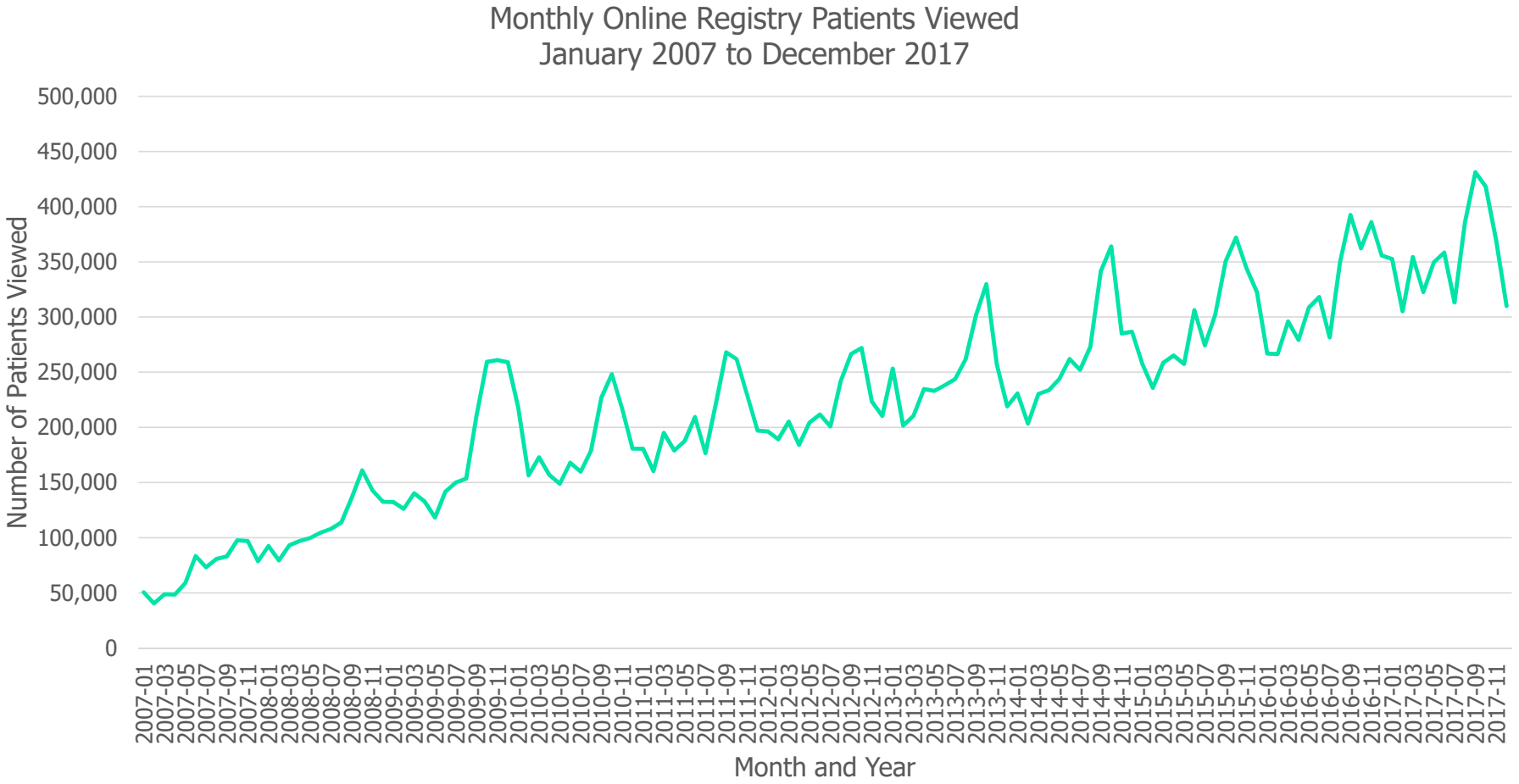
Provider View:

Provider View:

Scroll down to Lead Test History

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 1 MMR 11m 3w	05/25/2016 MMR 12m 2w	01/11/2018 MMR 2y 8m			Completed Vaccine Series
Varicella 0 Event/s						DUE NOW VARICELLA
HepA 0 Event/s						DUE NOW HEPA PED/ADOL 2-DOSE
Meningococcal (MenACWY) 0 Event/s						Recommended for high risk groups, otherwise 05/05/2026 MENACWY CONJUGATE
Human Papillomavirus 0 Event/s						05/05/2026 HUMAN PAPILLOMAVIRUS (HPV9-GARDASIL 9)


Monthly Online Registry Patients Viewed
January 2007 to December 2017
Number of Patients Viewed
500,000
450,000
400,000
350,000
300,000
250,000
200,000
150,000
100,000
50,000
0
2007-01
2007-03
2007-05
2007-07
2007-09
2007-11
2008-01
2008-03
2008-05
2008-07
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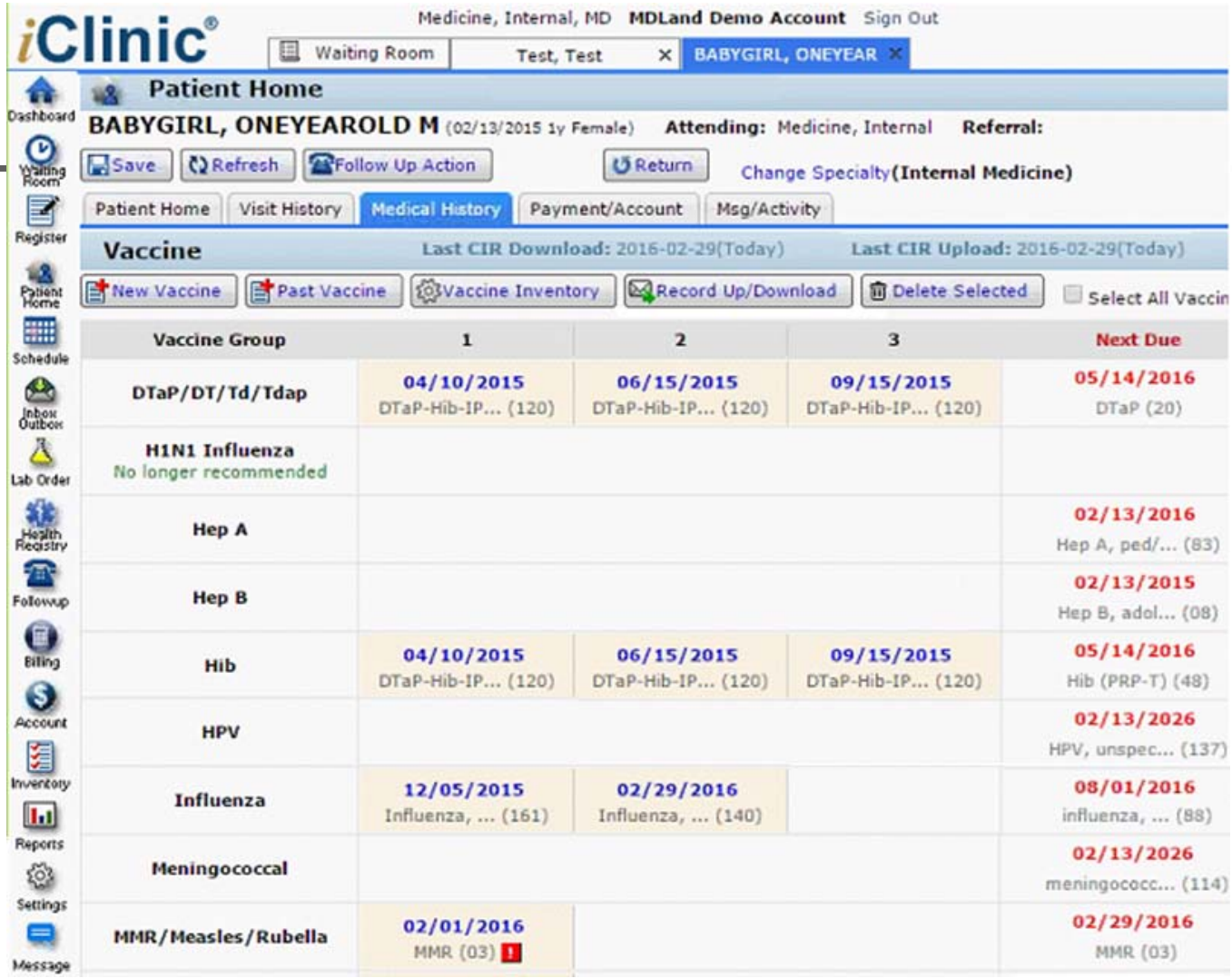
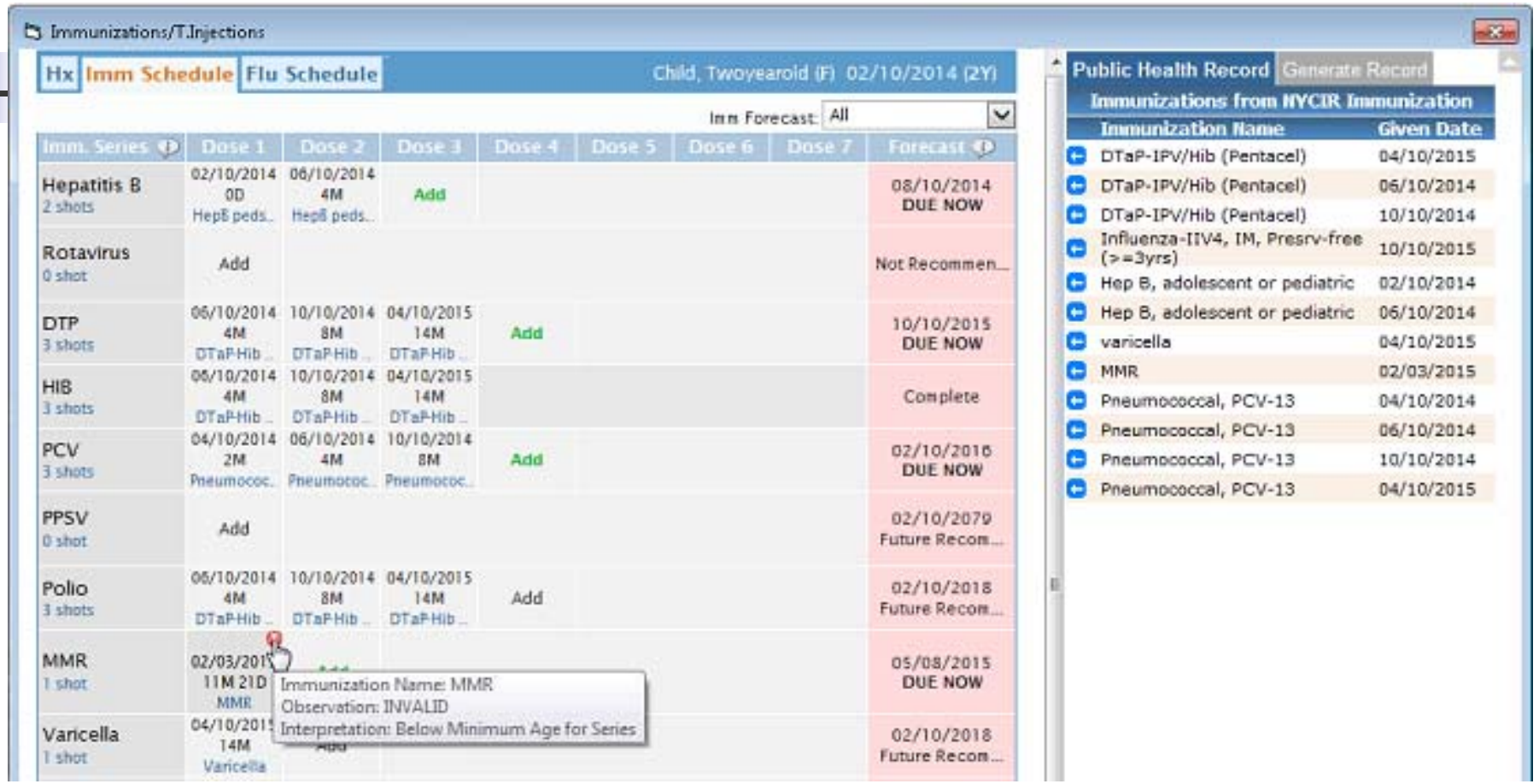
2017-05
2017-07
2017-09
2017-11
Month and Year

EHR to IIS Integration Features

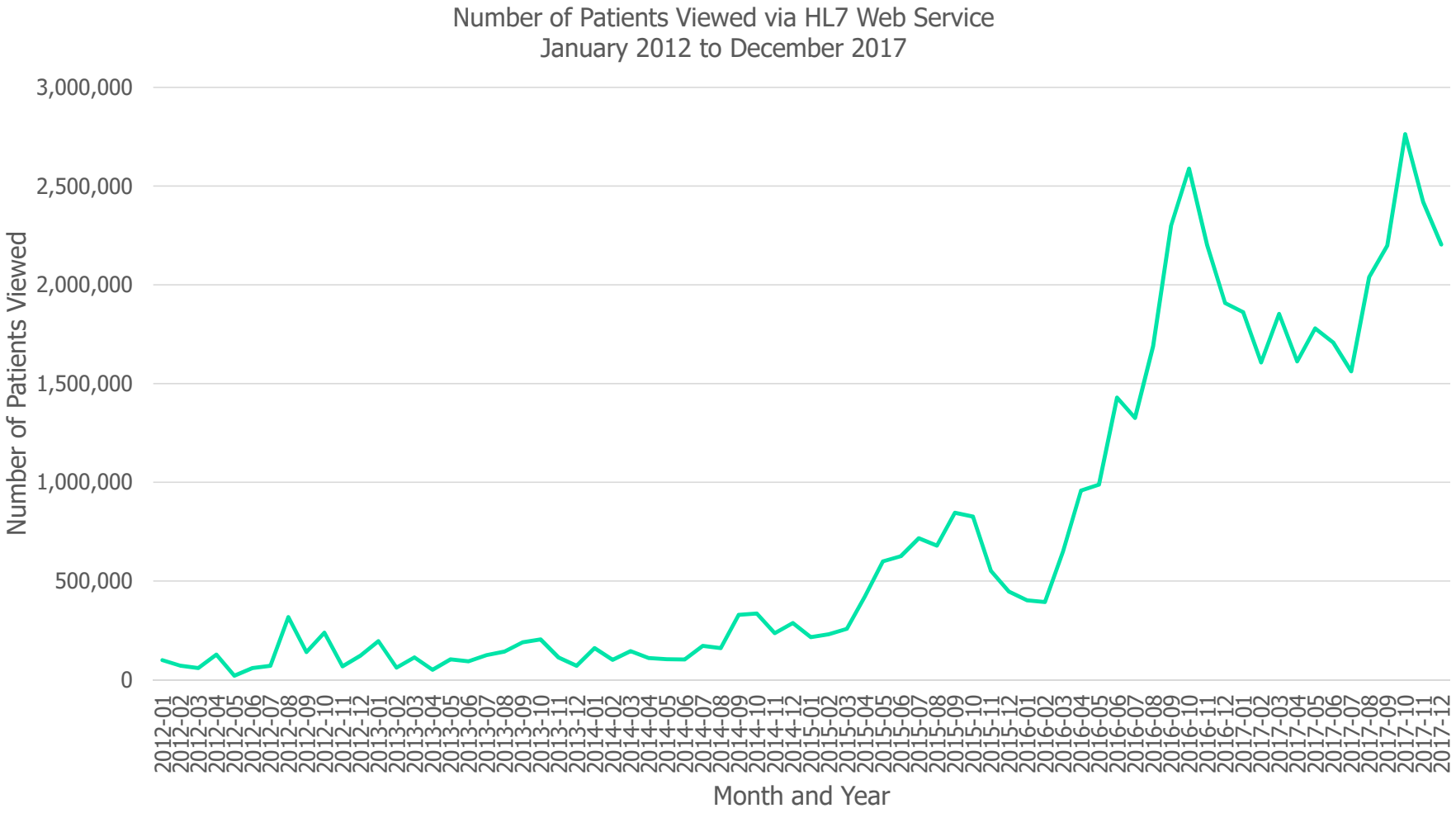
- Automatic or Manual
  - Immunization queries and uploads
  - Reconciliation of immunization information
  - Decision support update when new information is added to EHR
- EHR or IIS clinical decision support module
- User interface, color coding, and context-sensitive help
  - Immunization information source
  - Valid and invalid shots
  - Shots due now
  - Forecast to schedule appointment for future shots

MDLand

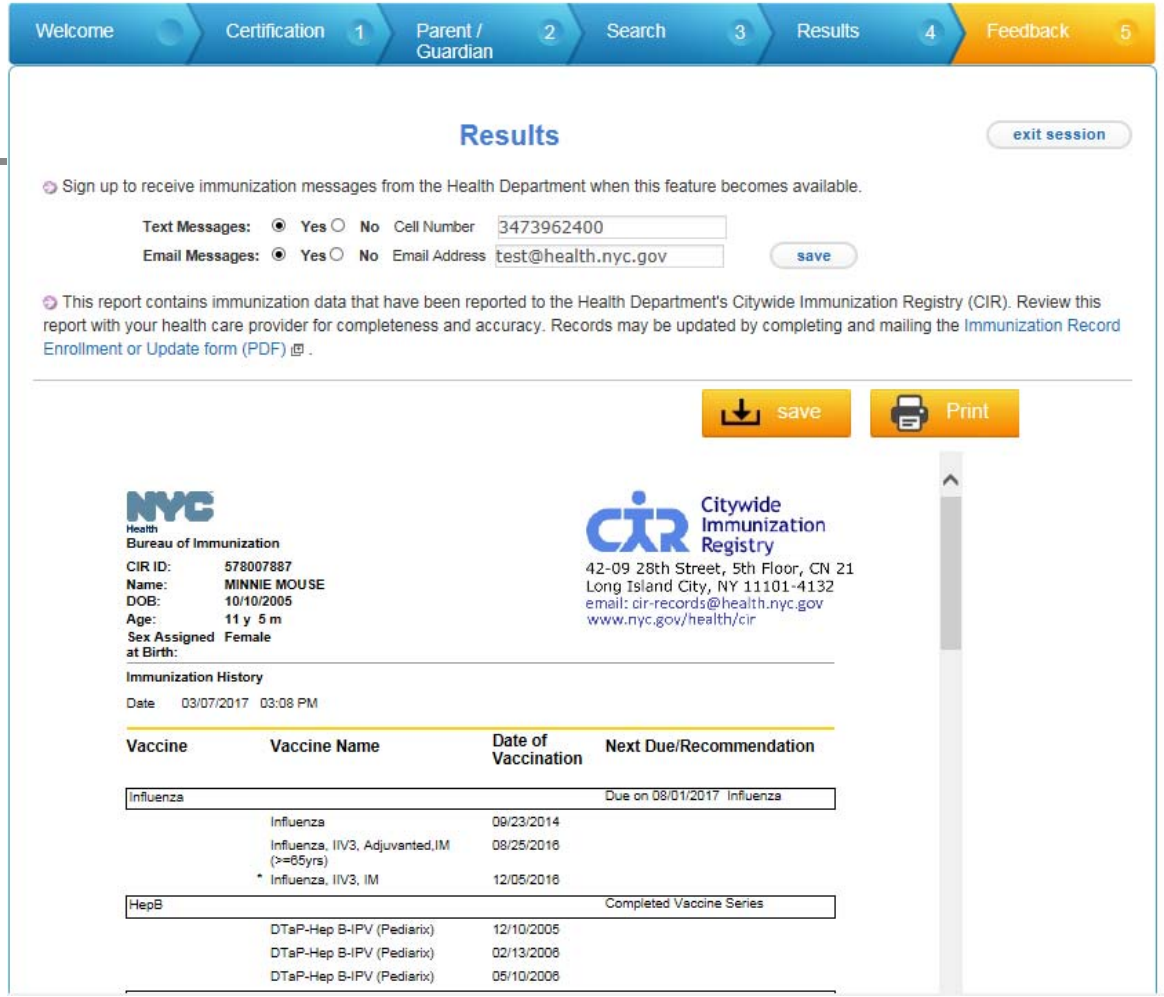

iClinic®
Medicine, Internal, MD MDLand Demo Account Sign Out
Waiting Room
Test, Test
BABYGIRL, ONEYEAR
Dashboard
Waiting Room
Register
Patient Home
Schedule
Inbox Outbox
Lab Order
Health Registry
Followup
Billing
Account
Inventory
Reports
Settings
Message
Patient Home
BABYGIRL, ONEYEAROLD M (02/13/2015 1y Female) Attending: Medicine, Internal Referral:
Save
Refresh
Follow Up Action
Return
Change Specialty(Internal Medicine)
Patient Home
Visit History
Medical History
Payment/Account
Msg/Activity
Vaccine
Last CIR Download: 2016-02-29(Today)
Last CIR Upload: 2016-02-29(Today)
New Vaccine
Past Vaccine
Vaccine Inventory
Record Up/Download
Delete Selected
Select All Vaccin
Vaccine Group
1
2
3
Next Due
DTaP/DT/Td/Tdap
04/10/2015 DTaP-Hib-IP... (120)
06/15/2015 DTaP-Hib-IP... (120)
09/15/2015 DTaP-Hib-IP... (120)
05/14/2016 DTaP (20)
H1N1 Influenza
No longer recommended
Hep A
02/13/2016 Hep A, ped/... (83)
Hep B
02/13/2015 Hep B, adol... (08)
Hib
04/10/2015 DTaP-Hib-IP... (120)
06/15/2015 DTaP-Hib-IP... (120)
09/15/2015 DTaP-Hib-IP... (120)
05/14/2016 Hib (PRP-T) (48)
HPV
02/13/2026 HPV, unspec... (137)
Influenza
12/05/2015 Influenza, ... (161)
02/29/2016 Influenza, ... (140)
08/01/2016 influenza, ... (88)
Meningococcal
02/13/2026 meningococc... (114)
MMR/Measles/Rubella
02/01/2016 MMR (03)
02/29/2016 MMR (03)

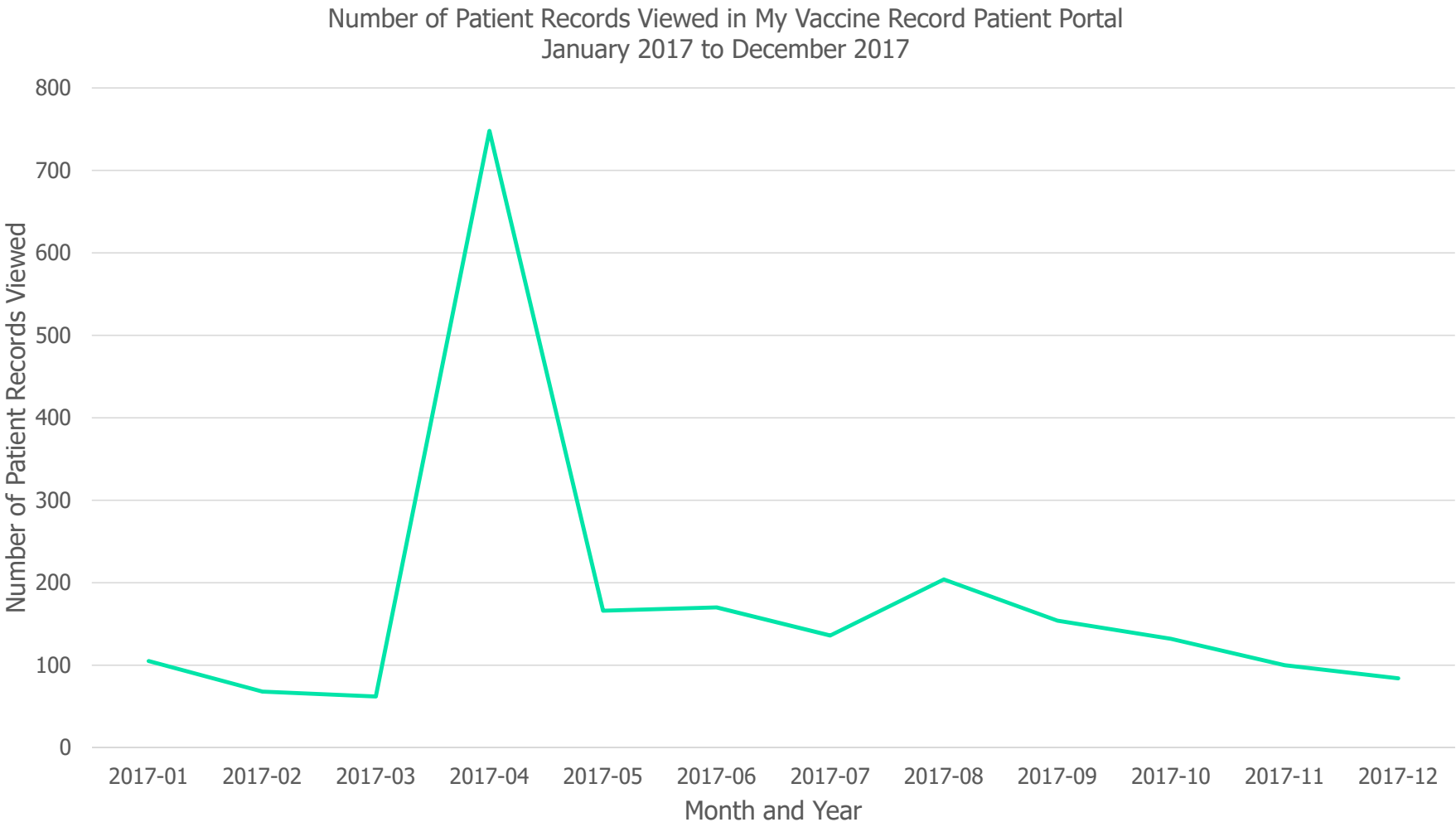


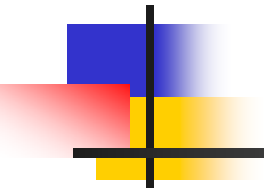
eClinicalWorks uses Open ICE


Number of Patients Viewed via HL7 Web Service
January 2012 to December 2017
Number of Patients Viewed
3,000,000
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
Month and Year

Consumer Access: My Vaccine Record




Number of Patient Records Viewed in My Vaccine Record Patient Portal
January 2017 to December 2017
Number of Patient Records Viewed
800
700
600
500
400
300
200
100
0
2017-01
2017-02
2017-03
2017-04
2017-05
2017-06
2017-07
2017-08
2017-09
2017-10
2017-11
2017-12
Month and Year



Questions? Comments?