



Methodology for Implementing Health Factors with Immunization Forecasting

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Authors: Janet Hui, MPH; Daryl Chertcoff; Maiko Minami; Sam Nicolary; Ruth Gubernick, PhD, MPH; Catherine Staes, PhD, MPH, RN



Objectives

- To provide a detailed case study for how HLN is implementing relevant HALO factors in an immunization forecasting system
- To share with the audience and larger immunization community the considerations, benefits, challenges and lessons learned in the implementation of health factors as part of clinical decision support and automated, systematized immunization forecasting



Background



Background

- The Veterans Health Administration (VHA) contracted HLN in 2016 to support the implementation of ICE in their EHR system
- The Immunization Calculation Engine (ICE) is an open-source immunization forecasting system available for free
- HLN first began developing ICE in 2011 for New York City Citywide Immunization Registry (CIR)



ICE Immunization Forecasting Software

- ICE implements a default schedule that is compliant with the CDC ACIP Guidelines
- ICE *evaluates* vaccination history for validity of shots
 - Tdap shot recorded as administered on May 1, 2004 is **INVALID**
 - Tdap shot recorded as administered on March 15, 2014 is **VALID**
- ICE *recommends* shots that are due next
 - Meningococcal vaccine is **DUE** on September 20, 2017
 - MMR vaccinations are **COMPLETE**



Input to ICE

- Patient parameters
 - Date of birth
 - Gender
 - Immunization history (vaccine and administration date)
 - Disease immunity



Output from ICE

- Evaluation of each dose
 - Evaluation = Valid, Invalid, or Accepted
 - Invalid Reason(s), for each Invalid dose
- Recommendation for each vaccine group
 - Recommendation = Recommended, Future recommended, Conditional, or Not recommended
 - Earliest recommended due date
 - Reason



“HALO” Factors

- As part of the VHA project, HLN began to incorporate health-related factors, colloquially called “**HALO**” factors, into immunization recommendations

HALO stands for:

Health-related

- Immuno-compromised
- Allergies
- Pregnancy Status

Age

Lifestyle

- International Travel
- Contact with immunocompromised person

Occupation



“HALO” Factors

- Have ICE vaccination recommendations take into consideration HALO factors to potentially change recommendations
- Examples:
 - If patient contains evidence of being immunocompromised, do not recommend Zoster vaccination
 - If patient works in a health care facility or is a student in post-high school educational institutions, then follow the 2-dose MMR schedule for recommendation



VHA HALO Activities

- **Identified** HALO factors associated with:
 - Zoster, Pneumococcal, HPV, Influenza, MMR
- **Translated** HALO factors into machine processable logic
 - Created logic to identify HALO factors based on EHR data
- *Not completed:* **Implementing** HALO rules
 - Plan: Incorporate HALO rules as VHA Clinical Reminders to be run and displayed when ICE was run
 - VHA Clinical Reminders included rules used by the VHA system to determine if and when reminder should be displayed to clinical staff



HALO Case Study

Goal: Expand upon HALO work done with the VHA

- **Identify** HALO factors for initial implementation
 - What HALO factors are there?
 - Are HALO factors operationalizable using EHR data?
- **Translate** HALO factors into machine processable rules
 - Create rules to identify HALO factors using EHR data
- **Implement and test** HALO rules
 - Implement HALO rules as standalone service that outputs whether a HALO factor was identified for a vaccine/vaccine group
- **Integrate** HALO rules with ICE immunization forecaster



Identifying HALO factors for implementation



Methods: Identifying HALO Factors

Use of Clinical Decision Support Immunization (CDSi) resources to identify HALO Factors

- CDSi guidelines based on ACIP guidelines
- Already in semi-structure/structured format

Manually reviewed Feb. 2019
CDSi artifacts to identify HALO factors

CDSi Logic Specification and Supporting Data

- [Clinical Decision Support for Immunization \(CDSi\); Logic Specification for ACIP Recommendations, version 4.0](#) [4 MB, 145 pages] Updated February 2019
Eight chapters, including an executive summary, and 6 appendices
- [Supporting Data Version 4.0](#) [ZIP - 1.3 MB]
Updated February 2019
These supporting data are the attributes and specific values required to support evaluation and forecasting as defined in the Logic Specification.

<https://www.cdc.gov/vaccines/programs/iis/cdsi.html>



Types of HALO Factors

Three scenarios where HALO factors impact immunization recommendations

- Contraindications
 - For an antigen
 - For a specific vaccine
- Indications, related to a vaccine series



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- **Contraindications**
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```
<vaccineGroup>
  <contraindication>
    <observationCode>080</observationCode>
    <observationTitle>Adverse reaction to
      vaccine component</observationTitle>
    <contraindicationText>Do not vaccinate
      if the patient has had an adverse
      reaction to a vaccine component.</contraindicationText>
  </contraindication>
</vaccineGroup>
```

CDSi XML artifact for Zoster (Some fields truncated for screenshot)



Types of HALO Factors

Three scenarios where HALO factors impact immunization recommendations

- Contraindications
 - For an antigen
 - For a specific vaccine
- Indications, related to a vaccine series

```
<vaccine>
  <contraindication>
    <observationCode>007</observationCode>
    <observationTitle>Pregnant</observationTitle>
    <contraindicationText>Do not vaccinate if the patient is
      pregnant.</contraindicationText>
    <contraindicatedVaccine>
      <vaccineType>Zoster live</vaccineType>
      <cvx>121</cvx>
    </contraindicatedVaccine>
  </contraindication>
</vaccine>
```

CDSi XML artifact for Zoster (Some fields truncated for screenshot)



Types of HALO Factors

Three scenarios where HALO factors impact immunization recommendations

- **Contraindications**
 - For an antigen
 - For a specific vaccine
- **Indications, related to a vaccine series**

```
<indication>
  <observationCode>
    <text>Travel to an area of active cholera
      transmission</text>
    <code>008</code>
  </observationCode>
  <description>Administer to adult travelers
    (aged 18-64 years) from the United
    States traveling to an area of
    active cholera transmission.</description>
  <beginAge>18 years</beginAge>
  <endAge>65 years</endAge>
</indication>
```

CDSi XML artifact for Cholera (Some fields truncated for screenshot)

Contraindications, by Vaccine Group

Vaccine Group	# of Antigen Level Contraindications	# of Vaccine Level Contraindications
Cholera	2	0
Dtap/Tdap/Td	2	78
Hepatitis A	4	1
Hepatitis B	3	4
Hib	4	4
HPV	4	0
Influenza	2	22
Japanese Encephalitis	3	0
Meningococcal	2	5
Meningococcal B	2	0
MMR	99	0
Pertussis	2	0
Pneumococcal	2	1
Polio	6	0
Rabies	2	0
Rotavirus	4	1
Tetanus	2	0
Typhoid	4	12
Varicella	33	0
Yellow Fever	15	1
Zoster	1	0
Total	198	129

87 contraindication codes used

- 21 are variants of “Severe allergic reaction after previous dose of X vaccine”

198 antigen-level Contraindications

- Most Common
 - Severe allergic reaction after previous dose of X vaccine (23)
 - Adverse reaction to vaccine component (22)
- High number of contraindications associated with MMR

129 Contraindications at the vaccine level

- Predominately associated with Dtap/Tdap/Td vaccine group

Indications, by Vaccine Group

Vaccine Group	# of Indications
Cholera	1
Dtap/Tdap/Td	1
Hepatitis A	31
Hepatitis B	73
Hib	8
HPV	31
Influenza	0
Japanese Encephalitis	1
Meningococcal	24
Meningococcal B	12
MMR	21
Pertussis	1
Pneumococcal	124
Polio	3
Rabies	5
Rotavirus	0
Tetanus	0
Typhoid	6
Varicella	0
Yellow Fever	4
Zoster	0
Total	198

81 indication codes used

346 Indications

- Most Common - Immunocompromised
 - HIV/AIDS – not severely immunocompromised (20)
 - HIV/AIDS – not severely immunocompromised (17)
 - Anatomical or functional asplenia (15)
 - Persistent complement, properdin, or factor B deficiency (14)
- Indications are associated with begin age / end ages
- High number of indications associated with Pneumococcal (124), followed by Hepatitis B (73)



HALO Factors, by Category

Category	Count
Vaccine Reaction	36
Diagnosis	30
Medication / Procedure	22
Demographic / Social History	18
Occupation	14
Travel History	11
Laboratory	8
Vaccine Administration	7
Epidemiologic	6
Total	152

Categories reflect how factors would be represented by data in a patient record

Factors may be represented by a combination of data.

Ex. HIV/AIDS – not severely immunocompromised may require both diagnosis + lab data

Note: Age is not included as a factor in these tables



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Examples

Vaccine Reaction

- Severe allergic reaction after previous dose of vaccine
- Allergic reaction to egg protein
- Hypersensitivity to yeast



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Examples

Diagnosis

- Acute febrile illness
- Chronic Liver Disease
- HIV/AIDS – not severely immunocompromised
- HIV/AIDS – severely immunocompromised

Diagnoses may be represented using laboratory results too



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Examples

Medication / Procedure

- Chemotherapy
- Immune globulin intravenous (IGIV)
 - Kawasaki disease
- Immunosuppressive treatment
- Receives treatment for STD



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Examples

Demographic / Social History

- Pregnant
- Family history of immunocompetence
- Homelessness
- Illicit drug use
- Not in a long term monogamous relationship



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Examples

Laboratory

- B-lymphocyte [humoral] - Less severe antibody deficiencies
- Phagocytic function - Leukocyte adhesion defect, and myeloperoxidase deficiency
- T-lymphocyte [cell-mediated and humoral] - Complete defects

Factors may be represented as diagnoses as well



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Examples

Occupation

- Health care personnel
- Microbiologists routinely exposed to *Neisseria meningitidis*
- Occupational exposure for Hepatitis A



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Examples

Travel History

- Travel to an area of active cholera transmission
- Travelling Internationally
- Travel to areas or countries where polio is epidemic or endemic



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Examples

Vaccine Administered

- Hep A IG Administration
- Measles prophylaxis IG administration -
Immunocompromised Contact
- Measles prophylaxis IG administration – Standard

Factors may be represented as medication/procedures as well



HALO Factors, by Category

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Examples

Epidemiologic

- Household and close contacts of immunocompromised persons
- Intimate exposure to a documented *S. typhi* carrier
- Persons at risk during an outbreak



Initial Rules Development Approach

Start with contraindications

- Develop rules for contraindications for antigens
- Vaccine-level contraindications required additional consideration, as to their impact on ICE recommendations
- Expand to indications later

Start with one vaccine group

- Selected vaccine group: Zoster
 - Small number of HALO factors
 - HALO factors shared across conditions
 - Previous VA work
- Expand to additional vaccine groups after



Translating HALO factors into machine-processable rules



Translating HALO Factors to IF/THEN Rules

- Translated HALO factors into IF...THEN statements
 - Used guidance provided in CDSi artifacts
 - Example: IF patient has [allergic reaction to ____] THEN output...
- Output of HALO rules = Flag
 - Flag to be used by ICE to update its recommendations
- Identified concepts that needed to be mapped to EHR data
 - Example: [Allergic Reaction to ____] can be represented using codes used in the EHR



Example: IF/THEN Rules for Zoster (DRAFT)

Rule 001-1: Patient has allergic or adverse reaction to Zoster Vaccine component

IF

Patient has an allergy or adverse reaction of [Allergy to Zoster Vaccine component]

THEN OUTPUT FLAG: Contraindication for Zoster: Allergy or Adverse Reaction to vaccine or vaccine component



Applying HL7 Standards

- While IF...THEN rules can be implemented as is, we wanted to standardize the HALO rules further
- Use of HL7 Standards
 - **Clinical Quality Language (CQL) to represent logic**
 - Specification for interoperable expression logic
 - Human-readable and machine-readable
 - **HL7 FHIR standards to represent concepts**
 - QUICK logic model / FHIR QICore – specific FHIR profile to support decision support and quality measures
 - FHIR STU 3 – “Base” FHIR standard

Example: HALO Factors mapped to FHIR resources

Concept	Base FHIR Resource	QI-Core Resource
Allergic Reaction to Zoster Vaccine Component	AllergyIntolerance Condition Flag	QICore- AllergyIntolerance QICore-Condition QICore-Flag
Diagnosis of Primary Immunodeficiency disorder	Condition	QICore-Condition
CD4 T-lymphocyte values < 200 cells per mm ³	Observation	QICore-Observation

Example: CQL Rules for Zoster (DRAFT)

/* Zoster Rule 001-1: Patient has allergic or adverse reaction to Zoster Vaccine component */

define 'Severe allergy to Zoster Vaccine component':

["Condition": "Allergic Reaction, Zoster vaccine component"]

union

["AllergyIntolerance": "Allergic Reaction, Zoster vaccine component"]

union

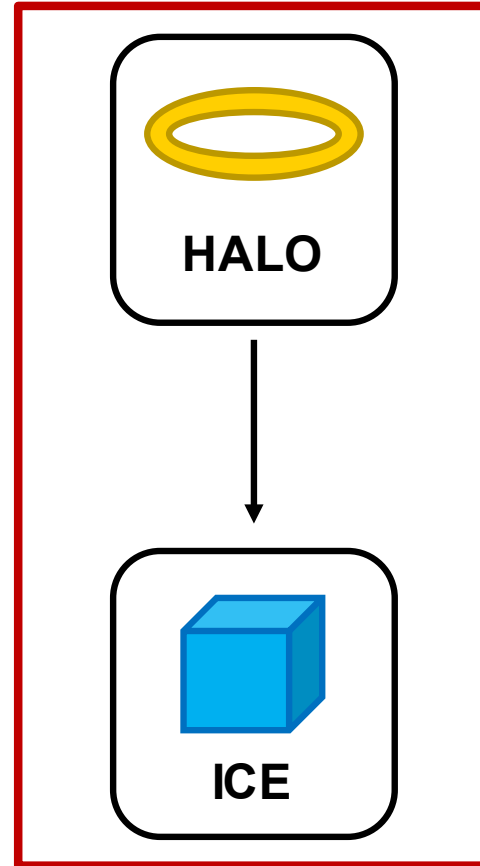
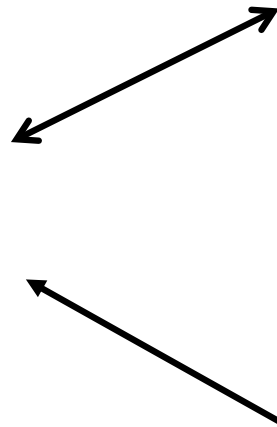
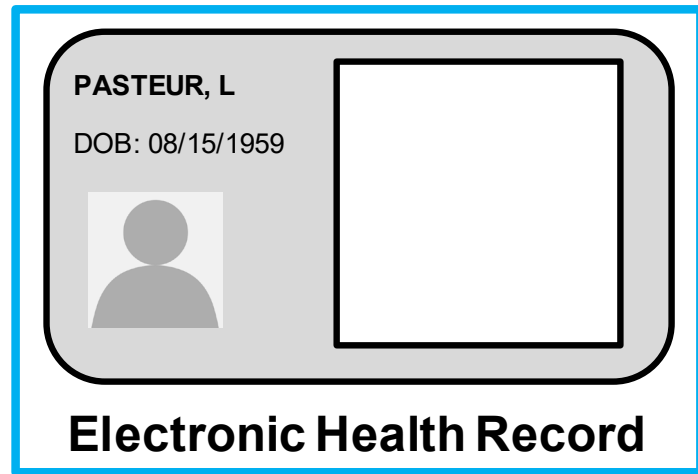
["Flag": "Flag for Allergic Reaction, Zoster vaccine component"]

then resourceType: 'Flag', text: { Contraindication for Zoster: Allergy or Adverse Reaction to vaccine or vaccine component } else null



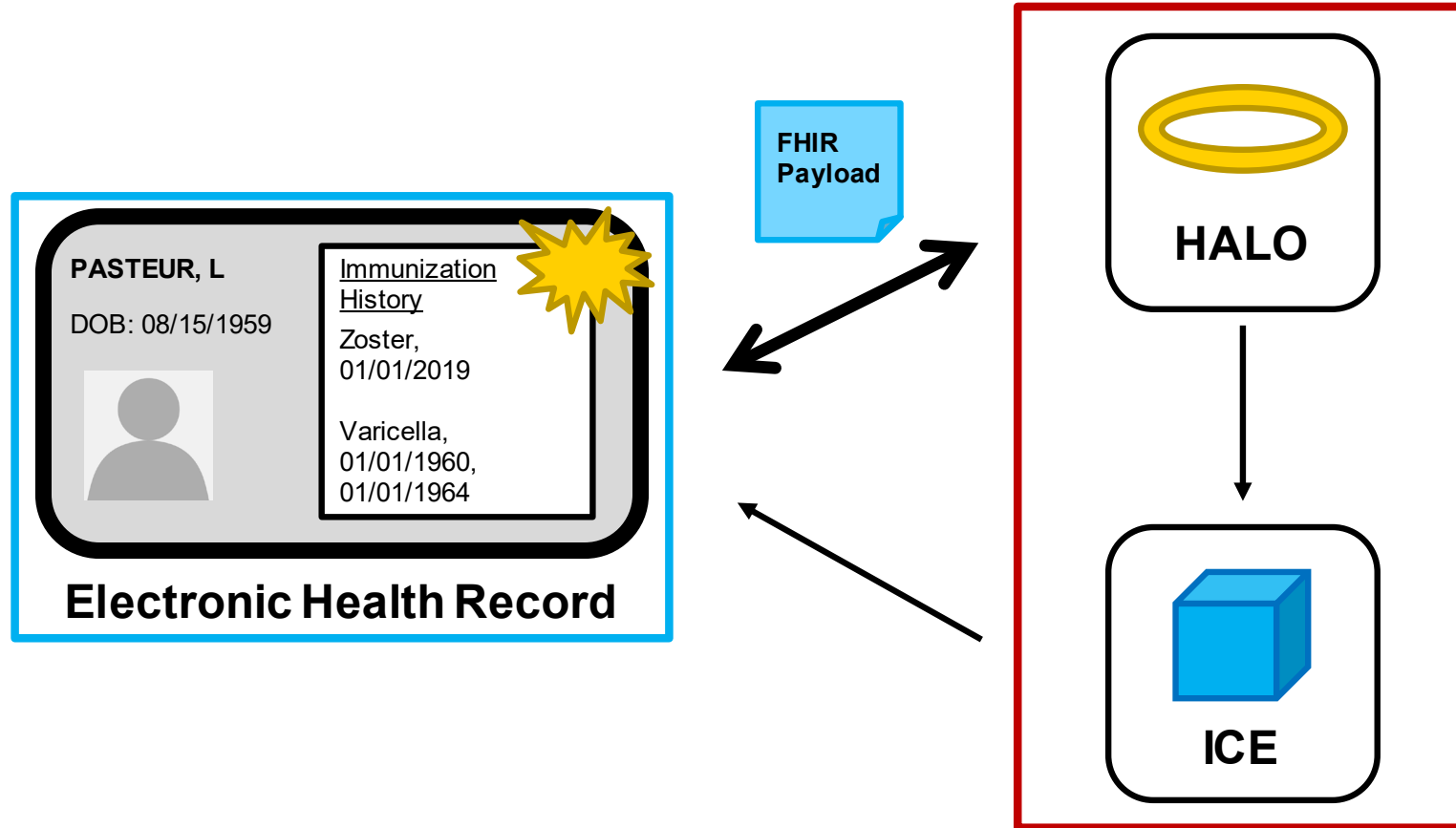
Implementing HALO rules and Integrating with ICE

Building the System



How will the rules be run?

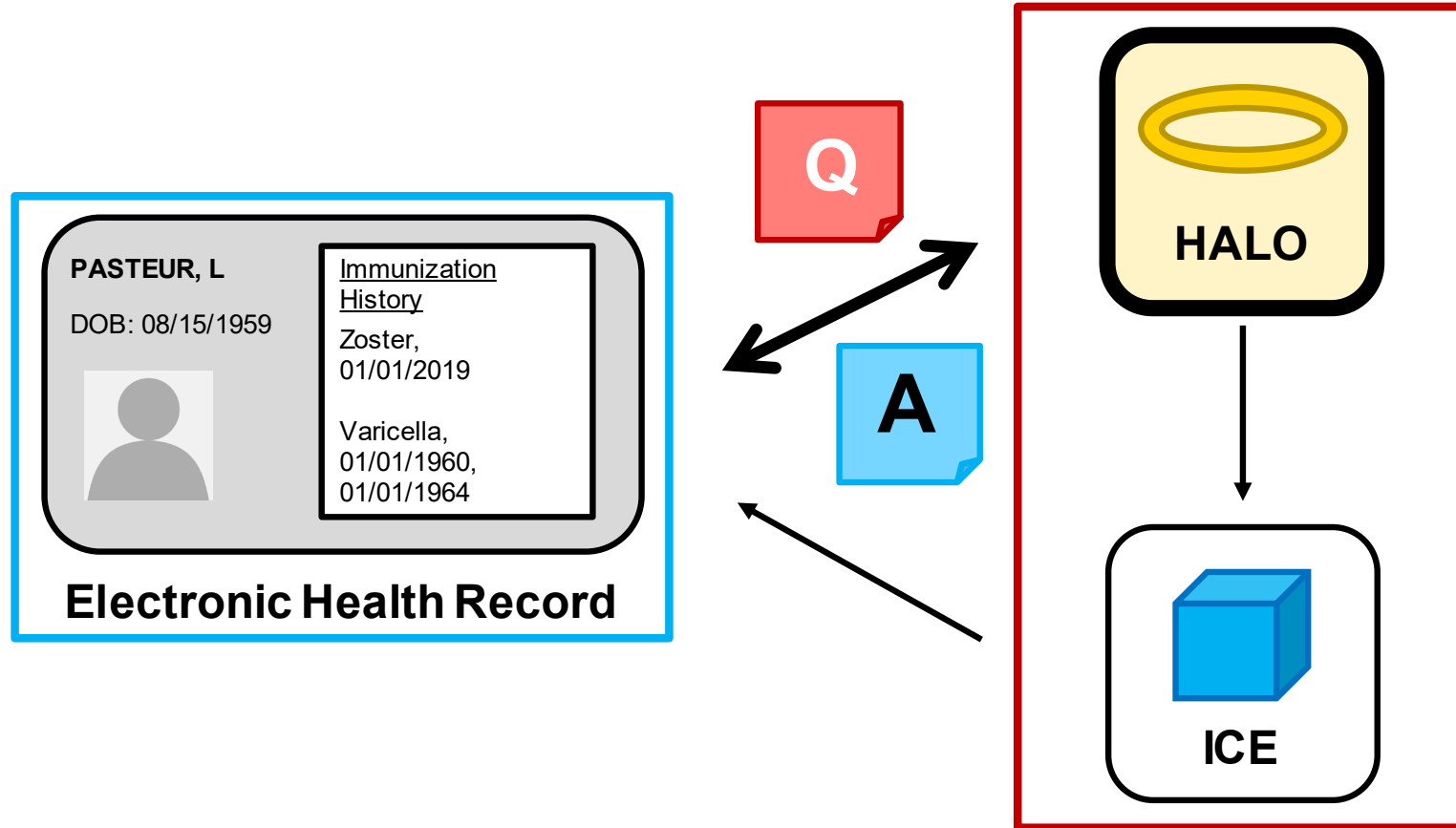
Building the System



In the EHR:

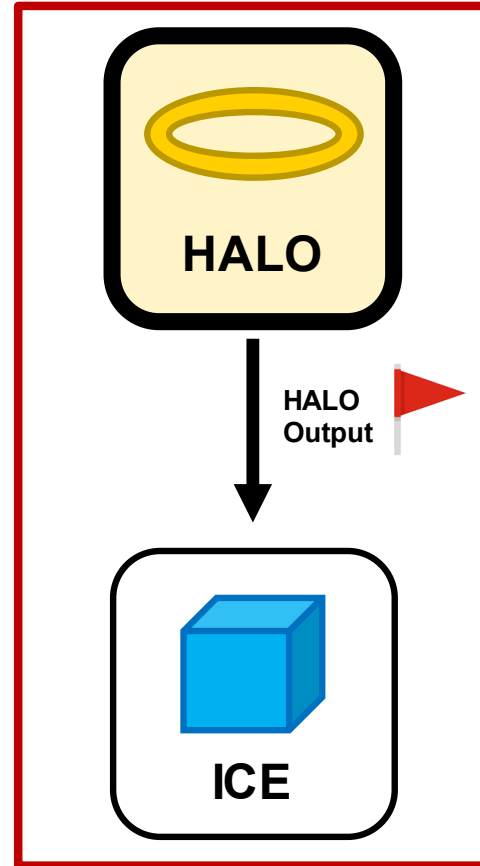
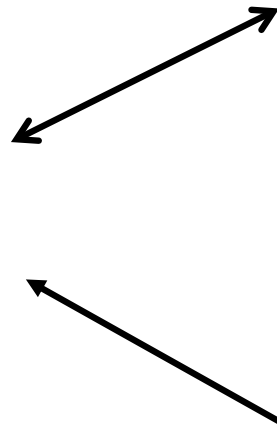
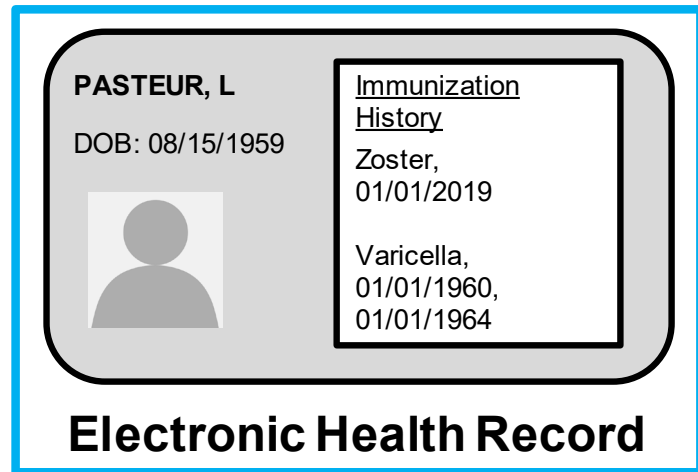
- Provider opens patient immunization record
- EHR system triggers call to HALO decision support
- EHR sends FHIR payload (message) with basic patient data

Building the System



- The CQL rules are implemented in HALO
- HALO receives the information from the EHR and runs the rules
- If additional information is needed to make a decision, the system will query the EHR

Building the System

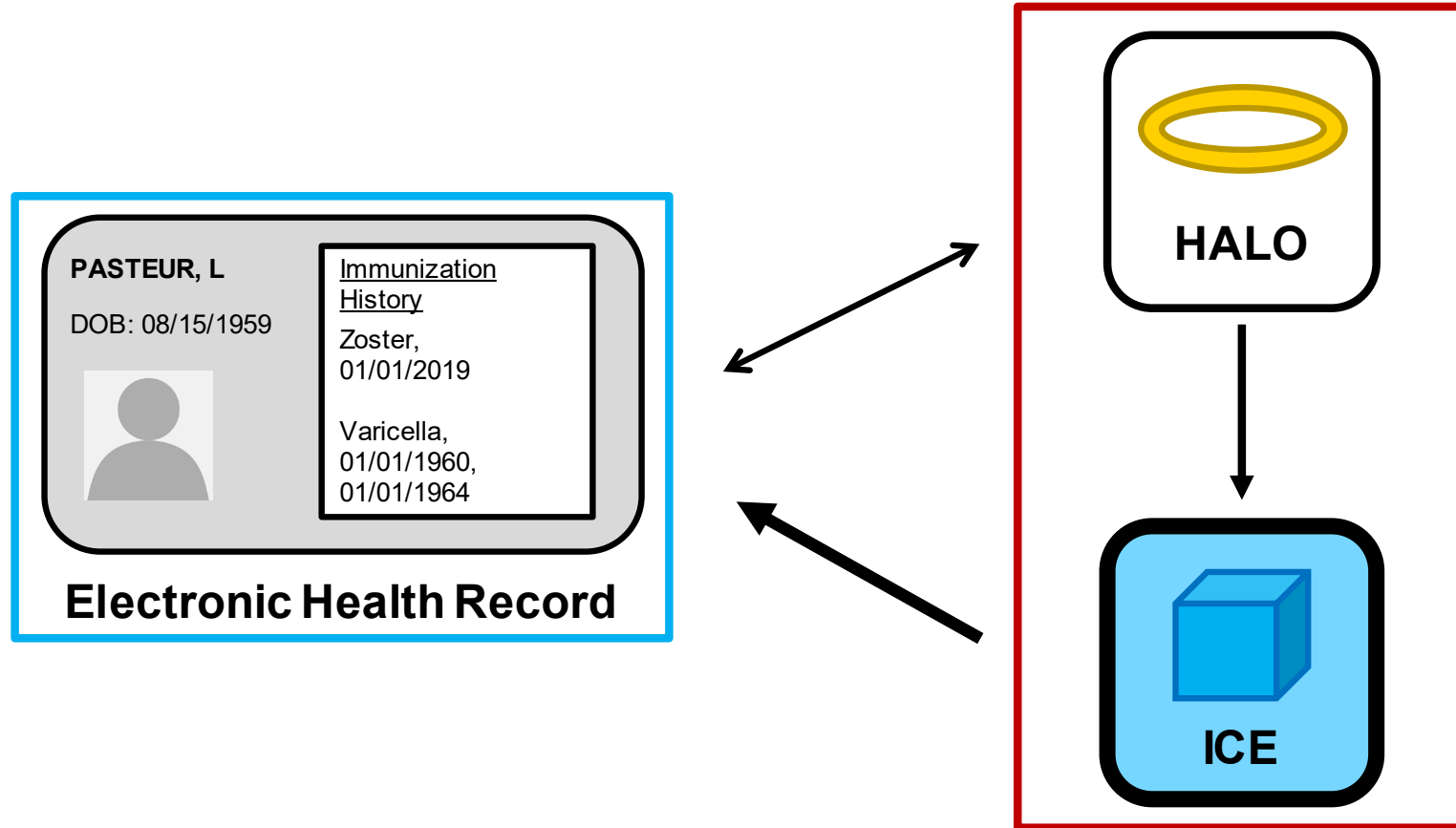


HALO outputs whether contraindications were detected and for what condition.

Example:
“FLAG: Contraindication for Zoster”

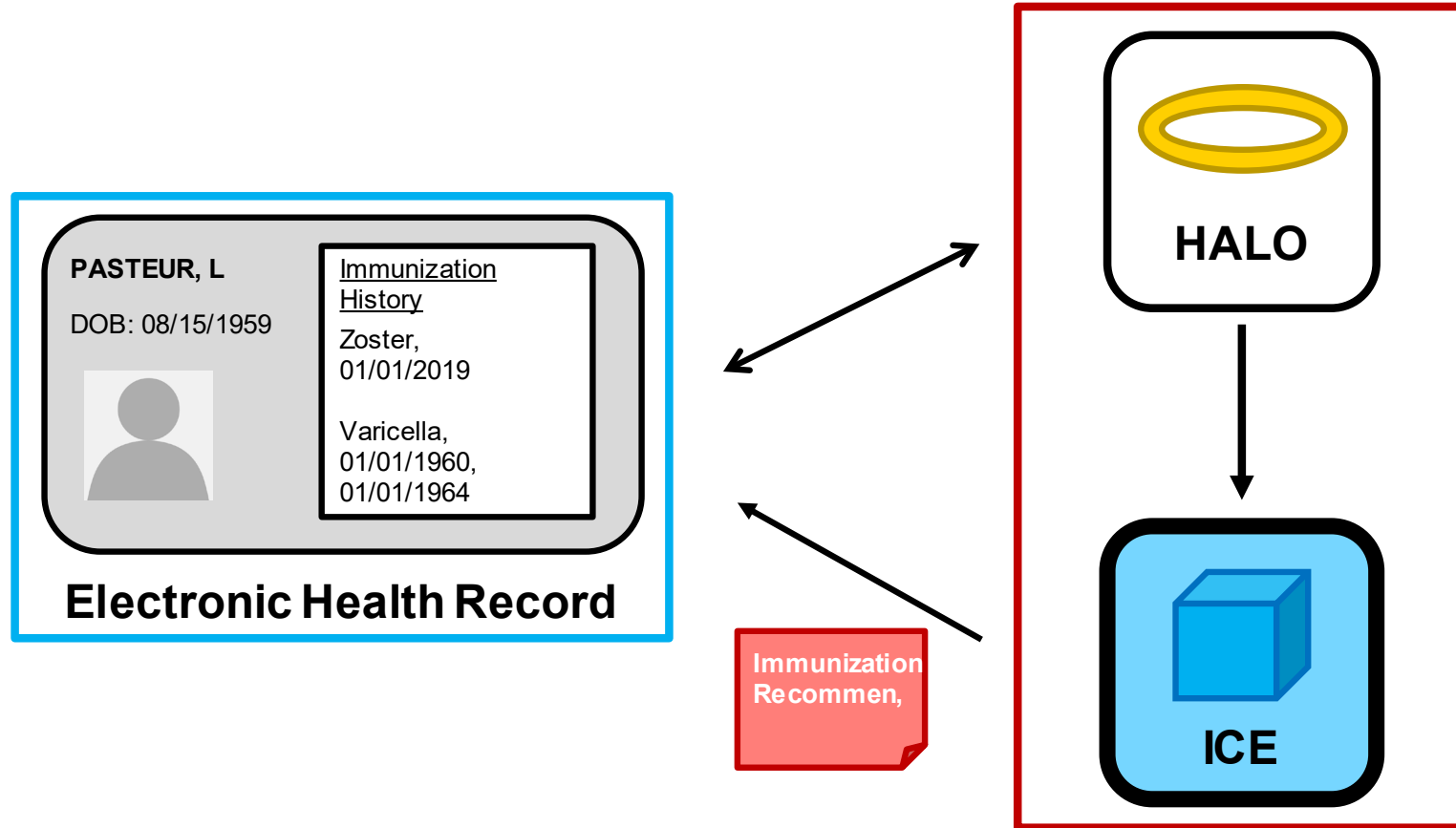
This is passed to the ICE forecaster.

Building the System



- ICE, the immunization forecaster, uses the patient information from the EHR to generate an initial recommendation.
- ICE then looks at the HALO output
- If a contraindication identified, ICE will output a “conditional” and provide reason

Building the System



- ICE outputs its final immunization recommendations
- The ICE output is returned to the EHR



Where We Are Now, Lessons Learned and Future Enhancements



Where We Are Now

- “Re-writing” CQL Rules
 - Emulating other CQL projects, wrote CQL rules in QUICK (Logic model related to FHIR QiCore)
 - Switching back to base FHIR resources for ease for testing
- Implementing FHIR Server / decision support service
 - Initial service implemented and tested
- Developing test cases and patient data to test HALO rules
- Implementing multiple sets of HALO rules together



Lessons Learned

- Rules development
 - Challenges using new technology
 - Creating HALO rules
 - Balancing positive predictive value and negative predictive value of rules
 - Variation between how concepts represented in different EHR systems
 - How should ICE use the HALO output?
 - Example: If HALO outputs a flag for a vaccine level contraindication, how does that impact ICE recommendations?
 - ICE currently outputs recommendations at vaccine group level
 - Would changes be needed to the ICE output to provide a clearer recommendation?



Lessons Learned

- Implementation: Architecture and workflow
 - HALO as a separate service vs adding HALO rules to ICE
 - For initial work, decision made due to staffing/resource considerations
 - Separating services created workflow questions, such as whether to call HALO or ICE first



Future Enhancements

- Completion of current activities
 - Delays due to competing projects
- Expansion to additional conditions
- Expansion to indications and other contraindications
- Integration into EHR system for pilot



Thank you!

Contact us for more information!

Janet Hui

janet@hln.com