

Kathleen Pittman, RN, MPH

Veterans Health Administration

National Program Manager for Health Promotion Disease Prevention Programs

Maiko Minami

HLN Consulting, LLC

Project Manager

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Objectives

- To describe how Veteran's Health Administration and HLN are implementing Health, Age, Lifestyle, and Occupation (HALO) factors in an immunization forecasting system
- To share considerations, benefits, and challenges in implementing health factors as part of Clinical Decision Support (CDS) and with immunization forecasting





Background





- HLN first began developing ICE in 2011 for New York City Citywide Immunization Registry
- ICE is now an open-source immunization forecasting system available for free
- VHA contracted HLN in 2016 to support the implementation of ICE in their EHR system and implement enhancements to ICE



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



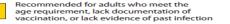
Excerpt of Immunization Schedule

https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

Figures 1 and 2 should be read with the footnotes that contain important general information and considerations for special populations.

Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2017

Vaccine	19–21 years	22–26 years	27–59 years	60–64 years	≥ 65 years
Influenza¹	1 dose annually				
Td/Tdap ²	Substitute Tdap for Td once, then Td booster every 10 yrs				
MMR³	1 or 2 doses depending on indication				
VAR⁴	2 doses				
HZV⁵				1 dose	
HPV–Female ⁶	3 doses				
HPV–Male ⁶	3 doses				
PCV13 ⁷	1 d <mark>ose</mark>				
PPSV23 ⁷	1 or 2 doses depending on indication				1 dose
HepA ⁸	2 or 3 doses depending on vaccine				
HepB ⁹	3 doses				
MenACWY or MPSV4 ¹⁰	1 or more doses depending on indication				
MenB¹º	2 or 3 doses depending on vaccine				
Hib ¹¹	1 or 3 doses depending on indication				









Excerpt of Footnotes

Footnotes. Recommended immunization schedule for adults aged 19 years or older, United States, 2017

1. Influenza vaccination

General information

- All persons aged 6 months or older who do not have a contraindication should receive annual influenza vaccination with an age-appropriate formulation of inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV).
- In addition to standard-dose IIV, available options for adults in specific age groups include: high-dose or adjuvanted IIV for adults aged 65 years or older, intradermal IIV for adults aged 18 through 64 years, and RIV for adults aged 18 years or older.
- Notes: Live attenuated influenza vaccine (LAIV) should not be used during the 2016–2017 influenza season. A list of currently available influenza vaccines is available at www.cdc.gov/flu/protect/vaccine/ vaccines htm.

Special populations

- Adults with a history of egg allergy who have only hives after exposure to egg should receive age-appropriate IIV or RIV.
- Adults with a history of egg allergy other than hives, e.g., angioedema, respiratory distress, lightheadedness, or recurrent emesis, or who required epinephrine or another emergency medical intervention, may receive age-appropriate IIV or RIV. The selected vaccine should be administered in an inpatient or outpatient medical setting and under the supervision of a healthcare provider who is able to recognize and manage severe allergic conditions.
- Pregnant women and women who might become pregnant in the upcoming influenza season should receive IIV.

2. Tetanus, diphtheria, and acellular pertussis vaccination General information

- Adults who have not received tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) or for whom pertussis vaccination status is unknown should receive 1 dose of Tdap followed by a tetanus and diphtheria toxoids (Td) booster every 10 years. Tdap should be administered regardless of when a tetanus or diphtheria toxoid-containing vaccine was last received.
- Adults with an unknown or incomplete history of a 3-dose primary series with tetanus and diphtheria toxoid-containing vaccines should complete the primary series that includes 1 dose of Tdap. Unvaccinated adults should receive the first 2 doses at least 4 weeks apart and the third dose 6-12 months after the second dose.
- Notes: Information on the use of Td or Tdap as tetanus prophylaxis in wound management is available at www.cdc.gov/mmwr/preview/ mmwrhtml/rr5517a1.htm.

Special populations

 Pregnant women should receive 1 dose of Tdap during each pregnancy, preferably during the early part of gestational weeks 27–36, regardless of prior history of receiving Tdap.

3. Measles, mumps, and rubella vaccination

General information

- Adults born in 1957 or later without acceptable evidence of immunity to measles, mumps, or rubella (defined below) should receive 1 dose of measles, mumps, and rubella vaccine (MMR) unless they have a medical contraindication to the vaccine, e.g., pregnancy or severe immunodeficiency.
- Notes: Acceptable evidence of immunity to measles, mumps, or rubella in adults is: born before 1957, documentation of receipt of MMR, or laboratory evidence of immunity or disease. Documentation of healthcare provider-diagnosed disease without laboratory confirmation is not acceptable evidence of immunity.

Special populations

- Pregnant women who do not have evidence of immunity to rubella should receive 1 dose of MMR upon completion or termination of pregnancy and before discharge from the healthcare facility; nonpregnant women of childbearing age without evidence of rubella immunity should receive 1 dose of MMR.
- Adults with primary or acquired immunodeficiency including malignant conditions affecting the bone marrow or lymphatic system, systemic immunosuppressive therapy, or cellular immunodeficiency should not receive MMR.
- Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count ≥200 cells/µl for at least 6 months who do not have evidence of measles, mumps, or rubella immunity should receive 2 doses of MMR at least 28 days apart. Adults with HIV infection and CD4+ T-lymphocyte count <200 cells/µl should not receive MMR.
- Adults who work in healthcare facilities should receive 2 doses of MMR at least 28 days apart; healthcare personnel born before 1957 who are unvaccinated or lack laboratory evidence of measles, mumps, or rubella immunity, or laboratory confirmation of disease should be considered for vaccination with 2 doses of MMR at least 28 days apart for measles or mumps, or 1 dose of MMR for rubella.
- Adults who are students in postsecondary educational institutions or plan to travel internationally should receive 2 doses of MMR at least 28 days apart.
- Adults who received inactivated (killed) measles vaccine or measles vaccine of unknown type during years 1963–1967 should be revaccinated with 1 or 2 doses of MMR.
- Adults who were vaccinated before 1979 with either inactivated mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection, e.g., work in a healthcare facility, should be considered for revaccination with 2 doses of MMR at least 28 days apart.

4. Varicella vaccination

General information

- Adults without evidence of immunity to varicella (defined below) should receive 2 doses of single-antigen varicella vaccine (VAR) 4–8 weeks apart, or a second dose if they have received only 1 dose.
- Persons without evidence of immunity for whom VAR should be emphasized are: adults who have close contact with persons at high risk for serious complications, e.g., healthcare personnel and household contacts of immunocompromised persons; adults who live or work in an environment in which transmission of varicella zoster virus is likely, e.g., teachers, childcare workers, and residents and staff in institutional settings; adults who live or work in environments in which varicella transmission has been reported, e.g., college students, residents and staff members of correctional institutions, and military personnel; nonpregnant women of childbearing age; adolescents and adults living in households with children: and international travelers.
- Notes: Evidence of immunity to varicella in adults is: U.S.-born before 1980 (for pregnant women and healthcare personnel, U.S.-born before 1980 is not considered evidence of immunity); documentation of 2 doses of VAR at least 4 weeks apart; history of varicella or herpes zoster diagnosis or verification of varicella or herpes zoster disease by a healthcare provider; or laboratory evidence of immunity or disease.

Special populations

- Pregnant women should be assessed for evidence of varicella immunity.
 Pregnant women who do not have evidence of immunity should receive the first dose of VAR upon completion or termination of pregnancy and before discharge from the healthcare facility, and the second dose 4–8 weeks after the first dose.
- Healthcare institutions should assess and ensure that all healthcare personnel have evidence of immunity to varicella.
- Adults with malignant conditions, including those that affect the bone marrow or lymphatic system or who receive systemic

 Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count ≥200 cells/µl may receive 2 doses of VAR 3 months apart. Adults with HIV infection and CD4+ T-lymphocyte count <200 cells/ul should not receive VAR.

5. Herpes zoster vaccination

General information

 Adults aged 60 years or older should receive 1 dose of herpes zoster vaccine (HZV), regardless of whether they had a prior episode of herpes zoster.

Special populations

- Adults aged 60 years or older with chronic medical conditions may receive HZV unless they have a medical contraindication, e.g., pregnancy or severe immunodeficiency.
- Adults with malignant conditions, including those that affect the bone marrow or lymphatic system or who receive systemic immunosuppressive therapy, should not receive HZV.
- Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count <200 cells/ul should not receive HZV.

6. Human papillomavirus vaccination

General information

- Adult females through age 26 years and adult males through age 21 years who have not received any human papillomavirus (HPV) vaccine should receive a 3-dose series of HPV vaccine at 0, 1-2, and 6 months. Males aged 22 through 26 years may be vaccinated with a 3-dose series of HPV vaccine at 0, 1-2, and 6 months.
- Adult females through age 26 years and adult males through age 21 years (and males aged 22 through 26 years who may receive HPV vaccination) who initiated the HPV vaccination series before age 15 years and received 2 doses at least 5 months apart are considered adequately vaccinated and do not need an additional dose of HPV vaccine.
- Adult females through age 26 years and adult males through age 21 years (and males aged 22 through 26 years who may receive HPV vaccination) who initiated the HPV vaccination series before age 15 years and received only 1 dose, or 2 doses less than 5 months apart, are not considered adequately vaccinated and should receive 1 additional dose of HPV vaccine.
- Notes: HPV vaccination is routinely recommended for children at age 11 or 12 years. For adults who had initiated but did not complete the HPV vaccination series, consider their age at first HPV vaccination (described above) and other factors (described below) to determine if they have been adequately vaccinated.

Special populations

- Men who have sex with men through age 26 years who have not received any HPV vaccine should receive a 3-dose series of HPV vaccine at 0, 1-2, and 6 months.
- Adult females and males through age 26 years with immunocompromising conditions (described below), including those with human immunodeficiency virus (HIV) infection, should receive a 3-dose series of HPV vaccine at 0, 1–2, and 6 months.
- Pregnant women are not recommended to receive HPV vaccine, although there is no evidence that the vaccine poses harm. If a woman is found to be pregnant after initiating the HPV vaccination series, delay the remaining doses until after the pregnancy. No other intervention is needed. Pregnancy testing is not needed before administering HPV vaccine.
- Notes: Immunocompromising conditions for which a 3-dose series of HPV vaccine is indicated are primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity, e.g., B-lymphocyte antibody deficiencies, complete or partial T-lymphocyte defects, HIV infection, malignant neoplasm, transplantation, autoimmune



Input to ICE

- Patient parameters
 - Date of birth
 - Gender
 - Immunization history (vaccine and admin date)
 - Disease immunity
 - NEW with VHA: HALO Factors



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





HALO Factors

- Purpose is for vaccination recommendations take into consideration HALO factors to potentially change recommendations
 - Health
 - Age
 - Lifestyle
 - Occupation





- Health-Related Factors include:
 - Pregnancy Status
 - Immunocompromised
 - Contraindications

- Medications
- Allergies
- High Risk

Examples:

- If patient contains evidence of being immunocompromised, do not recommend Zoster vaccination
- If patient has high risk of Pneumococcal disease due to taking long term steroids or due to being immunocompromised (along with other factors), then recommend Pneumococcal vaccination



Age Factors

Age factors

 Meeting an age threshold that adjusts the recommendation in addition to the default schedule age requirements

Example:

 If patient is an unvaccinated health care personnel born before 1957 who lacks laboratory evidence of measles, mumps or rubella immunity, then recommend 1 or 2 doses of MMR vaccine (based on other criteria)





Lifestyle Factors

- Lifestyle factors include:
 - International travel
 - Close contact with immunocompromised persons
- Example:
 - If patient plans to travel internationally or are close contacts of immunocompromised persons, then follow the 2-dose MMR schedule for recommendation





Occupational Factors

- Occupational factors include:
 - Working in a health care facility
 - Students in post-high school educational institutions

Example:

 If patient works in a health care facility or is a student in posthigh school educational institutions, then follow the 2-dose MMR schedule for recommendation





Process for Identifying HALO Factors Relevant to VHA





- Identify: How are HALO factors identified to be incorporated as part of the vaccination recommendations?
- Define: How are HALO factors defined and what is the data available from the VHA EHR system?
- Translate: How are HALO factors translated to the corresponding ICE forecasting rules for implementation?



Identifying HALO Factors

- Identify which HALO factors should be incorporated as part of the vaccination recommendations
- Used 3 processes to identify HALO factors:
 - Existing VHA Clinical Reminders: Zoster, Pneumococcal, HPV
 - Unreleased VHA Clinical Reminder in combination with VHA Guidance Statement: Influenza
 - VHA Guidance Statements with no VHA Clinical Reminders: MMR





- VHA Clinical Reminders include rules used by the VHA system to determine if and when reminders should be displayed to clinical staff
- VHA Clinical Reminders incorporate HALO factors as part of the rules set.
 - This provided a starting point for identifying HALO factors for ICE to consume.





VHA Clinical Reminders – Snapshot

Snapshot of Zoster Logic

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Customized PATIENT COHORT LOGIC to see if the Reminder applies to a patient: (SEX)&(AGE)&(FI(2)!FI(3))&'(FI(9)!FI(5))

Expanded Patient Cohort Logic: (SEX)&(AGE)&(FI(VA-SEX)!FI(VA-SEX))&'

(FI(VA-HPV VACCINE CONTRAINDICATED)!FI(VA-LIFE EXPECTANCY < 6 MONTHS))
```





- VHA Guidance Statements are written clinical guidelines to providers for giving vaccinations
 - Does not include any logic or rules consumable by software systems
- VHA Guidance Statement incorporate ACIP Guidelines, HALO factors, and other VHA guidelines specific to their patient population.



VHA Guidance Statements – Snapshot

Clinical Preventive Service Guidance Statement: Mumps, Measles and Rubella (MMR) Immunization

VHA recommends at least 1 dose of MMR vaccine against measles, mumps and rubella (unless contraindicated or already received) for all adults born during or after 1957, if there is <u>not</u> documented evidence of immunity.

VHA recommends a second dose of MMR vaccine (unless contraindicated) for adults born during or after 1957 who: 1) have been vaccinated previously with a killed or unknown type of measles vaccine; 2) are students in post-high school educational institutions; 3) work in a health care facility; 4) plan to travel internationally; 5) are close contacts of immunocompromised persons; or 6) have HIV with a CD4 count ≥200 lymphocytes/mm³ or a CD4+ T-lymphocyte percentage >15%. A second dose is not needed if there is adequate documentation of 2 doses of live vaccine, laboratory evidence of immunity or laboratory confirmation of disease.





- How are HALO factors defined and what is the data available from the VHA EHR system?
- A value must be provided to ICE indicating that a patient has a certain HALO factor that must be considered when making a recommendation



Defining HALO Factors

- Data are available through Value Sets/Taxonomy and Flags
- Depending on how granular the data are available to identify a factor, either the VHA system or ICE will determine whether the HALO factor applies to the patient
 - Value Set HALO determination made by ICE
 - Flag HALO determination made by VHA EHR system





Value Sets/Taxonomy

- Value Set for Zoster "Immunocompromised" contains 2160 codes from ICD-9/10 or SNOMED CT
- Example: Code "C81.98" for "Hodgkin Lymphoma, unspecified, Lymph Nodes of multiple sites"
- Example of Use: If a patient's record is sent to ICE containing a code from the Zoster "Immunocompromised" value set, then ICE does not recommend the vaccine

Defining HALO Factors - Flags

- Flag: Indicates that a particular HALO factor is applicable to the patient
- Used in cases where some factors are not available as coded data or where codes may be available, but frequently not coded in practice.
 - Examples: Occupation, Future International Travel, Living with Immunocompromised Persons, Men who have Sex with Men (MSM)
 - There are some factors where a flag is "reserved" for future use where data is not yet available but will be sent in the future





- Example of Flag: Pregnancy and HPV Vaccine
- Example of Use: If a patient record contains a pregnancy flag, then ICE should not recommend the HPV vaccine
 - While not contraindicated, HPV is not recommended for pregnant women.
 Therefore, VHA does not want ICE to recommend HPV.



Translating HALO Factors

- How are HALO factors translated to the corresponding ICE forecasting rules for implementation?
- The standard process was to identify for each potential factor:
 - 1) HALO Factor
 - 2) Flag or Value Set
 - 3) Rule How does this HALO Factor affect the recommendation?



Translating HALO Factors

ICE Clinical Rules – Example of HPV HALO Factors

```
Patient record contains evidence of:

[

Rule-HPV.001: Patient has contraindication to HPV vaccines.

OR

Rule-HPV.002: Patient has life expectancy less than 6 months.

OR

Rule-HPV.003: Patient is currently pregnant.

]

THEN

Do not recommend HPV vaccine
```





Lessons Learned from this Process

- Standardize the Process: Standardizing the process for identifying HALO Factors helped expedite activities:
 - Starting the process using VHA Clinical Reminders helped identify HALO factors in a concise and structured way
 - If we started with MMR where there are no existing VHA Clinical Reminders and only VHA Guidance, we would have not identified the standardized inputs and output as quickly.



Lessons Learned from this Process

- Changes to EHR System: By understanding the data used for HALO factors, changes were identified to be made to the VHA System:
 - Example: 'Immunocompromised' factor:
 - For Zoster, it was used to **not recommend** the vaccination.
 - For Pneumococcal, the same terminology was used to recommend the vaccination.
 - Discussion helped expose that while seemingly similar, the use of the 'Immunocompromised' taxonomy as exclusion vs inclusion criteria required the need for two different taxonomies with different codes



Considerations for HALO Factors

- Generalizing Usage: How to standardize the rules so that HALO factors can be used by non-VHA users of ICE as part of an open-source software feature?
 - General applicability and standards were kept in mind with value sets, flags and factors.
 - Value Sets use standard code systems. Other system can create their own value sets.
 - Flags are system-agnostic. There is nothing VHA-specific about the flags used for input. Similar concepts/flags already exist in ICE (e.g. Proof_of_Immunity and Disease_Documented)
 - Specifications will likely offer both options (flags and value sets) for all factors as input so that systems can provide either input based on data availability



- Better Accuracy: ACIP Recommendations is largely affected by special conditions (footnotes).
 - HALO factors allow for much more accurate immunization forecasting and recommendations
 - Increased Sensitivity and Specificity: Indications and contraindications were considered and can appropriately affect recommendations



Benefits of HALO Factors

- Future Ability: Some systems and IIS may not be able to incorporate HALO factors now, but it is worth future consideration.
 - This is a good prototype to demonstrate expanded usage
 - Takes into consideration issues that IIS deal with now.
 - It may be worth looking at existing data exchanges using standardized messages to see if this information can be provided and incorporated





- HLN's ICE Webpage (<u>www.hln.com/ice</u>)
- ICE Wiki (<u>cdsframework.org</u>)
- Public Wiki for ICE Software Downloads (https://cdsframework.atlassian.net/wiki/display/ICE/Downloads)
- VHA Public Health Vaccines and immunizations (http://www.publichealth.va.gov/vaccines.asp)



Contact Us for More Information

Maiko Minami, HLN

maiko@hln.com

Kathy Pittman, VHA

kathleen.pittman@va.gov

Robert Silverman, VHA

Robert.Silverman@va.gov

