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# Background

A workgroup of subject matter experts convened over the course of several weeks in 2020 to determine the technical requirements for an IIS to receive and store messages containing population group and tier allocation during a mass vaccination event. Mass vaccination events are events where many people receive immunizations; this could be in response to a pandemic, natural disaster, or routine immunization campaign, such as annual flu. This effort was initiated to address proactively the potential need for IIS to support vaccine allocation in response to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19.

#### **Preliminary Guidance**

This guidance was published in preliminary format to assist IIS, EHR vendors, and other stakeholders in preparing for the technical requirements of the COVID-19 response. This document will be updated as necessary over the course of the response. See Appendix A for items that have not been clarified and still require community discussion.

The Centers for Disease Control and Prevention (CDC) has developed a targeting strategy for the effective allocation and administration of vaccine during a pandemic. Every person in the United States will be included in at least one population group based on their occupation, age, or risk level. These population groups will be assigned to tiers based on the severity of the pandemic. Population groups can be assigned to different tiers through the course of the pandemic, and persons can move into and out of population groups.

The purpose of this guide is to cover the technical aspects of how an electronic health record (EHR) captures an individual's population group and tier and communicates that information to an IIS. This information may be exchanged at the patient or vaccination level.

# Scope of Guidance

## In scope

The scope of this *Preliminary Reporting Mass Vaccination Population Groups and Tiers* guidance includes the receipt and reporting of population group and tiers in Health Level 7 (HL7) messaging. This document will present vocabulary terms and guidance for IIS to receive population group and tier classifications at the patient and vaccination level.

## Out of scope

The scope of this guidance does not extend to:

- The creation of population groups and tiers
- The workflow of assigning an individual to one or more population groups
- Vaccine allocation and distribution based on group or tier classification
- Importing lists of patients of specific population groups into the IIS in a non-HL7 format (e.g., importing a list of employees who need to be vaccinated as a group)

- The use of priority groups and tiers in forecasting logic
- IIS reminder/recall functionality based on population groups or tiers
- Reports an IIS may generate to report on population groups or tiers
- Storage and management of the population and tier groups of individuals over time
- Reporting the population group or tier information in a query response (RSP) message

# Keywords

This document will use keywords defined by IETF RFC 2119 (<a href="https://tools.ietf.org/html/rfc2119">https://tools.ietf.org/html/rfc2119</a>). Briefly, the keywords used in this document include:

- **Must** This word and the terms "required" or "shall" mean that the definition is an absolute requirement of the specification.
- **Should** This word and the adjective "recommended" mean that there may exist valid reasons in particular circumstances to ignore a particular item but the full implications must be understood and carefully weighed before choosing a different course.

## Guidance

**Table 1 - Vocabulary** 

Term	Definition	Example
Mass vaccination event	Large scale vaccination event.	Annual influenza clinic for a college campus, COVID-19 pandemic vaccine, or vaccination campaign in response to a natural disaster or bioterrorism threat
Population group	Groups of individuals targeted for vaccination and defined by occupation, age, or risk level. Individuals can be in more than one population group (e.g., front-line health care worker who is pregnant). They can move in and out of population groups as time progresses.	Front line health care workers, emergency response, adults over 65 years, pregnant women
Tier/priority group	Priority designation for vaccine allocation and	Tier 1, Tier 2, Tier 3

Term	Definition	Example
	administration for population groups. All groups designated for vaccination within a tier will have equal priority for vaccination. Tier/priority designation of population groups will vary depending on pandemic severity.	
Effective date	The date the individual was assessed by the administering provider for population group and tier for a mass vaccination event.	

#### Available standards

HL7, AIRA, and CDC have published or are developing several interoperability standards and guides which may be relevant to the exchange of population group and tier data. The following standards may be relevant to the remainder of the document.

- HL7 Version 2.5.1 Implementation Guide for Immunization Messaging
  - This is the current implementation guide for immunization messaging and contains guidance on transmitting mass vaccination event data elements.
  - o <a href="https://repository.immregistries.org/files/resources/5bef530428317/hl7\_2\_5">https://repository.immregistries.org/files/resources/5bef530428317/hl7\_2\_5</a> 1 release 1 5 2018 update.pdf

## Population group and tier HL7 exchange

Individuals will be assigned to population groups and these groups to tiers based on CDC or local guidance. Using HL7 2.5.1 Release 1.5 standards, these data fields can be captured and communicated in the observation (OBX) segment at the patient and the vaccination level.

Table 2 - Message type and data location

Message Type	Location
Patient level	Grouped under an ORC/RXA combination where RXA-3 indicates "998^No vaccine administered^CVX," following the same pattern as reporting patient related information, such as reporting contraindications or precautions.
Vaccination level	Grouped under an ORC/RXA that reports the administration of the vaccination related to the mass vaccination event.

Each OBX segment is a question and an answer, where Observation Identifier (OBX-3) indicates the question and Observation Value (OBX-5) indicates the answer.

**Table 3 - Concept and message location** 

Concept	Location	LOINC Details in OBX-3
Mass vaccination event	OBX-5	Where OBX-3 indicates: 90064-7^Public health emergency event name^LN
Population group	OBX-5	Where OBX-3 indicates: 95715-9^ Population group^LN
Tier	OBX-5	Where OBX-3 indicates: 95793-6^ Immunization priority tier^LN
Effective date	OBX-14	The preceding OBX segments must all indicate the same effective date.

The Observation Identifier (OBX-3) and Observation Value (OBX-5) must be assigned coded values. Additional community discussion will be needed to determine how the answers in Observation Value (OBX-5) will be coded.

In order to communicate a complete set of information, the information in Table 4 must be communicated.

**Table 4 - Concept communication** 

Concept	Status	Details
Mass vaccination event	Required	Population group and tier assignment occurs within the context of a specific event, and this must be indicated to both differentiate from other events and provide meaning to the other concepts.  In order to communicate any of the following concepts, the mass vaccination event must be indicated.
Population group	Required if known but may be omitted if tier is indicated	Population group must be indicated if known. If it is not known or was not determined, then it must be omitted. A person can be in more than one population group.  If the tier is omitted, then the population group is required.
Tier	Required if known but may be omitted if	Tier must be indicated if known. If it is not known or was not determined, it must be omitted.

Concept	Status	Details
	population group is indicated	If the population group is omitted, then the tier is required.
Effective date	Required if known but may be empty	Each OBX segment described above must indicate the effective date of patient assignment in OBX-14. If the effective date cannot be determined or is unknown, then OBX-14 must be left empty.

## Interaction between population group and tier

The guidance from the CDC indicates that, as the severity of a pandemic changes, population groups may be reassigned to new tiers. For example, in low severity, a certain population might not be indicated to receive a vaccination but will in a high-severity situation. The guidance for messaging this information is:

- Senders must always communicate the population group and/or tier as it was determined to be as of the effective date.
- Receivers must assume that patients may move in and out of population groups based on personal status changes (e.g., employment changes).
- Receivers must be prepared for population groups to be reassigned to tiers as a pandemic progresses.

# Appendix A: Items for Future Discussion

Below is the list of additional questions that were asked by Standards and Interoperability Steering Committee (SISC) reviewers and need further discussion by SISC or a future SISC Small Work Group. These are being documented here as a starting point for further discussion on future versions of this guidance.

#### Patient versus vaccination level data exchange:

- Do we really need to distinguish between patient and vaccination level group/tier data exchange?
- Will an IIS save the data differently depending on the context in which the assignment was made?
- Does it matter if the assignment was made as part of a vaccination event? Is the patient level about the overall patient assignment and the vaccination level the "why" the vaccine was administered?
- Is there a difference? Do providers really need to rationalize their decision to vaccinate?

#### Mass vaccination event (MVE):

- Should MVE information be incorporated into priority group or tier code?
- Is there a need to be able to analyze patient categorization tiers across MVEs?

### Multiple population groups:

- How should an individual's multiple population groups be communicated?
- Is the recommendation for vaccination made at the tier level?
- If so, does the recommendation change because a population group is moved to a new tier?

#### MVE event data storage:

- Should a patient have only one active tier/group per MVE?
- If a new tier/group is received by the IIS, should this be stored?
  - o If so, how should it be stored or merged?

### Proposed code set

• Review proposed code set in Appendix B and D.

# Appendix B: Proposal for Managing Code Sets

The codes for each of these sets will need to be defined by the authority overseeing the pandemic. For a US-wide pandemic, the federal level would be responsible for assigning and publishing these code sets. For state declared/managed pandemics/disasters, this would be managed by the state.

#### Mass vaccination

For mass vaccination, the following format is recommended:

- Nationally: YYYY-[Event], e.g. 2020-COVID
- State: YYYY-ST-[Event], e.g. 2017-TX-Harvey (Hurricane Harvey hit Texas in 2017)
- Code Set: 99MVE

A state would define a mass vaccination event code only if the event is local and not defined nationally. A national event would be used as is by all states and does not need to be redefined locally.

### Population group

For population group, the following format is recommended:

- Nationally: [DISEASE]-nn, e.g. COVID-01, or FLU-07
- State: [DISEASE]-ST-nn, e.g. COVID-TX-01
- Code Set: 99PG

A state would use national codes if available and define local ones only if no national match could be found. Messaging could be a mix of both national and local codes. For example, a local event could use a mixture of both nationally defined population groups and locally defined ones.

#### Tier

For tier, the following format is recommended:

- T1...T9 for Priority 1 to Priority 9 (if needed)
- NT for Not Targeted
- Code Set: 99TIER

Tier groups will most likely not need to be dynamically updated. In most cases only a few tiers are needed, and it is most natural to have them numbered. Having a static set of tiers that are used for all events will be easier to message and manage.

# Appendix C: Examples and Test Cases

Warning: The HL7 examples shown in this appendix are preliminary and not yet tested or verified.

The use cases below describe situations an IIS must be prepared for. The following format will be used:

#### Use case name

- Actors: Who is establishing the process or using the process
- Description: Description of the process
- Expected outcome: Describes the expected output of the process
- General messaging guidance: Describes how to submit mass vaccination event (population groups, tier, and effective date) in an HL7 message

### Use Case 1: patient (client) level mass vaccination identification

- Actors: provider, patient, submitting system, receiving system.
- Description: Provider identifies the population group and/or tier the patient is in for the mass vaccination event and records that information in the submitting system.
- Expected outcome: The provider's system sends the mass vaccination event information as well as the patient's population group and/or tier into the IIS.
- General messaging guidance:
  - o No vaccine administered RXA segment
  - OBX group submission
    - Mass vaccination event information
    - Population group information
    - Tier information

#### Use Case 1 example

RXA|0|1|20200605||998^No Vaccine Administered^CVX|999|||||||||NA|A

OBX|1|CE|90064-7^Public health emergency event name^LN |1|2020-COVID^2020 COVID-19^999 |||||F|||20200524

OBX|2|CE|95715-9^ Population group^LN |1| COVID-01^Deployed \T\ mission essential personnel^999|||||F|||20200654

OBX|3|CE|95793-6^ Immunization priority tier^LN |1|T1^Tier 1^999|||||F|||20200524

## Use Case 2: patient mass vaccination vaccine administration

- Actors: provider, patient, submitting system, receiving system.
- Description: Provider identifies the population group and/or tier the patient is in for the mass vaccination event and records that information in the submitting system.
   Patient is identified as being in the population group and/or tier that is being vaccinated currently. Patient receives the vaccine available for the mass vaccination event.

- Expected outcome: The provider's system sends the mass vaccination event information as well as the population group and/or tier the patient is in to the IIS as well as the vaccine information that was administered to the patient.
- General messaging guidance:
  - o Vaccine administered RXA segment
  - OBX group submission
    - Mass vaccination event information
    - Population group information
    - Tier information

## Use Case 2 example

RXA|0|1|20200524||135^Influenza, high dose seasonal^CVX|0.5|mL^mL^UCUM||00^New Record^NIP001|7824^Jackson^Lily^Suzanne^^^^NIST-PI-1^L^^^PRN|^^^NIST-Clinic-1|||315841|20201216|PMC^Sanofi Pasteur^MVX|||CP|A

RXR | C28161^Intramuscular^NCIT | RD^Right Deltoid^HL70163

 $OBX|1|CE|64994-7^{Vaccine}\ funding\ program\ eligibility\ category^{LN}|1|V05^{VFC}\ eligible\ -\ Federally\ Qualified\ Health\ Center\ Patient\ (under-$ 

insured)^HL70064|||||F|||20200524|||VXC40^Eligibility captured at the immunization level^CDCPHINVS

OBX|2|CE|30956-7^vaccine type^LN|2|88^Influenza, unspecified formulation^CVX|||||F

OBX|3|TS|29768-9^Date vaccine information statement published^LN|2|20120702|||||F

OBX|4|TS|29769-7^Date vaccine information statement presented^LN|2|20200524|||||F

OBX|5|CE|90064-7^Public health emergency event name^LN |3|2020-COVID^2020 COVID-19^999 |||||F|||20200524

 $OBX|6|CE|95715-9^{population group^LN}|3|COVID-01^{Deployed \T\ mission essential personnel^999|||||F|||20200654}$ 

OBX|7|CE|95793-6^ Immunization priority tier^LN |3|T1^Tier 1^999|||||F|||20200524

# Appendix D: Proposed Priority Group Codes

The *Priority Group Preliminary Guidance* document outlines the format of reporting priority groups and tiers through HL7 messaging; the authority overseeing the pandemic defines the code sets for these categories. This appendix proposes a code set based on the Advisory Committee on Immunization Practices (ACIP) priority groups and tiers as of the December 20, 2020, meeting. Communicating priority group is not currently a national COVID-19 requirement; IIS are encouraged to adopt these national values where they align with local definitions. The goal of this guidance document is to aid jurisdictions that request this information from their partners.

These proposed codes based on the ACIP recommendations should be communicated in the OBX-3 segment as outlined in this guide.

Concept	Proposed Code	Definition
Mass vaccination event	COVID19	SARS-CoV-2 pandemic
Priority group	HCP	Health care personnel*
	LTCR	Long-term care facility resident
	FEW	Frontline essential workers**
	AGE75	Persons aged ≥75 years
	OEW	Other essential workers as defined by ACIP
	AGE65	Persons aged 65–74 years
Tiers	1A	Phase 1a of vaccine allocation
	1B	Phase 1b of vaccine allocation
	1C	Phase 1c of vaccine allocation
	2	Phase 2 of vaccine allocation

<sup>\*</sup> ACIP uses the following definition for health care personnel (HCP): all paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted from HCP and patients. For this update, HCP does not include dental health care personnel, autopsy personnel, and laboratory personnel, as recommendations to address occupational infection prevention and control (IPC) services for these personnel are posted elsewhere.

\*\* ACIP defines the following essential workers as frontline: firefighters, police officers, corrections officers, food and agricultural workers, Postal Service workers, manufacturing workers, grocery store workers, public transit workers, those who work in the education sector (teachers and support staff), as well as daycare workers.

### Locally created codes

The recommendation for jurisdictions that are creating their own codes is to keep their code set as simple as possible and in line with the ACIP recommendations.

Local jurisdictions should use the national codes whenever possible but must create local codes for priority groups that are defined differently in the locale. Local jurisdictions must not redefine or change the meaning of nationally defined codes. To ensure that all codes for a pandemic are unique nationally, local codes must be prefixed with their grantee assigning authority code and a dash. (See table 0363 in the CDC IG v.1.5 Appendix A for a list of grantee assigning authority codes.)

It is recommended that the codes selected be human readable and short, as it is likely that implementation of these coded values will require data entry and handling directly by users. The code after the prefix is completely under the control of the local jurisdiction and can be determined by what will best meet operational needs of the IIS and those that report to the IIS.

For example, if the state of Alaska wished to request a higher level of detail on the OEW (Other essential workers), it could create these more specific codes:

- AKA-FIRE "Firefighters"
- AKA-POLICE "Police Officers"
- AKA-CORR "Corrections Officers"

# Appendix E: References

- IETF RFC 2119: <a href="https://tools.ietf.org/html/rfc2119">https://tools.ietf.org/html/rfc2119</a>
- HL7 Version 2.5.1 Implementation Guide for Immunization Messaging:
   https://repository.immregistries.org/files/resources/5bef530428317/hl7\_2\_5\_1\_release\_1\_5\_2018\_update.pdf
- CDC Flu Pandemic Resource Guide: <a href="https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf">https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf</a>
- CDC Vaccination of Tier 1 at All Pandemic Severities: <a href="https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/pandemic-severities-tier-1.html">https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/pandemic-severities-tier-1.html</a>
- CDC Roadmap <a href="https://www.cdc.gov/flu/pandemic-resources/pdf/roadmap-panflu.pdf">https://www.cdc.gov/flu/pandemic-resources/pdf/roadmap-panflu.pdf</a>
- CDC Table of Categories, Population Group, Tiers: <a href="https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/guidance\_508.html#table-1">https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/guidance\_508.html#table-1</a>
- LOINC Code Sets https://loinc.org/downloads/loinc-table/

# Appendix F: Acknowledgements

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