



AIRA

AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

Vaccine Code Set Considerations

If Only It Were Rocket Science

May 21, 2020

Executive Summary	2
Introduction	3
IIS Code Sets in Action	5
Current state	5
Supporting immunization program operations	8
Immunization program operations tools.....	10
IIS Code Set Management Challenges	10
Challenge #1: Change management	10
Challenge #2: Synchronization.....	11
Challenge #3: Timeliness	11
Challenge #4: The need for supporting data	13
Impact of Challenges on Stakeholders	14
Strategies to Advance Code Set Management	15
Vaccine code set supporting data and specifications.....	15
Specification of Code Set Model	16
Code set and supporting data.....	16
Test cases	16
Vaccine Code Set Management System (VCSMS).....	18
Terminology service	19
Conclusion	19
Appendix A: References	21
Appendix B: Technical Resources	22
Appendix C: Acknowledgements	23
Appendix D: Graphics	25

Executive Summary

Immunization information systems (IIS) have evolved over time to become a critical component of immunization program operations. They not only document vaccine doses administered for all ages but can also provide important reports and analyses to support decision making for various stakeholders. IIS-generated reports can support immunization program staff as well as clinical and population health information needs, while official immunization certificates inform consumers, schools, and childcare facilities of important vaccination status.

A cornerstone of IIS infrastructure is the use of vaccine code sets to facilitate the documentation and electronic data exchange of consolidated immunization record information between IIS and other health information systems like electronic health records (EHRs). A code set “lists acceptable values in tables supported by a standards organization such as HL7 or CDC.”¹ Since the first publication of vaccine administered (CVX) and manufacturer (MVX) code sets by the Centers for Disease Control and Prevention (CDC) in 1999,² more code sets have been incorporated into regular use by IIS. CVX and MVX, along with the national drug code (NDC) published by the Food and Drug Administration (FDA), are examples of standard code sets used to record immunizations in health information systems. Use of these and other code sets has resulted in a complex grid of relationships between code sets.

This document will provide a general overview of vaccine code sets and also briefly describe how code sets are used in support of multiple and varied IIS functions, including electronic data exchange with EHRs and other health information systems, and vaccine ordering and inventory management. The key challenges and issues that impact the implementation and management of vaccine code sets will be described, along with how those challenges may affect IIS stakeholders. Those challenges include: (1) change management, (2) synchronization, (3) timeliness of implementation, and (4) the need for supporting data. Considerations for code set management process improvement and building upon the critical role of vaccine code sets in IIS operations will be also highlighted.

Introduction

Standardized code sets and vocabulary are critical to supporting and maintaining high-quality data and facilitating standardized electronic data exchange between health information systems. They are a core component of the IIS consolidated immunization record. Code sets most commonly leveraged by the IIS community are vaccine administered (CVX) and manufacturer (MVX), published by the Centers for Disease Control and Prevention (CDC), and the national drug code (NDC), published by the Food and Drug Administration (FDA). These codes capture important information about vaccine administrations necessary to support successful Health Level 7 (HL7) data exchange, which is dependent on accurate and continuous management of code sets.

CVX identifies vaccine type, MVX identifies vaccine manufacturer, and NDC identifies vaccine product, manufacturer, and packaging information.² Another code set that may be used to document a vaccine administration is the current procedural terminology (CPT[®]), which is developed and maintained by the American Medical Association (AMA). However, since CPT codes are not preferred, when health information systems send data to IIS using CPT codes, the IIS then maps them to a CVX code.³ CDC maintains tables for managing relationships between code sets and other data sources used in health care and by health information systems, including IIS and electronic health record (EHR) systems. Examples of these tables include product name mapped to CVX/MVX, NDC unit of use and unit of sale crosswalk tables, CPT mapped to CVX, and CVX mapped to vaccine group. A vaccine group is a set of individual vaccines that when grouped together may vaccinate against one or more than one disease (e.g., HepA, MMR, and DTaP).⁴

Early on, most immunizations were recorded by direct data entry into the IIS. This began as a primarily manual process with providers mailing or faxing in paper forms to be entered into the IIS, followed by providers eventually entering their own data through an online user interface.⁵ Over time, IIS were also able to consume data extracted from provider systems and processed into the IIS through batch files. As formal standards for data exchange were adopted and meaningful use initiatives (now referred to as Promoting Interoperability Programs) were implemented, IIS focused efforts on developing capabilities to support real-time, bidirectional data exchange of vaccine doses administered from other health information systems (primarily EHRs). In the current state, the majority of immunization data is sent electronically to IIS from provider EHRs through HL7 interfaces. This evolution has highlighted the need for EHRs and IIS to leverage the same vaccine code sets to ensure accurate interoperability.

In 2018, AIRA's Joint Development and Implementation (JDI) Advisory Workgroup launched a project to examine vaccine code set management practices across the IIS community to begin to describe the existing processes in place and identify challenges and issues that may impede the processes at any given point. It was also important to better understand the nuanced differences in the ways IIS programs and IIS stakeholders address common challenges related to code set management. To gather information on these different perspectives, AIRA conducted an informal survey and engaged several IIS subject matter experts (SMEs) in discussions to zero in on the most pressing challenges of this complex topic. Valuable information on vaccine code set management was also gathered during the AIRA 2019 National IIS Meeting.

Four challenges that impact the management of vaccine code sets will be explored in this document. The topics are listed in the order in which stakeholders generally experience the most challenges:

1. **Change management** – Maintaining awareness of code set changes as they are published and the process for implementing those changes
2. **Synchronization** – Keeping multiple IIS environments current with updates
3. **Timeliness of implementation** – Identifying processes and expectations for timely code set updates across IIS and EHRs
4. **The need for supporting data** – Identifying additional data points and interpretation needed to augment and more fully leverage vaccine code set data

It is important to begin to better understand these challenges from the perspective of how they impact IIS and other health information systems. These dependencies should be considered when identifying potential solutions.

In addition to an overview of code set management challenges, the impacts these challenges have on IIS stakeholders will be described. This will help to delineate specific areas where targeted solutions to improve efficiency could be identified. Finally, this document will outline ideas for moving forward by exploring potential opportunities to address challenges by leveraging existing solutions, like the CDC Vaccine Code Set Management Service (VCSMS). CDC developed VCSMS to inform IIS and other data partners of new code updates. VCSMS has three primary functions: (1) maintain CDC's vaccine code sets, (2) publish code set data for use by health information systems, and (3) answer questions about the use of code set data.

IIS Code Sets in Action

The use of standards has always been important in the IIS community but took on a more central role within IIS operations upon release of the first HL7 Implementation Guide (IG) for Immunization Messaging. This HL7 IG included references to CVX and MVX code sets which are still maintained and updated by CDC today and used throughout the IIS community.⁶ Since that time, the use of code sets and the complex environment in which they must be managed has grown as the scope of IIS has expanded to support many core immunization program operations.

As a result, there is a need to recognize the continuous support for standards adoption within the IIS community and conversely to identify the challenges that have developed over the years as code use and complexity have expanded. This is the first and arguably the most important step. Before solutions can be identified or strategies proposed, we must better understand how different stakeholders approach code set management. Once there is a common knowledge of what is working and what is not, the next step can be to analyze the challenges and begin to identify opportunities where process improvements can be made. This document aims to shine a light on some of the persistent challenges affecting code sets and to set the stage for IIS community-wide collaboration to tackle those challenges.

Current state

Information gathering on the current processes used by IIS stakeholders to manage code sets has been ongoing since the initiation of this exploratory effort. In 2019, an informal survey was conducted to gather targeted feedback from IIS on several aspects of code set management. Responses were received from 38 unique IIS, or approximately 60% of the 63 active IIS across the country. High-level topics covered included identifying (a) the primary owners of IIS code set changes, (b) the amount of time it takes to implement changes, (c) estimates of staff resources needed to implement code set changes, (d) suggestions on how to improve current processes, and (e) process-related pain points. Responses to these and other questions provided the building blocks to begin constructing a picture of the overall complexity of code set management within an IIS and the systems with which they interface.

A recurring theme that was present throughout the responses was variability across platforms and implementations. There is a high degree of familiarity with the CDC Code Set web page, and a majority of respondents subscribe to email notifications of changes. Although there is common knowledge regarding CDC resources available, there was

variability in the supporting resources respondents use to check for code updates. Other survey takeaways include:

- Variability in who takes the lead in managing code sets for the IIS.** In many cases it is a coordinated effort between IIS program and IIS vendor staff. IIS program staff may primarily manage NDCs through the IIS user interface (UI), and IIS vendor staff may manage other code set changes, such as CVX, MVX, and other relationships between code sets. Seventeen respondents (45%) said their vendor has primary responsibility for code set updating, while 13 respondents (34%) said it was the primary responsibility of IIS staff. Four respondents said it was a joint effort between the IIS staff and their vendor, while two respondents said health department central IT staff are responsible for code set updates.
- Management of code set changes in systems is overwhelmingly manual.** Some respondents indicated that they download code sets in an Excel format when updates are made, but the process most used is to “look up information on the website and make manual changes to my system.”

The code set tables referenced in the survey are maintained by CDC. These nine CDC-maintained code set tables support a network of IIS program operations that could be described as being held together by the connection of codes from one functional area to another. The most frequently used CDC-maintained code sets identified in the survey are depicted in Table 1.

Table 1. Commonly used CDC code set tables

Table	% of Respondents Referencing Its Use
CVX	89%
NDC Crosswalk	79%
Product Name Mapped to CVX/MVX	74%
MVX	68%
CPT Mapped to CVX	63%
CVX Mapped to Vaccine Group	53%

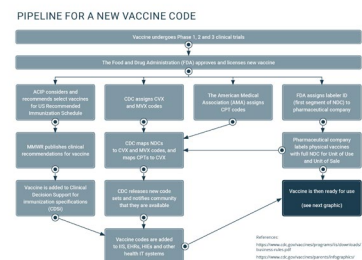
Information was not gathered on all available CDC code set resources, but it is worth noting that the following code set resources are also available on the CDC Code Set web page related to NDC code management:

- NDC Lookup Crosswalk
- NDC Unit of Use
- NDC Unit of Sale
- Vaccine NDC Linker
- NDC11 to NDC10 Crosswalk Reference

In addition to the survey, there were other methods used to gather information on code set management within the IIS community. Other information gathering efforts included one-on-one discussions with IIS subject matter experts, review of IIS technical guidance and current code set tables, discussions with the JDI Workgroup, and at roundtable discussions at the AIRA 2019 National Meeting. Outcomes from each of the efforts are reflected throughout the document and in many cases supported the findings from the survey, but there were several notable points that arose throughout the interviews.

- The range in timing cited for code set updates extended from 15 minutes (if the IIS staff was solely responsible for the update) to many months (if dependencies and multiple handoffs were involved). In one case where a vendor managed code set updates, a two-month minimum time period was referenced from the announcement of a code set change to full implementation. Some updates had to coincide with a patch or release, which affected timing.
- The manual process of updates was cited as a pain point by multiple SMEs, particularly because of the number of environments (test, training, production, etc.) and the number of tables (import, forecast, reports, etc.) that must be updated. Automation of code set updates was referenced repeatedly as a way to improve both timeliness and accuracy of code set changes and the ability to synchronize across systems. That being said, there may still be a need to test new codes or updates in a test environment prior to going live in production, so any automated solutions to improve synchronicity need to be balanced with testing needs.
- Several SMEs noted that, even if their IIS implementation and mapping of code sets was timely and efficient, there was limited opportunity to exercise control over the codes submitted by clinicians, EHRs, health information exchanges (HIEs), and others, highlighting that vaccine code set management is a shared responsibility across all data exchange partners.

To illustrate the complexities of vaccine code set assignment and use, including the number of stakeholders engaged, AIRA and our community partners developed two graphics to illustrate this process. One is focused on the pipeline for a



new vaccine, and the other is focused on the many uses of vaccine codes in IT systems. These can be found in [Appendix D](#).

Supporting immunization program operations

Code sets are embedded in the fabric of each IIS and are a critical component of most core IIS functionality. Adding to the complex nature of maintaining code sets is the fact that most functional areas have a one-to-many relationship with code sets. Rarely is there only one code set used to support these functions throughout the system.

A review of several functional areas within an IIS quickly highlights the interconnectedness of these system components.

Administered vaccinations

The CVX and MVX code sets are used for documenting the vaccine and manufacturer, respectively, of vaccine doses administered in the IIS. NDC and CPT may also be used to document an administered vaccine, so it is important for IIS to be able to map between code sets when varying code sets can be received by the IIS to document an administered vaccine. As part of meaningful use Stage 3 preparation, IIS are expected to be able to support HL7 version 2.5.1, Release 1.5. A component of that includes the ability to accept NDC for new vaccine administrations.⁷ This requirement, along with the use of NDC as a critical component of vaccine ordering and inventory management, highlights the importance of keeping this code set current in the system. There are relationship tables available to link the code sets that are needed to document an administered vaccine.

Historical vaccinations

It is also important for IIS to be able to document historical vaccine doses administered or immunization history data for inactive codes. This introduces an added layer of complexity when it comes to managing these as well as currently active codes.

The [Interoperability Standards Advisory \(ISA\)](#) managed by the Office of the National Coordinator for Health IT (ONC) provides guidance on representing administered and historical immunizations in health information systems and also calls out specific considerations for IIS regarding code sets that should be used.⁸ It is important to note that, currently within the IIS community, CVX codes are the preferred method for documenting historical vaccine doses.

Interoperability

There are many code sets that are necessary to facilitate successful data exchange between IIS and other health information systems like EHRs and HIEs. In addition to data on administered vaccines, HL7 messages sent to an IIS will include many other data points related to demographics, immunization route and site, lot numbers, etc. Data queried from an IIS may also contain vaccines due and past due, in addition to the consolidated record. Ensuring uniform code sets is essential for accurate interoperability.

Vaccine ordering and inventory management

Functionality to support vaccine ordering and inventory management of publicly purchased vaccine in the IIS has steadily developed and become more robust over the years. The implementation of NDC to order vaccine was one of the factors that catapulted this code set into widespread use in the IIS. It also introduced the concept of accommodating and documenting NDC Unit of Use (UoU) and NDC Unit of Sale (UoS). The UoU is typically the NDC that is found on the individual vial or syringe, while the UoS is typically the NDC associated with the entire pack or box of the vaccine. Taken together with other related features such as tracking of vaccine returns and wastage, use of these code sets facilitates immunization program vaccine accountability efforts. The variation in NDCs poses a challenge when managing inventory. The following guidance for managing varied vaccine lot numbers was developed by AIRA in partnership with CDC: [Vaccine Lot Number Patterns: Unit of Sale/Unit of Use Guidance](#). In addition, CDC has published guidance acknowledging that providers may submit either unit of use or unit of sale NDCs as part of their workflow, recommending that IIS must be ready to receive either.⁹

Clinical decision support

Providing evaluation and forecasting services is a core tenet of an IIS. The results from a clinical decision support engine are used for direct patient care, coverage reports, reminder/recall efforts, and even responding to the IIS Annual Report (IISAR). At this time, CVX codes are typically used to identify the vaccines for evaluation and forecasting purposes. When NDC is used to document a vaccination event, in most cases NDC currently must be mapped to CVX codes for the CDS engine. Furthermore, each CVX code must be compared to the Advisory Committee on Immunization Practices (ACIP) schedule to determine when the CVX code would be valid or invalid based on several factors, such as the age at administration and spacing from other vaccination events. The [Clinical Decision Support for Immunization \(CDSi\)](#) project could also be leveraged for this process.

Immunization program operations tools

In addition to the functional areas referenced, code sets for immunizations are also leveraged by the following key areas across the IIS community:

- [National Institute of Standards and Technology \(NIST\) Immunization Test Suite](#)
- [NIST Forecasting for Immunization Test Suite](#)
- [Message Quality Evaluation \(MQE\) Tool](#)
- [AIRA Aggregate Analysis Reporting Tool \(AART\)](#)
- [AIRA Measurement and Improvement Project](#)

IIS Code Set Management Challenges

Several recurring themes present as challenges to efficient code set management. These challenges have some measure of impact across IIS stakeholders. The topics highlighted have been curated from the various data collection methods referenced in this document. The overview of each challenge will describe the processes currently in place and some of the known gaps related to each particular aspect of the management process.

Challenge #1: Change management

Description: With multiple vaccine code sets used to support immunization program operations, there are a number of resources from which this information can be gathered. Email notifications of CDC code set updates are a critically important resource for staying abreast of upcoming changes to core code sets. Some code set managers (e.g., IIS staff, IIS vendor staff, EHR staff, central IT staff) find it necessary to also consult other resources for awareness of current and upcoming changes. Examples of other resources IIS stakeholders use include manufacturer websites, the CDC Federal Vaccines List, FDA licensing and supply lists, online search of vaccine package descriptions, My Flu Vaccine, American Academy of Pediatrics (AAP), Morbidity and Mortality Weekly Report (MMWR), ACIP, and sometimes other IIS.

Current implementation process: The most widely used approach to maintain awareness of code set changes is to subscribe to all available email notifications for the code sets implemented in the system. This is also often supported through manually checking the CDC code set web page. Sometimes IIS become aware of changes to the current codes because there has been a data exchange issue and provider EHRs may be sending codes that have not yet been added in the IIS. This scenario requires a reactive response and introduces the added task of cleaning up the rejected data that came in prior to the codes' being available in the IIS production environment.

Process improvement opportunities: The availability of CDC code set update emails and the addition of the VCSMS web service and content management client have helped substantially to keep code sets current. However, further automation of the code notification and update process was referenced several times as a desired solution to challenges related to change management. Identifying how this might be done and which parts of the process, some or all, could be automated, requires additional analysis. Areas that could be explored are automatically pushing code set changes to IIS or creating a single location to update codes in the system for all supporting IIS functions.

Challenge #2: Synchronization

Description: The IIS production environment is the externally facing system that users interact with, but there are typically several other environments that are updated with code set changes as well. A jurisdiction may have several environments to update and keep synchronized. Although these will vary by jurisdiction, they may include production, testing or user acceptance testing (UAT), training, development, and/or quality assurance (QA). Many times, the changes to each environment are done manually and must be repeated, creating inefficiencies.

Current implementation process: Manually implementing code changes in multiple systems introduces a time constraint and potentially a resource burden. There is also the risk that all environments will not be updated consistently. The extent of the burden may depend on who is primarily responsible for managing code set changes, which may be IIS program staff, immunization program staff, IIS vendor staff, or a combination of all. Although the current process for maintaining synchronization varies by IIS vendor platform and jurisdiction, a commonality is that the code set update process is likely repeated separately for each environment.

Process improvement opportunities: A possible approach for improvement could be to automate the process of implementing updates to IIS production and other environments. This could be helped in part by having a central reference table for code sets across all environments. Additional analysis would be beneficial to identify IIS that may have already automated this process and could share implementation strategy and best practices. As mentioned above, there may still be a need to test new codes or updates in a test environment prior to going live in production, so any automated solutions to improve synchronicity need to be balanced with testing needs.

Challenge #3: Timeliness

Description: Similar to many facets of code set management, there is considerable variation among IIS—and between IIS and their EHR counterparts—on the time frame for

updating systems with new or updated code information. Based on an inquiry of some IIS stakeholders, implementation time estimates range from a few hours to a few months. The disparity is largely dependent on the type of change, with those updates made through the IIS UI (typically new NDCs) generally taking less time than primarily back-end system changes, such as updates to or introductions of new CVX codes. There is also an added complexity of implementing changes related to the mapping of NDC unit of use and unit of sale that might not be reflected in the overall time frame as a separate process step.

A shared challenge is the expectation of and sometimes delay in updated or new codes' being available in the provider EHR to send or being available in the IIS to receive when messaged from an EHR. A mismatch here results in a failed message to the IIS, which triggers an alternate set of steps to get the missing immunization data into the IIS.

Current implementation process: The first few steps of implementing vaccine code changes are generally similar across IIS: (1) receive notification of update to code sets from email subscription or review of website, followed by (2) identify and communicate changes to the appropriate staff who will initiate changes to the system. This may be IIS program staff, IIS vendor staff, or health department central IT staff. At this point, the number of steps diverges depending on the primary code-change implementer. The level of involvement of IIS program staff in this process varies. It may require little to no involvement beyond UAT and approval of changes, or it may need a collaborative handoff between multiple stakeholders with each taking the lead at different points in the process.

- **IIS vendor**-managed changes may be slated for a predefined patch cycle and involve minimal IIS staff involvement until the testing phase.
- **IIS program** staff-managed changes may be done in close coordination with central IT or IIS technical staff.
- **Coordinated IIS vendor/IIS program** staff-managed changes require an added coordination effort to ensure effective communication of current and upcoming code set changes and engagement by all actors in their primary role in the overall process.

A bottleneck in one step can have downstream impact when a change is implemented in the production environment.

Process improvement opportunities: Reduce manual steps where possible. One of the suggestions from the informal survey was to create a more automated process which could include importing code set files into IIS through flat files or through automated services. Any increase in automation could have potential time savings for those currently manually entering code set updates through the UI or in database tables. Feasibility and potential

risk related to this approach must be considered from several angles. One such consideration is that IIS would need to be able to import the code set file(s), which could require a development effort. Beyond the initial import, the IIS would need to develop and implement rigorous business rules to define where new codes would need to be added, what existing codes they may need to be mapped to, and what specific functions may be directly or indirectly affected by these new codes.

To achieve true gains in timeliness, a similar automated process would need to be adopted and implemented by EHR partners as well, and we recommend that EHR partners be fully engaged in future vaccine code set work.

Challenge #4: The need for supporting data

Description: Some code sets don't have all of the data elements necessary to manage the processing of code changes. Mature vocabularies have additional "meta data" or "supporting data" that helps to provide information needed to properly use a vocabulary term. A good example of this is any English dictionary. The dictionary not only defines the term but also gives additional information such as part of speech, pronunciation, word origin, alternative spellings, and related concepts.

Immunizations are complicated and require similar types of information, particularly if the goal is to automate the use of immunization information.

Most information that changes rapidly in the vaccine code sets is updated by CDC, but to allow for automation, additional information on the interpretation of that information is needed. Associated with the CDC-coded values are guidance documents, best practices, and other supporting documents. These are useful resources that still must be interpreted for implementation in the IIS or another health information system, which can be time-consuming and inconsistent across systems.

In addition to IIS, the Message Quality Evaluation (MQE) Tool also uses vaccine code set supporting data. The MQE Tool is an open-source application "designed to assist sites in consistently evaluating and improving the quality of data coming into their IIS."¹⁰ There are several meta data the MQE Tool uses that are not currently provided but are updated with input from the IIS community. Extended supporting data used in the MQE Tool include Status, Valid Start, Valid End, and Notes.¹¹

Current implementation process: Many IIS rely on industry knowledge to implement code changes. More analyses are needed to determine how IIS are currently approaching this challenge as it relates to active and inactive dates and other supporting data.

Process improvement opportunities: The immunization community needs the current CDC Code Set project to include additional supporting information to match the type of support given by the Clinical Decision Support for Immunizations (CDSi) project. Expanding this project to build out full specifications would allow significantly more automation of vaccine code set updates.

Additional materials for vaccine code sets may include:

- **Specification of Code Set Model** – This model would explain the current code sets, elaborate on additional modeling concepts, and formally connect the code sets to other projects such as CDC’s CDSi project and the vaccine deduplication best practices published by AIRA’s Modeling of Immunization Registry Operations Workgroup (MIROW). In particular, vaccine groups used for ACIP recommendations need to be aligned with the code sets provided by VCSMS.
- **Code set and supporting data** – Consistent with the specification, this would provide specific guidance and classification of all coded elements within the specification framework. The supporting data would be updated as new coded concepts are created.
- **Test cases** – Based on the supporting data, specific test cases would be created with expectations about how IIS and immunizing systems (such as EHRs) should support specific code set data. These test cases would be updated as new codes are created.

More information on this approach is included in a later section.

Impact of Challenges on Stakeholders

Challenges related to code set management may be common across IIS stakeholders, but their impact varies. This is evident by the differences in roles that stakeholders take on in the combined code set management process. The combined process includes some degree of collaboration between IIS program and IIS vendor staff to ensure that codes are updated, added, and linked. There is also collaboration between the EHR vendor and provider to ensure provider systems are up to date with the current codes to send to IIS. This complex process with multiple actors and many parallel actions speaks to how delayed implementation in one system may impact the other. A high-level overview of impacts to different stakeholders include:

IIS program

In their response to the AIRA informal survey, several IIS noted a pain point related to not being able to easily identify which codes within the code set were added or changed. This may have an impact on efficiency and may cause IIS to implement inaccurate information.

Another area that impacts IIS processes for managing code sets is the maintenance of local codes in the IIS, or internal immunization IDs. These internal IIS codes add another layer of mapping within the IIS infrastructure and another potential point of error in updates or mapping. These codes are likely to be maintained by the IIS vendor.

IIS vendors

IIS vendor staff in many cases collaborate with IIS program staff on code set management. As a first step, there may be reliance on the IIS program to provide information on code updates. This dependency and the back and forth needed to test and approve changes have an impact on the timeline in which an IIS vendor can complete code changes and update customer environments.

EHR vendors

Sometimes there is a time gap between becoming aware of upcoming code changes and the publication of those changes. This has an impact on the code set management update process and may result in changes being ready for implementation but not released for use. There is also the issue of messages being rejected by the IIS. In some cases, this may be due to codes not yet being updated in the IIS, but this can also be the result of incorrect or deprecated codes being sent to the IIS or not all necessary codes sets being updated (e.g., NDC unit of use, NDC unit of sale).

Strategies to Advance Code Set Management

There will not be one perfect solution to address the various challenges that IIS stakeholders experience with code set management. The more likely scenario is one where there are several approaches to solving different components of the issue that, when taken together, improve code set management processes for respective stakeholders. Several survey respondents and IIS SME discussion participants highlighted the desire for more automated code set management processes. A good first step may be to explore opportunities to best leverage existing tools, such as the VCSMS and Fast Healthcare Interoperability Resources (FHIR) Terminology Services, along the path to more automated processes. VCSMS will likely continue to be the primary author for vaccine code set additions/modifications, recognizing that the code sets could then be published in multiple locations, including with the Value Set Authority Center (VSAC).

Vaccine code set supporting data and specifications

As mentioned above, there is a need for vaccine code set specifications similar to the Clinical Decision Support for Immunizations (CDSi) specifications created by CDC. In the same way that CDSi specifications support the automation of CDS engines, supporting data

for vaccine code sets would support automation of vaccine code set updates as well as the analysis and use of vaccine code sets overall. The audience for these resources would be business and technical implementers of vaccine code set data and supporting functionality. These implementers would include both EHRs and IIS. These resources could be implementation-neutral and would facilitate the use of various vaccine code sets in an unambiguous manner while improving the uniform representation of vaccines.

As outlined above, this set of resources should consider three key components:

Specification of Code Set Model

This model would explain the current code sets, elaborate additional modeling concepts, and formally connect the code sets to other projects, such as CDSi and vaccination deduplication.

Code set and supporting data

Consistent with the specification, this would provide specific guidance and classification of all coded elements within the specification framework. The supporting data would be updated as new coded concepts are created.

Test cases

Based on the supporting data, specific test cases would be created with expectations about how IIS and immunizing systems (such as EHRs) should support specific code set data. These test cases would be updated as new codes are created.

These resources could meet multiple goals across the IIS and EHR community, including improving the process of updating vaccine code sets, increasing the accuracy of vaccine code set information exchanged across systems, and improving the process of developing functionality that leverages vaccine code set data. Other countries have already embarked on similar vaccine code set specification efforts, such as [Canada's Vaccine Catalogue project](#), and may serve as a good model for the aspects of this project that can be built out moving forward.

A critical part of ensuring accuracy in the update process is the creation of test cases that verify that a system can test for new code changes and also that a system has properly implemented these changes. There are currently gaps between what is being documented and what expectations can be tested in regard to vaccine code sets. For example, below are recently published code set release notes that need more guidance for testing. Information on the questions below may be available in various documents, but typically these documents include human readable English and cannot be unambiguously interpreted.

Example code set updates and accompanying questions:

Release Notes	Questions in need of computable guidance
<p>NDC Influenza Season Update: Sanofi Product FLUZONE High-Dose Quadrivalent was previously introduced and described for the influenza season 2019/2020. The correct influenza season for this product is 2020/2021. The NDC descriptions have been updated to reflect this correction. The notes for the associated CVX code 197 and the CDC Product have also been updated to reflect the correct starting season for this new product.</p>	<ul style="list-style-type: none"> • Should IIS accept this code now? Is there any need for the IIS to notice that this code is not yet valid and issue a warning? EHR systems should not be reporting this now, right? If they do report under these NDC, then what should the IIS do with that information? Keep it? Reject it? • When should IIS start to be able to receive this code and process it? The guidance indicates “flu season,” but the start of this is not defined. Can we always assume July 1? • After flu season in 2021, should this code no longer be used? What should an IIS do if it receives data in the fall of 2021 with the code on it?
<p>NDC Codes Retired: The following NDC codes have been retired from the FDA files received.</p>	<ul style="list-style-type: none"> • Is there a definition for how to handle “retired” codes in general? What does this mean exactly? • What should IIS do when they receive “retired” codes? Should they try to store these vaccinations or issue an error? • When should the “retirement” take effect? As of 02/12/2020? Or is product still in circulation for some time to come? • What should an IIS do with old data stored with these NDC? Does any of it need to be updated with newer codes since these are no longer valid? Or are the codes on older reported vaccinations still valid? • Can IIS still accept reports of older vaccinations using these NDC?

One of the key components missing from our current tools is specific guidance that defines the terms used in English and explains how they must be operationalized using computer algorithms. To incorporate these codes quickly, IIS need computable guidance. To date, training has substituted for computable guidance, but if we are dependent on more training to answer these questions, then we are expecting the process to always include a trained expert who translates the requirements for code set updates into an operational system. If we want to remove these experts and have automatic updates, then these questions have

to be answered by a structured set of data and a set of requirements on how that data is to be used. This would allow for the process of automating these updates.

The CDC-developed VCSMS discussed below could be the primary resource for accessing vaccine code set supporting data. Use and availability of this tool are evolving. Defining the specifications for this supporting data would likely include an in-depth analysis of the challenges IIS and other stakeholders are experiencing with interpreting the code sets currently available. This would be followed by identifying the gaps that exist between the information available and the information that is needed regarding vaccine codes to allow for computable guidance. A final step would be to develop this guidance along with best practices to support consistent implementation and interpretation of code sets across stakeholders.

Vaccine Code Set Management System (VCSMS)

In an effort to inform IIS and other data partners of new code updates and to ensure that IIS have easy access to code sets, CDC developed VCSMS. The current VCSMS has three primary functions: (1) maintain CDC's vaccine code sets, (2) publish code set data for use by health information systems, and (3) answer questions about the use of code set data. The VCSMS offers three options for accessing code set data.

1. Content cloud agent

A desktop application provided by CDC that allows users to manually search for and review content for code set updates. The content cloud agent provides the ability to browse and subscribe to content and then receive automated notifications of updates to flagged content. Once configured, the content cloud agent will manage subscriptions and download new packages as soon as they are published.

2. Content cloud web services

Provides opportunities for individual system customization and would allow for a more automated process for accessing code set updates and integration of the code set data back into the system. The back-end services used by the content cloud agent are available for direct use and allow users to review code set updates.

3. Download updates from CDC website

The CDC will continue to update the public website with code set updates. Users may subscribe to and receive email notifications of updates to the code sets.

Every IIS and EHR team should familiarize itself with these code set resources and leverage them as fully as possible. However, with all three options, it is still dependent upon each system to write business rules for how to handle the information and define the

relationships between the different code sets. The specifications and supporting data referenced above could expand VCSMS and make the data and information supplied by CDC more accessible through automation. Supporting the automation of vaccine updates would improve both timeliness and efficiency of vaccine code set updates.

Terminology service

A terminology service “lets healthcare applications make use of codes and value sets”¹² and could serve as a central resource for accessing vaccine code sets. A FHIR terminology service could potentially build on the HL7 FHIR framework, which is not yet broadly used by IIS. There are a number of commercially available health care terminology services in the current marketplace. These services cover a breadth of concepts and code sets, including ICD, CPT, SNOMED, LOINC, etc., and are used widely by EHR and other health IT vendors. Research is needed to determine the feasibility of this approach and if it potentially constitutes a duplication of effort.

One example of a current implementation of a FHIR terminology service is the FHIR Terminology Service for Value Set Authority Center (VSAC) Resources. There are a number of code sets available in this service, including CVX and CPT.¹³ Gathering information on strategic approaches and lessons learned from implementing a terminology service would provide useful information for decision making on feasibility.

Conclusion

The management of vaccine code sets is a process with multiple stakeholders. Each stakeholder is charged with managing its own process for updating vaccine codes in its own system and then interacting with others to support immunization program operations, such as facilitating the documentation of vaccination administrations, forecasting, and vaccine ordering and inventory management. There are similar challenges experienced by all related to the steps taken to update and add new codes, as well as the need for several resources to move the process along. The agencies and organizations that develop and publish code sets are also critical to the code set management process among IIS stakeholders because the release of code changes initiates the process that a system must undergo every time an update is released.

The key in moving forward may be to take a standardized approach to vaccine code set updates as opposed to asking people to build code to use a proprietary API or install products on servers. The added benefit to a standardized approach would be that it would be easier for both IIS and EHRs to work this into their systems. That being said, it is important to recognize recent improvements. Although the current process is complex to maintain, efficiencies

have been realized, and many IIS programs and IIS vendors collaborate to manage code set updates.

To continue to move forward and make progress will require maximizing the use of tools already available and exploring ways to leverage new resources to build on what's already in place. It may also be appropriate to conduct broader focus groups among expanded IIS stakeholders, EHR vendors, and other health care organizations to be more representative. This would also allow for the identification of code set management best practices and identification of specifications and useful supporting data that are not currently available to inform automated tools. Future projects should consider the suggestions above to continue to improve and automate the process of managing vaccine code sets across the IIS and EHR communities.

Appendix A: References

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14. NIH Value Set Authority Center National U.S. National Library of Medicine FHIR Terminology Service for VSAC Resources. <https://cts.nlm.nih.gov/fhir/>

Appendix B: Technical Resources

- Centers for Disease Control and Prevention Immunization Information System Code Sets. <https://www.cdc.gov/vaccines/programs/iis/code-sets.html>
- U.S. Food and Drug Administration National Drug Code Directory. <https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory>
- American Medical Association Category I Vaccine Codes. <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>
- American Immunization Registry Association MQE Project Tools and Documents. <https://repository.immregistries.org/resource/mqe-project-tools-and-documents/>
- National Institute of Standards and Technology Immunization Test Suite. <https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home>
- Centers for Medicare and Medicaid Services Promoting Interoperability Programs. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index?redirect=/EHRIncentivePrograms/30_Meaningful_Use.asp
- Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. <https://www.cdc.gov/vaccines/acip/index.html>
- Centers for Disease Control and Prevention Clinical Decision Support for Immunization. <https://www.cdc.gov/vaccines/programs/iis/cdsi.html>
- My Flu Vaccine. <http://www.myfluvaccine.com/about-mfiv/about-myfluvaccine.html>

Appendix C: Acknowledgements

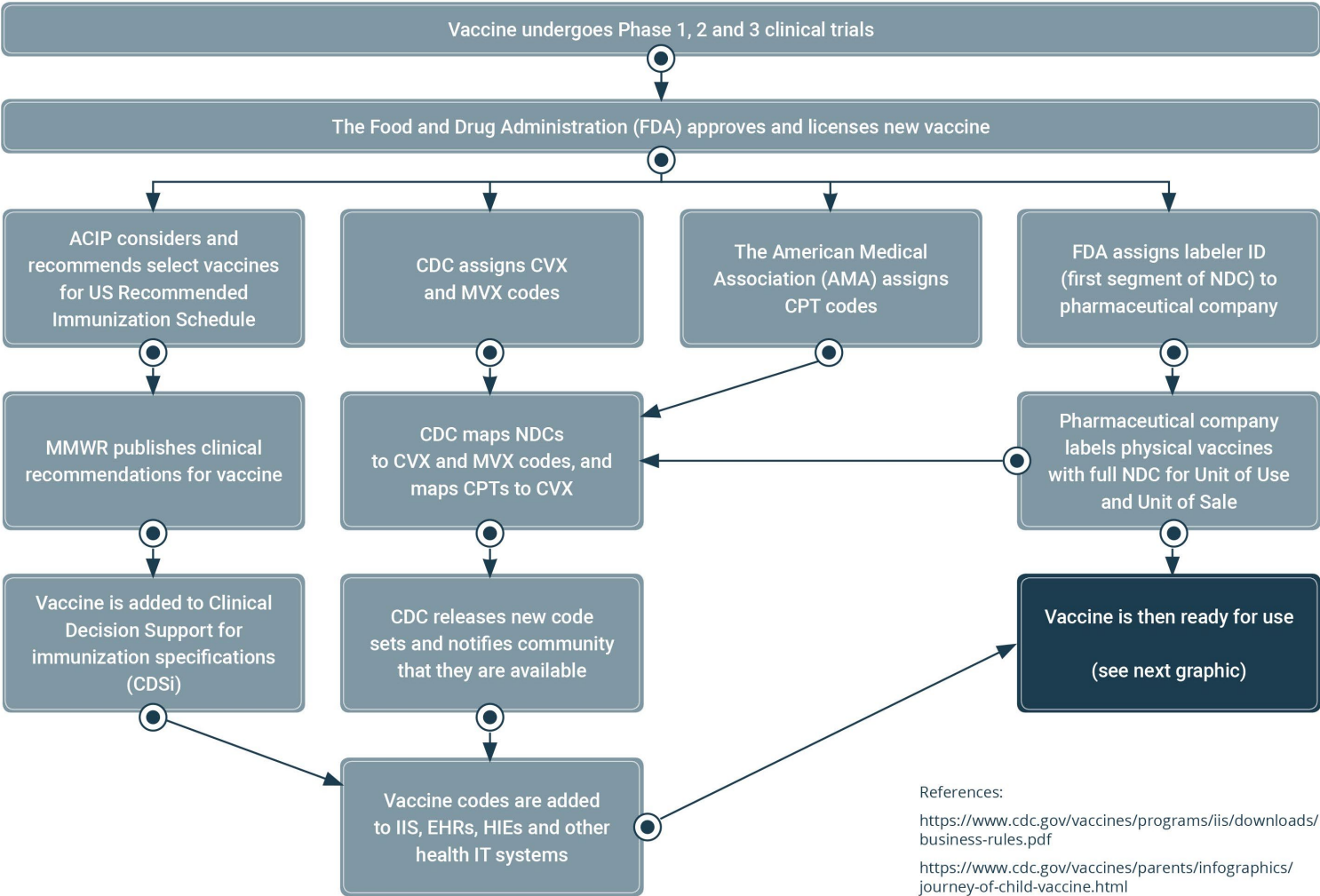
Special thanks and appreciation are extended to the following individuals for providing their expertise and experience throughout various stages of development of this document.

- Centers for Disease Control and Prevention (CDC)
 - Kafayet Adeniyi, Public Health Project Manager
 - Stuart Myerburg, Informatics Team Lead
 - Millie Malai, Deloitte Consulting, CDC Contractor
- American Immunization Registry Association (AIRA)
 - Nathan Bunker, Senior Technical Project Manager
 - Eric Larson, Senior Technical Project Manager
 - Mary Beth Kurilo, Policy & Planning Director
 - Maureen Neary, Senior Project Manager
 - Kristi Siahaya, Senior Project Manager
 - Ulrica Andujar, AIRA Consultant
 - Danielle Reader-Jolley, AIRA Consultant
 - Chris Sorenson, AIRA Consultant
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 - Kevin Snow, Envision Technology Partners
 - Kim Tichy, Iowa
 - Joey Zehner, Iowa
 - Matt Verdon, Minnesota
 - Mary Woinarowicz, North Dakota
- Joint Development and Implementation (JDI) Advisory Workgroup
 - Kafayet Adeniyi, CDC
 - Noam Arzt, HLN
 - Mike Bin, Washington
 - Bill Brand, PHII
 - Tricia Charles, Massachusetts
 - Aras Islam, Philadelphia

- Millie Malai, Deloitte
- Mike Marini, Deloitte
- Judy Merritt, STC
- Amy Metroka, New York City
- Steve Murchie, Envision Technology Partners
- Miriam Muscoplat, Minnesota
- Stuart Myerburg, CDC
- Teri Nicholson, Illinois
- Michael Powell, California
- Tina Scott, Michigan
- Gary Wheeler, DXC

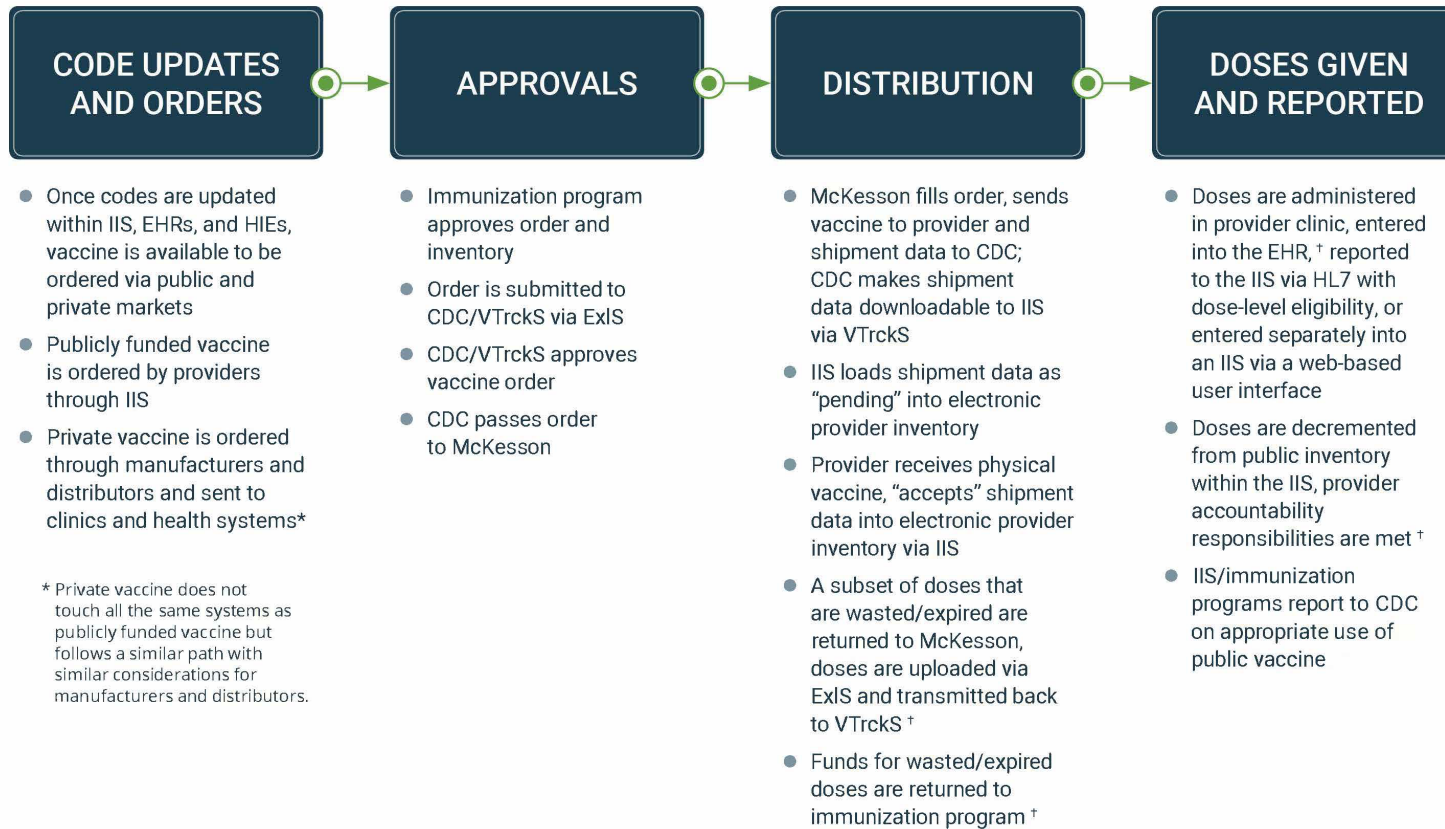
Appendix D: Graphics

PIPELINE FOR A NEW VACCINE CODE



VACCINE CODES TOUCH MANY SYSTEMS

The full complexity of this process is simplified here. Each step requires coordinated, accurate, and timely updates of vaccine codes by multiple systems and industries.



† Variations may exist among IIS, EHRs, or clinicians regarding this item.