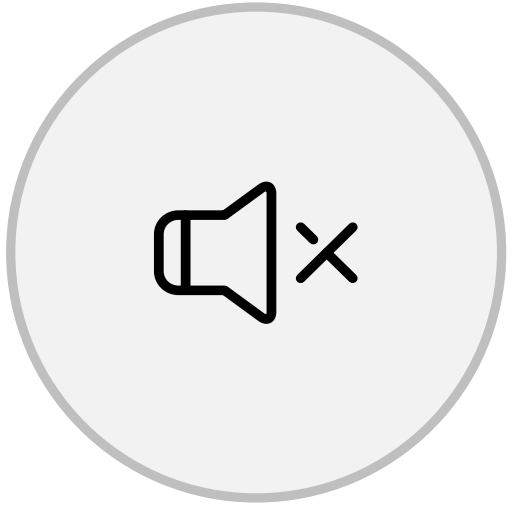
Vaccine Code Sets – A Community Update

Discovery Session
May 28, 2020
4pm EST

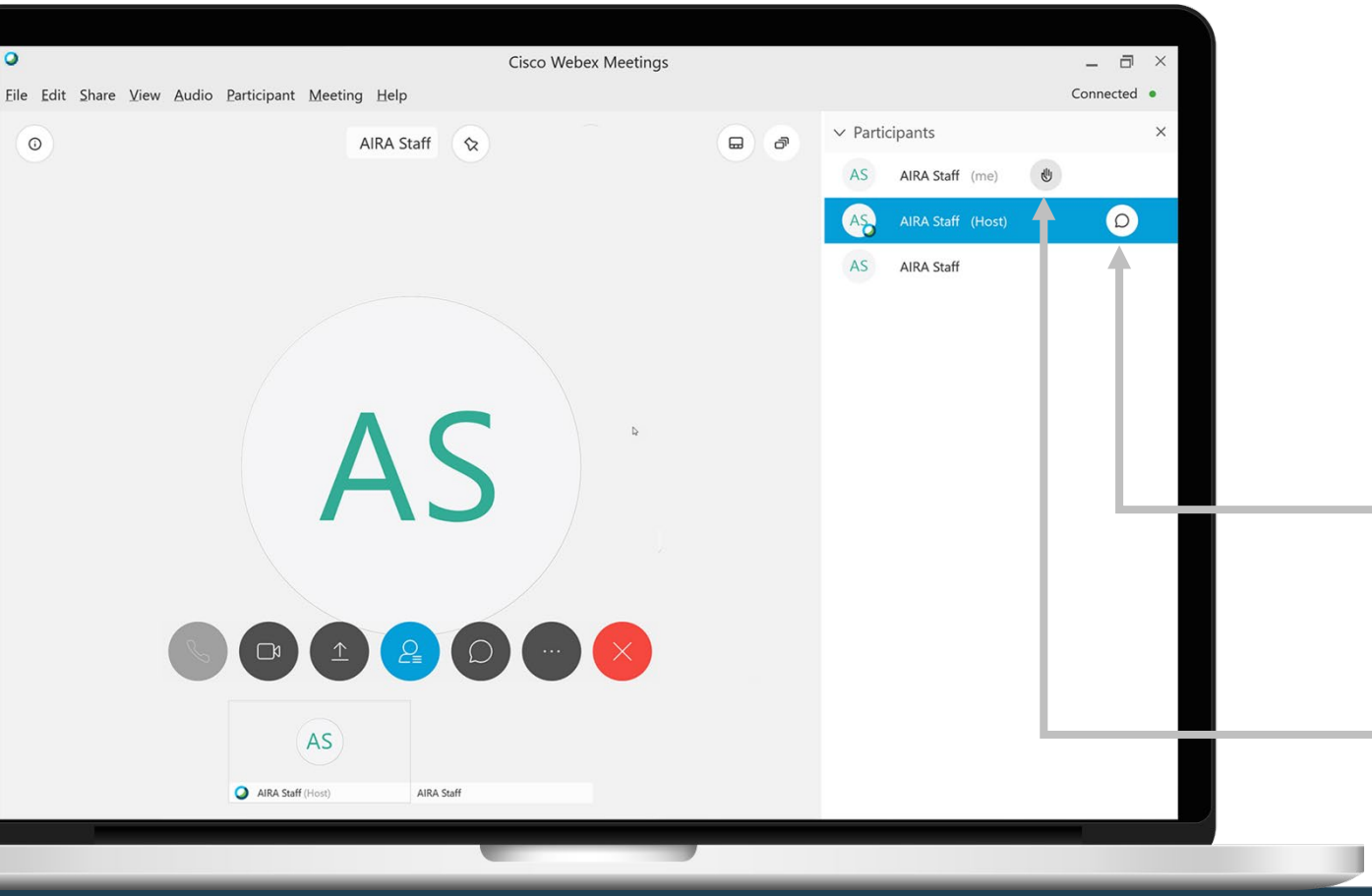
AIRA Discovery Session



All phone lines
are muted

This meeting is being recorded
and will be posted on the
AIRA repository

AIRA Discovery Session



- **How do I ask a question?**
  - There will be time allotted for Q&A following each of the updates, to unmute your line press *6
  - Via WebEx:

Select the chat icon next to the host and type question into the chat box.

Select the hand icon next to your name and you will be called on.

Today's Topics

- Vaccine Code Set Considerations Document – Recently Released
- Exploring a Potential Future Direction for Vaccine Code Set Work
- Update on CDC's Vocabulary Code Set Management Work

Today’s Speakers

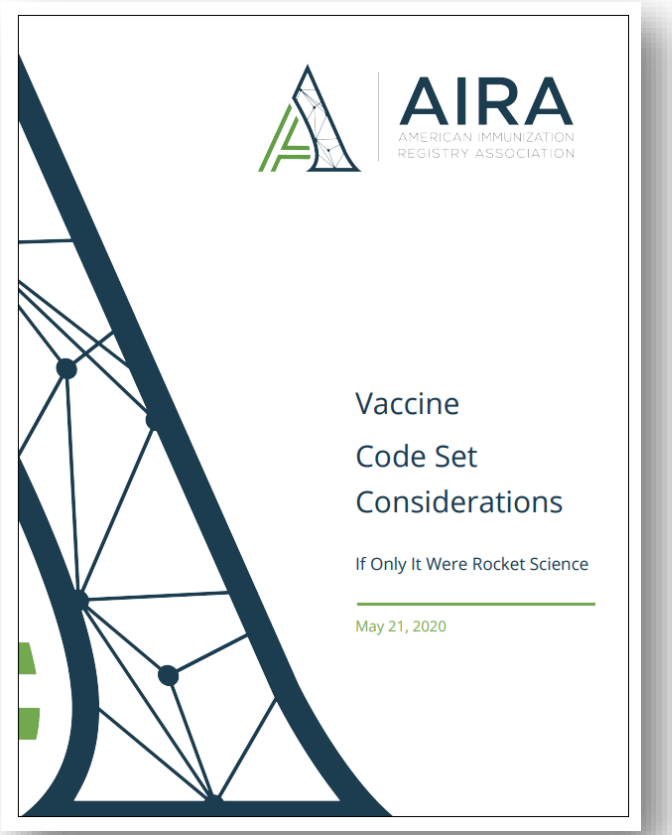
- Mary Beth Kurilo, AIRA
- Nathan Bunker, AIRA
- Paloma Hawry, Deloitte
- Jay Schroeder, Deloitte

Vaccine Code Set Considerations Document

Mary Beth Kurilo

Project Origins and Evolution

- The Vaccine Code Set Project began as a Joint Development and Implementation (JDI) effort to support and document the pilot roll-out of new functionality within CDC's Vocabulary Code Set Management System in early 2019
- It evolved into an exploration of challenges and complexities inherent in vaccine code set management, and makes suggestions for solutions/improvements



https://repository.immregistries.org/resource/vaccine-code-set-considerations/

Acknowledgments

IIS Expert Contributors

- Mike Bin, Washington
- BJ Bloom, Office Practicum
- Sue Kressly, MD, Office Practicum
- Michael Powell, California
- Steve Murchie, Envision Technology Partners
- Kim Tichy, Iowa
- Joey Zehner, Iowa
- Ernad Klipic, Nebraska
- Kevin Snow, Envision
- Aaron Bieringer, Minnesota
- Matt Verdon, Minnesota
- Mary Woinarowicz, North Dakota

Acknowledgments

Joint Development and Implementation (JDI) Advisory Workgroup

- Kafayet Adeniyi, CDC
- Stuart Myerburg, 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

Vaccine Code Set Project

Considerations Document High-Level Outline

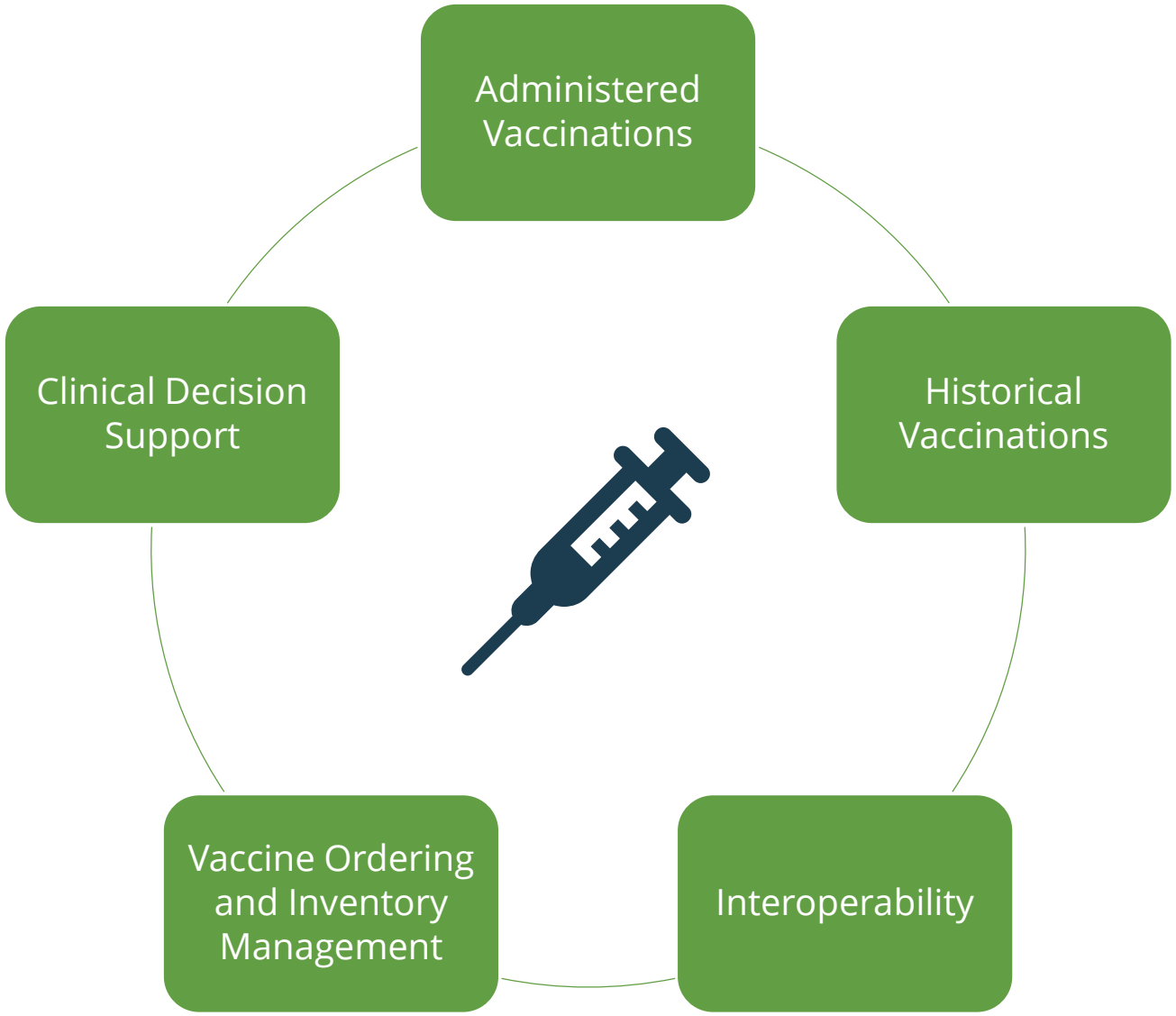
1. Executive Summary
2. Introduction
3. IIS Code Sets in Action
    1. Code sets overview, survey results summary, supporting immunization program functions
4. IIS Code Set Management Challenges
    1. Description of key challenges
5. Impact of Challenges on Stakeholders
6. Strategies to Advance Code Set Management
7. Conclusion and Appendices

Vaccine Code Set Project

IIS SME Survey and Discussions

- Conducted a Community Survey
- Gathered additional information through key contact interviews
  - Brief calls with IIS Programs (4), IIS Vendor (1), EHR Vendor (1)
  - Sample discussion questions:
    - On average, how much time do you spend from when you are notified of new code set updates, to the time changes are implemented in the IIS? How does it differ for flu vaccines?
    - What is the step-by-step process used for making code set changes from notification to implementation including IIS Vendor involvement?
    - What code set metadata, if any, do you currently use and what metadata is needed or desired to improve code set management?

Key Areas for Use of Code Sets in Supporting Immunization Program Operations



Vaccine Code Set Considerations Document

IIS Code Set Management Challenges

Four challenges described in the document, along with possible suggestions/solutions:

1. Change Management
   - Maintaining awareness of code set changes as they are published and the process for implementing those changes
2. Synchronization
   - Keeping multiple systems and 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/Specifications
   - Identifying additional data points and interpretation needed to augment and more fully leverage vaccine code set data

Challenges

Change Management

Challenge: Staying current with code set changes (NDC, CVX, etc.)

Process Improvement Opportunities: Leverage code set web service, automate notifications, share with partners

Synchronization

Challenge: Ensuring synergy across multiple IIS environments

Process Improvement Opportunities: Automate updates to production, test, training, etc., create central reference tables

Timeliness

Challenge: Lack of clear expectations and process for updating new codes in a timely basis

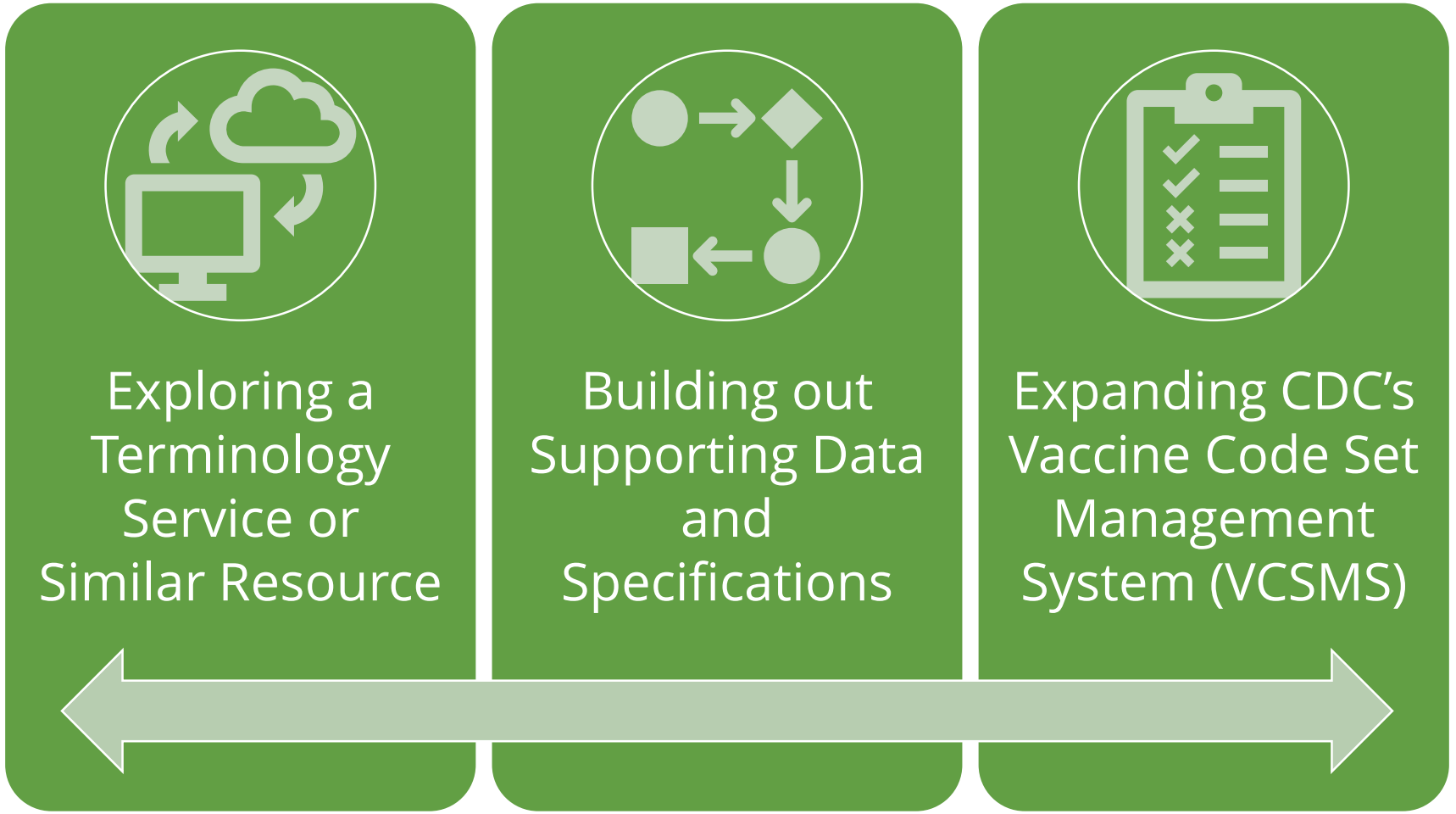
Process Improvement Opportunities: Clarify roles (IIS vs. Vendor), reduce manual steps, explore collaborative IIS/EHR guidance

Need for Supporting Data

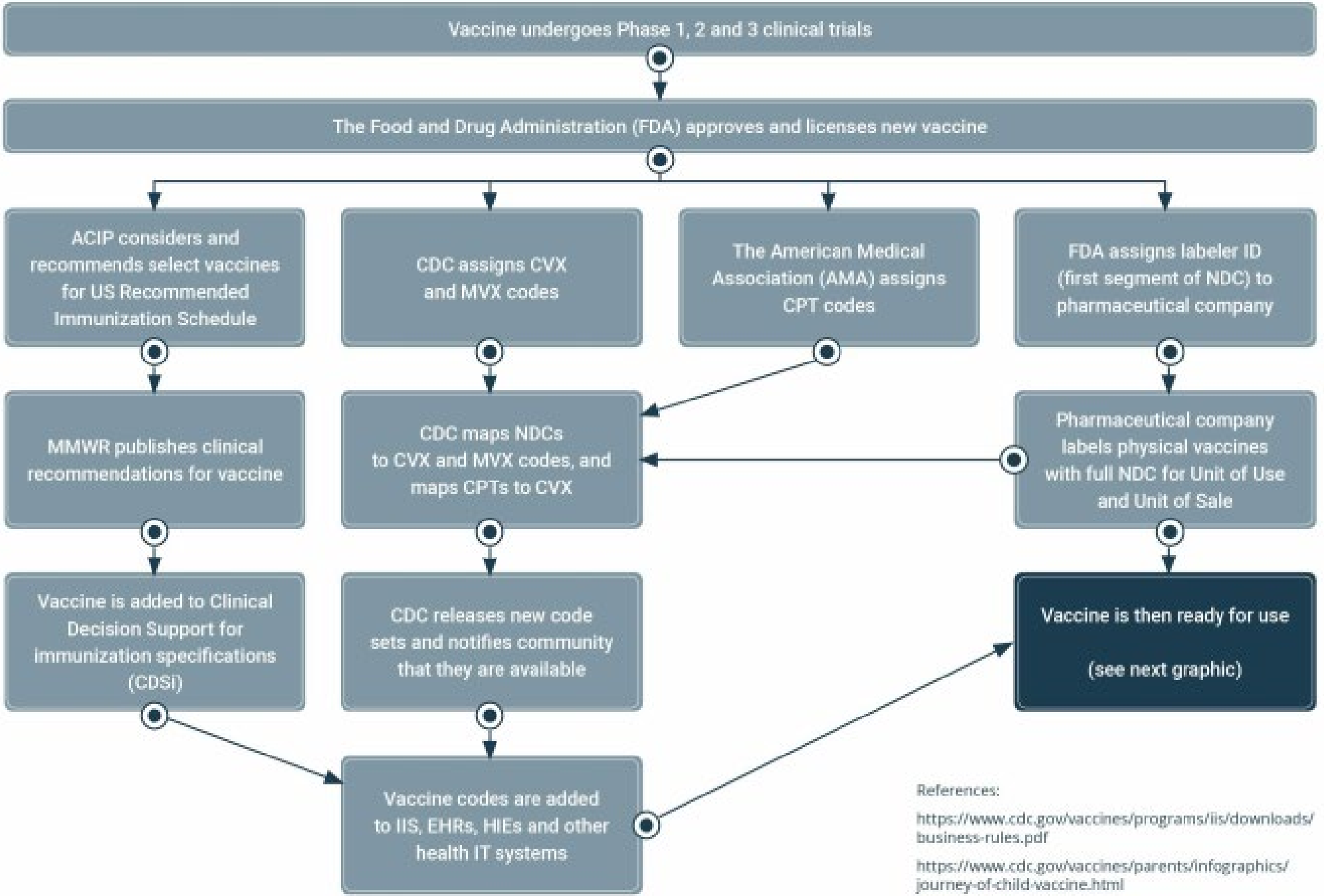
Challenge: Some code sets don't have all of the data elements necessary to managing the processing of code set changes

Process Improvement Opportunities: Build out full specifications to support automation of new codes

Broader Strategies



Vaccine Pipeline



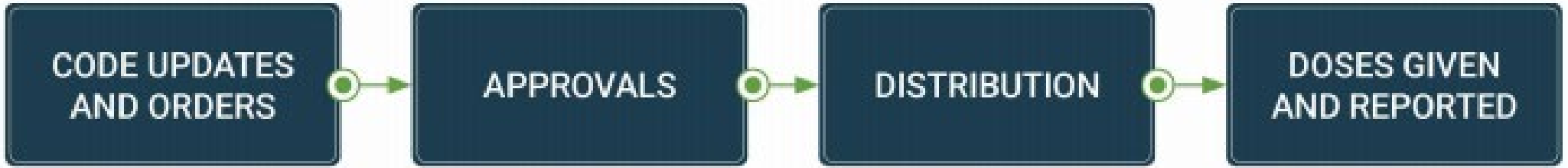
References:

https://www.cdc.gov/vaccines/programs/iis/downloads/business-rules.pdf

https://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html

Vaccine Code Use

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.



- Once codes are updated within IIS, EHRs, and HIEs, vaccine is available to be ordered via public and private markets
- Publicly funded vaccine is ordered by providers through IIS
- Private vaccine is ordered through manufacturers and distributors and sent to clinics and health systems*

* Private vaccine does not touch all the same systems as publicly funded vaccine but follows a similar path with similar considerations for manufacturers and distributors.

- Immunization program approves order and inventory
- Order is submitted to CDC/VTrckS via ExIS
- CDC/VTrckS approves vaccine order
- CDC passes order to McKesson

- McKesson fills order, sends vaccine to provider and shipment data to CDC; CDC makes shipment data downloadable to IIS via VTrckS
- IIS loads shipment data as "pending" into electronic provider inventory
- Provider receives physical vaccine, "accepts" shipment data into electronic provider inventory via IIS
- A subset of doses that are wasted/expired are returned to McKesson, doses are uploaded via ExIS and transmitted back to VTrckS †
- Funds for wasted/expired doses are returned to immunization program †

- Doses are administered in provider clinic, entered into the EHR, † reported to the IIS via HL7 with dose-level eligibility, or entered separately into an IIS via a web-based user interface
- Doses are decremented from public inventory within the IIS, provider accountability responsibilities are met †
- IIS/immunization programs report to CDC on appropriate use of public vaccine

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

Updating Code Sets

Exploring a Potential Future Direction for Vaccine Code Set Work

Updating Code Sets

- Why does it take time to update code sets in IIS and EHRs?

- While creating test cases for Measurement & Improvement we had an *aha moment!*

Measurement & Improvement

- HL7 Testing and Discovery
  - Report is under continuous improvement
  - Discovery testing is:
    - Informative, not binding
    - Exploratory, not definitive
    - Potentially a precursor to more formal measurement later
  - Looking to add test cases to measure when IIS adopt code changes
  - Ideally test cases should be supported by published standards or guidance
    - We do not have enough guidance to support full measurement of code set adoption

Measurement & Improvement

- Process for making tests:
  - Review announcements from CDC that document change
  - Create test cases to verify behavior from IIS:
    - VXU/ACK: What data should the IIS accept or not accept?
    - QBP/RSP: What data should the IIS return or not return?
  - Look at code sets for details
  - Assume a naïve perspective, do not insert expert knowledge
    - Test cases need to be specific
    - Shouldn’t make assumptions
    - Can’t assume implementors are experts
    - Test cases should be defensible

Measurement & Improvement

- Creating test cases for changes from 03/18/2019 until 02/12/2020
  - Challenge: Translating human language into operational expectations
    - Most of the contextual information is expressed for a human to understand
    - Requires a vaccination expert to read, understand and implement
  - Highlighted 14 changes that needed further clarification
    - Generated 32 unique questions under these changes
    - A vaccination expert should be able to provide a workable answer to these questions
      - But these experts might not come to the same answer
  - Will show you two basic examples:
    - Two manufacturers merged
    - NDC's retired

Example Change: MVX TVA added

08/09/2019: MVX Code Added: MVX TVA – TEVA Pharmaceuticals USA. Important NDC mapping changes and information related to this new MVX code include NDCs which have been remapped to the new MVX “TVA” code:

- Unit of Sale 51285-138-50 and Units of Use 51285-174-02 and 51285-175-02 for “Adenovirus Type 4 and Type 7 Vaccine, Live KIT”.
- The above NDCs were previously mapped to MVX “BRR” – Barr Laboratories. BRR is an inactive MVX code. TEVA merged with Barr Laboratories in 2008 and now manufactures former Barr vaccine products.

TEVA merged with Barr Laboratories

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If an IIS receives this vaccine recorded under BRR, what should it do:

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What about data already stored in IIS:

- Map data-at-rest from BRR to TVA?
- Map when sending out in RSP?
- All data, or just data after a certain date?
  - If so, after what date?

Example Change: NDC Retired

02/12/2020: NDC Codes Retired: The following NDC codes have been retired from the FDA files received.

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- As of the OuterEndDate/UseUnitEndDate?
- What if these dates are not specified?
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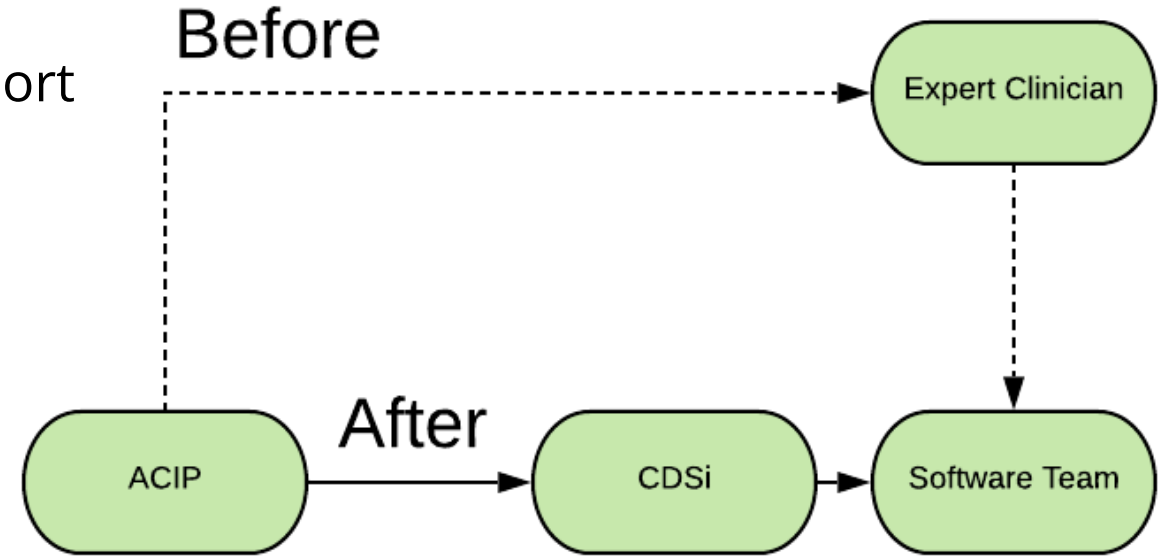
Can these codes still be used to report older data? Can IIS continue to store older data with these codes? Is it okay for IIS to report these older codes out for old data?

What is Needed

- CDS was in the same position five years ago:
  - Guidance from ACIP was in human language
    - Questions were left to experts to sort out
    - Different teams made different decisions
- CDSi project created several critical resources:
  - Processing model
  - Supporting data
  - Test cases

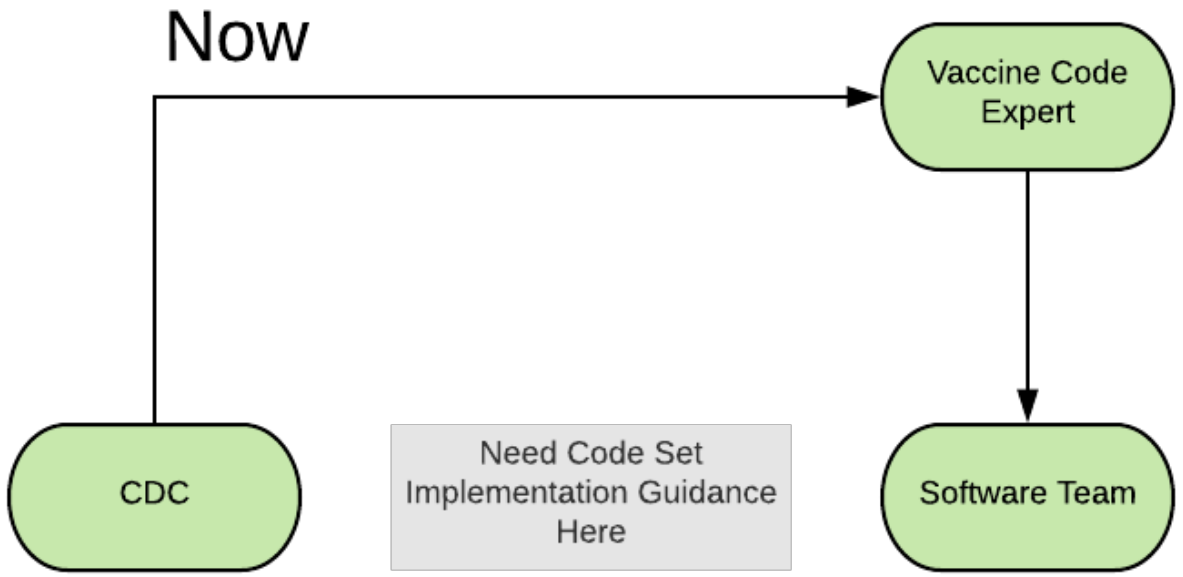


What is Needed

- Code set project needs the same resources:
  - Need standard definitions and operations
  - Need additional supporting data
    - Need more start and end dates, and connect those to specific requirements
    - Need to code information from human language into a computable resource
  - Test cases that can be used to verify support for changes:
    - IIS HL7 test cases
    - EHR behavior test cases
- Keep up-to-date with every change to the code set

What is Needed

- Where are the roadblocks?
  - Downloading codes
    - Not too hard today
  - Implementation by expert
    - Experts are busy
    - Not all teams have them
- Need guidance that can bridge the gap



Vaccine Code Sets Management Service Update

AIRA Discovery Session

May 28th, 2020

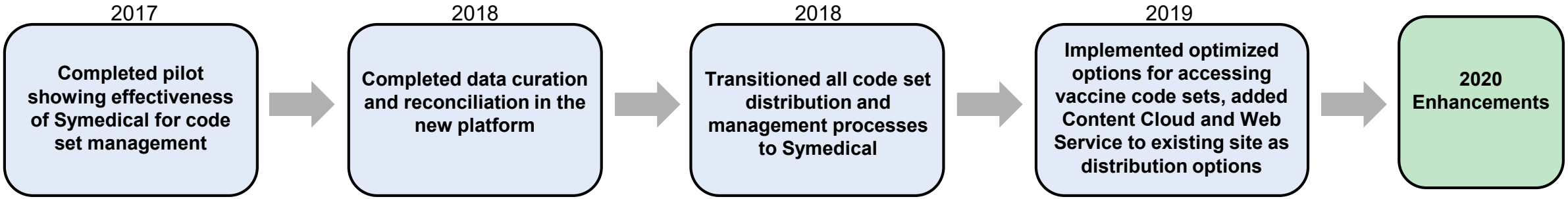
Paloma Hawry
Jay Schroeder

VCSMS Background

The CDC Immunization Information Systems Support Branch (IISSB) publishes vaccine terminology code sets used for interoperability and reporting across vaccine delivery communities. A goal of IISSB is to provide enhanced and centralized vaccine code set management and enhanced distribution options for the Vaccine Code Set Management Service (VCSMS).

- Vaccine code sets include catalogs of codes authored by the CDC, Food and Drug Administration (FDA), and American Medical Association (AMA).
- CDC also generates maps from the externally-authored codes to the CDC-authored codes.

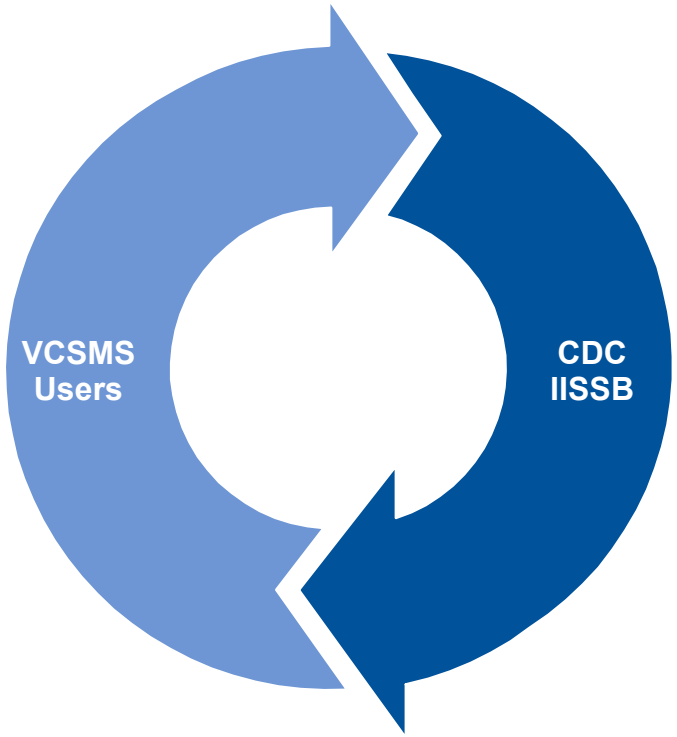
Successes to Date:



CDC IISSB Values Grantee Feedback

Grantee Outreach:

- AIRA workshops
- Meetings
- Interviews
- Training Sessions
- Surveys



Outcomes:

- Upcoming release communications
- Detailed release notes
- More frequent release schedule during busy periods such as seasonal flu updates
- Documented and validated requested enhancements

Enhancements Provide New Ways to Access Vaccine Data

Transactional Web Service

The transactional web service enhancement will empower registered users to specifically query the CDC vaccine code set information and metadata that they seek, without having to parse through data they don't want. This will increase efficiency and help IIS and other HIS align more closely to industry web services.

Dynamic Search and Browsing

CDC plans to deploy a browsable web-interface based in Viewpoint, enabling the public to interact with vaccine code set data on-demand – without sifting through tables or flat files. Users can search by CVX, vaccine group, NDC, and other vaccine attributes to investigate the code set information.

Consolidated File

CDC's legacy vaccine code sets have been available in flat file formats, and CDC recognizes the value of creating a consolidated file for application-agnostic use. CDC plans a file that will consolidate almost all existing vaccine content, including new metadata.

Vaccine Code Set Content Enhancements

CDC is researching updates to vaccine effective end dates as well as enhancements to other code attributes.

Looking Ahead

Content Review:

- The VCSMS team has been conducting regular deep-dives with AIRA to review potential data issues and inconsistencies in data use.
- We will continue our collaborative efforts to research these issues and reach consensus on a consistent approach.
- Agreed upon direction can be used as a basis for communication to the broader community to provide clarity and consistency for use of vaccine data.
- Identify content enhancements and guidance to aid the vaccine community in their use of the code sets.
- Continue to monitor the technical landscape community need for emerging standards such as FHIR and JSON.

Key Dates for VCSMS:

- User Acceptance Testing for enhancements began on 5/21 and goes through 7/10.
- Updates to code sets for 2020/2021 Flu vaccines are planned for release in July-September as they become available.
- Technical enhancements are planned for release into Production in October 2020.
- Effective dating for codes are planned for 2021.

Questions

Questions, Comments, Discussion?

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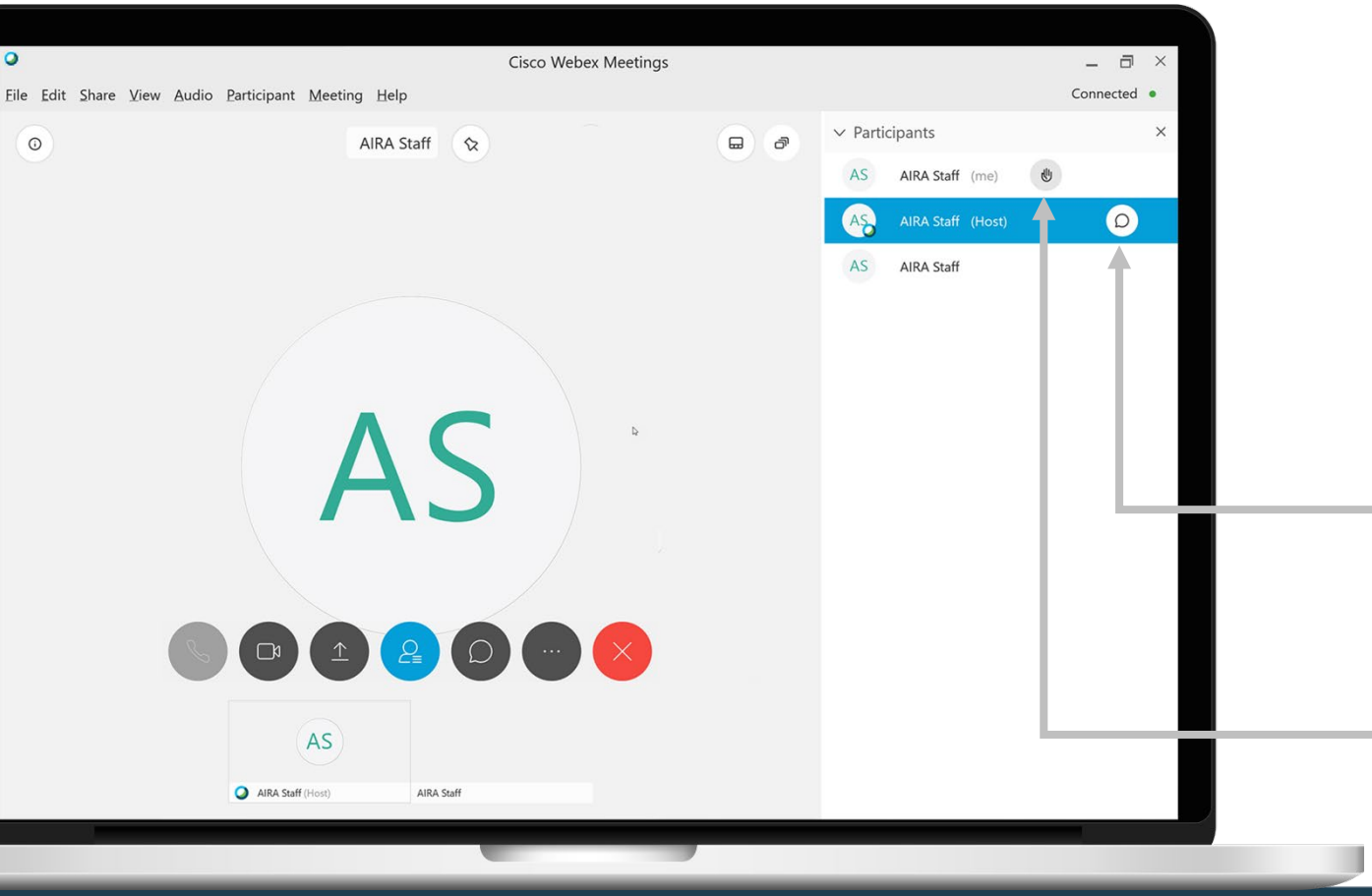

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Thank you to our presenters, and thanks to all of you for joining us!

A brief evaluation survey will be sent out following this webinar

The next Discovery Session will be June 22nd at 4pm ET